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Kumar Keshav¹ · Anurag Baghel¹ · Vishal Kumar² · Deepak Neradi² · Kumar Kaustubh³ · Prabhaker Mishra⁴

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Abstract

Introduction The aim of systematic review and meta-analysis was to find out whether minimally invasive plate osteosynthesis (MIPO) is better than open reduction and internal plate fixation (ORIF) in terms of functional outcome, achieving union (union time and incidence of non-union), intraoperative parameters (surgical duration, blood loss, and radiation exposure), and complications (iatrogenic radial nerve palsy and infection) for humeral shaft fractures.

Materials and Methods We searched online databases (Pubmed, Embase, Scopus, and The Cochrane Library) from inception till 3rd September 2020 for articles comparing MIPO with ORIF for humeral shaft fractures. The methodological quality of randomized controlled trials (RCTs) was done by Cochrane Risk of Bias assessment tool 2 (RoB2) and of non-randomized studies (case–control and cohort studies) by Methodological Index for non-randomized studies (MINORS). Meta-analysis was performed using Review Manager 5.4 software.

Results 11 studies (5 RCTs and 6 non-randomized comparative studies) involving a total of 582 patients (MIPO-290, ORIF-292) meeting our inclusion criteria were included in the study. There was no statistically significant difference in pooled analysis of functional outcome scores between MIPO and ORIF. Union time was significantly lesser (mean difference = 3.12 weeks) and incidence of non-union lower (odd’s ratio = 0.27) in MIPO group. Surgical duration and intraoperative blood loss were significantly lesser in MIPO group. Iatrogenic radial nerve palsy and infection were higher in ORIF group.

Conclusions This study showed that MIPO gives similar functional outcomes as compared to ORIF but causes significantly lesser blood loss, requires lesser operative duration and has a lesser incidence of major complications.

Trial Registration International prospective register of systematic reviews (PROSPERO)—CRD42020208346, Date of registration 09/10/2020

Keywords Humeral shaft fractures · Humeral diaphyseal fractures · Minimally invasive plate osteosynthesis · MIPO · Open reduction and internal fixation · ORIF · Open reduction and plate fixation · ORPO · Minimally invasive surgical procedures

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Introduction

Humeral shaft fractures are one of the common injuries, constituting roughly 3% of all fractures. Currently, conservative management in the form of functional bracing is being considered as the treatment of choice [1]. However, it results in quite a high rate of mal-union and also instances of delayed union and non-union [2–4]. Operative treatment gives more predictable alignment and faster healing but complications like iatrogenic radial nerve palsy, loss of fixation and infection are more common [1, 4, 5]. Currently, there are three operative modalities of internal fixation in humeral shaft fractures—(a) open reduction and internal fixation (ORIF) by plating, which is considered the gold standard (b) intramedullary nailing (IMN) and (c) recently introduced minimally invasive plate osteosynthesis (MIPO) [1, 4–11]. Intramedullary nailing has been seen to cause shoulder impingement issues and rotator cuff injury, which has been highlighted in almost all the studies which compared plating with nailing [6, 7].

Once the MIPO technique started becoming popular, numerous studies were published which have talked about the functional outcome of MIPO plating in fractures of the humeral shaft [12–14]. However, most were case series and only few amongst them compared MIPO plating with the conventional gold standard operative modality, ORIF [15–26]. There were few systematic reviews published around half a decade back which have compared MIPO with conventional fixation techniques—both ORIF and IMN [8–11]. In these reviews, the number of studies that compared MIPO with ORIF ranged from two to seven [15–22] and also few studies which did not compare ORIF with MIPO were included erroneously [17]. In the last 5 years, four more comparative studies, two amongst which were randomised controlled trials (RCTs) were published [23–26]. We, a team of orthopaedic surgeons and biomedical researchers decided to conduct a systematic review of all the comparative studies of conventional open plating (ORIF) with MIPO published till 3rd September 2020. The purpose of conducting this systematic review and meta-analysis was to compare the functional outcome, time required for union, intraoperative parameters (surgical duration, intraoperative blood loss and radiation exposure) and complications (non-union, iatrogenic radial nerve palsy and infection) of the two different methods of plating—MIPO and ORIF for humeral shaft fractures.

Methods

Search Strategy

We registered the protocol of this systematic review and meta-analysis on the PROSPERO international prospective register of systematic reviews (CRD42020208346) [27]. The study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [28]. (Supplementary File 1). Two reviewers (KK and DN) searched the online databases (Pubmed, Embase, Scopus, and The Cochrane Library) from inception till 3rd September 2020. We did not impose any language restriction at the time of initial search. We also searched the reference list of included studies and earlier narrative/systematic reviews on the topic. The search strategy used for various medical databases has been mentioned in Table 1.

Inclusion and Exclusion Criteria

We selected studies which satisfied the following inclusion criteria: (1) comparative studies (randomised controlled trials, non-randomised clinical trials, case control studies, cohort studies and other comparative studies) where

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<th>Search database</th>
<th>Search Strategy</th>
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<tr>
<td>Pubmed</td>
<td>((&quot;Humeral Fractures&quot;[MeSH] OR (humer* AND fracture*)) AND (&quot;shaft&quot; OR &quot;midshaft&quot; OR &quot;diaphys*)) AND (&quot;Minimally Invasive Surgical Procedures&quot;[MeSH] AND &quot;Bone Plates&quot;[MeSH]) OR (anterior AND plat*) OR (percutaneous AND plat*) OR (&quot;minimally invasive&quot; AND plat*) OR (&quot;minimal invasive&quot; AND plat*) OR (bridge AND plat*) OR &quot;MIPO&quot; OR “MIPPO”)</td>
<td>229</td>
</tr>
<tr>
<td>Embase</td>
<td>Humer* AND fracture* AND (shaft OR midshaft OR diaphys*) AND plat* AND (minimal* OR mippo OR mipo OR percutaneous OR bridge)</td>
<td>256</td>
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<tr>
<td>Scopus</td>
<td>TITLE-ABS-KEY (humer* AND fracture* AND (shaft OR midshaft OR diaphys*) AND plat* AND (minimal* OR mippo OR mipo OR percutaneous OR bridge))</td>
<td>263</td>
</tr>
<tr>
<td>Cochrane</td>
<td>Humer* AND fracture* AND (shaft OR midshaft OR diaphys*) AND plat* AND (minimal* OR mippo OR mipo OR percutaneous OR bridge) in All Text</td>
<td>26</td>
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minimally invasive plating osteosynthesis (MIPO) was compared with open reduction and internal fixation (ORIF) by plating, (2) studies dealing with non-pathological humeral shaft fractures in patients over 15 years of age and (3) English language articles. Studies dealing with (1) paediatric humeral fractures, (2) proximal or distal humeral fractures (3) plating vs nailing and (4) non-union of humeral shaft fractures following conservative or operative treatment, (5) non-comparative studies like case series and (6) non-English language articles were excluded.

**Study Selection**

After pooling all the studies extracted from online databases and other sources with their abstract and other publication details in a single excel file, two independent reviewers (KK and AB) first screened the study titles, abstract and other publication details like author, year of publication, journal name, etc. for duplication. Thereafter, the titles and abstract of the remaining studies were checked for eligibility based on our inclusion and exclusion criteria. The full texts of these potentially eligible studies were then retrieved and were assessed for eligibility independently by the two review team members. Any disagreements between them over the eligibility of particular studies were resolved through mutual discussion and even if unresolved, by discussion with the third reviewer (DN).

**Data Extraction**

Two independent authors (KK and AB) extracted the following information from all the articles: lead author, publication year, country of study, type of study, number of patients enrolled and followed, follow-up duration, mean age of participants, male: female ratio, fracture types and associated injuries, if any. Clinical and functional outcome data in terms of various clinical scores mentioned across studies were compiled. Union time and incidence of major complications like non-union, delayed union, mal-union, iatrogenic radial nerve palsy, infection and consequent requirement of secondary surgery were extracted from various studies and summarised. Intraoperative parameters—duration of surgery, blood loss and radiation exposure due to requirement of intraoperative fluoroscopy—were also extracted from the studies. All the data were extracted on a standardized excel file.

**Quality Assessment**

All the studies were categorized as per the level of evidence. The methodological quality of randomized controlled trials (RCTs) was done by Cochrane Risk of Bias assessment tool 2 (RoB2) [29] and of non-randomized studies (case-control and cohort studies) by methodological index for non-randomized studies (MINORS) [30] by two independent authors (KK and DN) and any disagreements between them were resolved by mutual discussion. Robvis tool, which is available online, was used to create risk-of-bias plots for RCTs included in our study [31].

**Statistical Analysis**

Meta-analysis was performed using the Review Manager 5.4 software (Cochrane Collaboration, U.K.). For continuous variables, standard mean difference (SMD) or weighted mean difference (MD) with 95% confidence intervals was calculated. Odd’s ratio (OR) and risk ratio (RR) with 95% confidence intervals (CI) was used for dichotomous variables. The level of significance was set at p value <0.05. Whether to use fixed effect or random effects model was decided on the basis of heterogeneity, which was evaluated by \( \chi^2 \) test and \( I^2 \) statistics. If the statistical heterogeneity was significant (\( p \) value <0.10 or \( I^2 > 50\% \)), random-effects model was used, otherwise fixed-effects model was used. In those cases of continuous variables where standard deviation was not mentioned, the RevMan calculator available online, which calculates on the basis of the method described in Cochrane Handbook of Systemic Review of Interventions from sample size, sample mean and \( p \) value, was used [32]. In few cases, it was calculated from range where it was given in the paper.

**Results**

**Literature Search**

The search strategy used and the number of results obtained for the four scientific literature database—PubMed, Embase, Scopus and Cochrane—were as shown in Table 1. Seven hundred and seventy-five (775) records were identified by the initial literature search, of which 418 were duplications. Then, out of remaining 357, 341 were excluded on the basis of title and abstract as per the exclusion criteria. 16 full text articles were accessed for eligibility. Four of these articles were not in English (two each in Russian and Chinese) and one was of proximal humerus. Finally, 11 studies (five RCT and six non-randomized comparative studies) met our inclusion criteria and were included for systematic review and meta-analysis (Fig. 1). The complete list of studies at various stages of literature search has been enumerated in Supplementary file 2.
**Study Characteristics**

The studies included in our studies were published between 2010 and 2019. Four of these studies were from Korea, three from China, two from India and one each from Egypt and Iran. There were five RCTs [19–21, 25, 26] while others were observational studies/non-randomized trials (one prospective [18], one prospective and retrospective [16] and four retrospective studies [15, 22–24]). The major demographic and preoperative characteristics of studies and the duration of follow-up have been mentioned in Table 2. A total of 582 patients (MIPO-290, ORIF-292) were enrolled of which 560 (MIPO-281, ORIF-279) were followed up and finally evaluated. The number of patients amongst individual studies that were evaluated ranged from 30 to 72. Table 3 summarises the intraoperative, postoperative and follow-up data extracted across the studies in a tabular format.

**Methodological Quality**

Based on the Oxford Centre for Evidence-based Medicine Levels of Evidence, all the 11 studies were graded as shown in Table 2 [32]. Amongst RCTs [19–21, 25, 26], overall risk of bias as per Cochrane Risk of Bias assessment tool 2 (RoB2) was low in one, some concerns in one and high in three. (Figs. 2 and 3). For the six non-RCTs included in our study [15, 16, 22–24], the Methodological Index for non-randomized studies (MINORS) [30] was used which ranged from 15 to 20 (Table 4).

**Functional Outcome: UCLA, MEPS, DASH and ASES**

University of California, Los Angeles (UCLA) Shoulder Scale [34] was the most common outcome score for shoulder function mentioned amongst the papers (seven studies) [15, 16, 19–21, 23, 24] while, for the elbow function, Mayo...
<p>| Study          | Type of study | Level of evidence | Year | Country | No. of patients enrolled (MIPO, ORIF) | No. of patients followed up (MIPO, ORIF) | Mean age (Overall (MIPO, ORIF)) | Male/Female ratio (MIPO, ORIF) | Mode of injury (MIPO/ ORIF) | Fracture types (MIPO, ORIF) | AO/OTA classification A/B/C | Fracture location (proximal/middle/distal) | Open fracture (Gustilo Anderson Grade I/II/ IIIA) | Associated Injuries | Follow-up duration (months) (Overall (MIPO, ORIF)) |
|---------------|---------------|-------------------|------|---------|---------------------------------------|------------------------------------------|---------------------------------|-------------------------------|--------------------------|-------------------------------|-----------------------------|--------------------------------|--------------------------------|-------------------------------|---------------------------------|--------------------------------------------------|
| An et al. [15] | Retrospective | III               | 2010 | China   | 17,16                                  | 17, 16                                   | 37.59 ± 9.2 (19–60), 36.93 ± 11.4 (24–62) | 12/5, 9/7                      | RTA- 9/6, Falls- 3/6, Machinery- 5/3 | NA                           | 0/8/9, 0/9/7                 | 0/18/5, 0/18/5, 0/18/5 | MIPO- 3 pelvic fractures, 1 Distal radius fracture with ipsilateral surgical neck of humerus fracture ORIF- 1 case of lung contusion with rib fractures | 25.94 ± 9.3 (14–44), 32.88 ± 12.62 (13–48) |
| Oh et al. [16] | Prospective   | III               | 2012 | Korea   | 34, 35                                  | 29,30                                    | 39.6 (16–83), 42 (17–82)          | 16/13, 16/14                   | RTA- 19/21, Falls- 10/9   | 11/11/7, 15/8/7, 6/18/5, 3/2/0 | MIPO- Associated Injuries in 14 patients, 3 radial nerve palsy, 1 brachial plexus injury ORIF- Associated Injuries in 16 patients, 3 radial nerve palsy, 2 brachial plexus injury | 18, 22 (minimum-12 for both) |
| Study    | Type of study | Level of evidence | Year | Country | No. of patients enrolled (MIPO, ORIF) | No. of patients followed up (MIPO, ORIF) | Mean age (Overall (MIPO, ORIF)) | Male/Female ratio (MIPO, ORIF) | Mode of injury (MIPO/ ORIF) | Fracture types (MIPO, ORIF) | AO/OTA classification A/B/C | Fracture location (proximal/middle/distal) | Open fracture (Gustilo Anderson Grade I/II/IllA) | Associated Injuries | Follow-up duration (months) (Overall (MIPO, ORIF)) |
|---------|---------------|------------------|------|---------|--------------------------------------|------------------------------------------|--------------------------------------|--------------------------------|----------------------------|-------------------------------|------------------|--------------------------------|-----------------------------------------------|-----------------------------------|--------------------------------|-----------------------------------|
| Wang et al. [18] | Prospective | II | 2015 | China | 26, 27 | 22, 23 | 39.3 ± 10.1, 35.7 ± 10.9 | 14/8, 16/7 | RTA- 7/12, Falls- 11/6, Crush- 1/3, Belt twisted injury in workshop-3,2 | 5/8/9, 5/12/6 | 4/13/5, 2/15/6 | None | Only closed unilateral humeral shaft fractures without associated Radial nerve palsy or ipsilateral shoulder injury/disease were included | 12 months |
| Kim et al. [19] | RCT | I | 2015 | Korea | 36, 36 | 36, 32 | 40.6 (15–86), 44.4 (17–84) | 19/17, 18/14 | NA | 19/17/0, 21/11/0 | 4/21/11, 4/16/12 | 1/2/0 | Multiply injured patients-37 (54%) MIPO- 3 Radial nerve palsy ORIF- 4 Radial nerve palsy | 15 months |
| Hadhoud et al. [20] | RCT | II | 2015 | Egypt | 15, 15 | 15, 15 | 39.7± 12.7 (22–67), 36.1 ± 12.8 (20–65) | 9/6, 11/4 | RTA- 8/8, Falls- 7/7 | 9/3/3, 10/4/1 | NA | Patients upto Grade I were included | NA | 6–10 months (till bony union) |</p>
<table>
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<tr>
<th>Study</th>
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<th>Year</th>
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<th>No. of patients enrolled (MIPO, ORIF)</th>
<th>No. of patients followed up (MIPO, ORIF)</th>
<th>Mean age (Overall (MIPO, ORIF))</th>
<th>Male/Female ratio (MIPO, ORIF)</th>
<th>Mode of injury (MIPO, ORIF)</th>
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<th>Fracture location (proximal/middle/distal)</th>
<th>Open fracture (Gustilo Anderson Grade I/II/IIIA)</th>
<th>Associated Injuries</th>
<th>Follow-up duration (months) (Overall (MIPO, ORIF))</th>
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<td>Esmailiejah et al. [21]</td>
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<td>II</td>
<td>2015</td>
<td>Iran</td>
<td>32,33</td>
<td>32,33</td>
<td>33.4 ± 10.6 (15–53), 34.6 ± 12.1 (16–56)</td>
<td>24/8, 24/9</td>
<td>RTA- 11/12, Falls- 5/11, Sports-16/10</td>
<td>10/9/13, 12/10/11</td>
<td>NA</td>
<td>None</td>
<td>Fractures extended to shoulder and elbow joints and those with preoperative radial nerve injury were not included</td>
<td>Till union</td>
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<tr>
<td>Study</td>
<td>Type of study</td>
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</tr>
<tr>
<td>Lee et al.</td>
<td>Retrospective</td>
<td>III</td>
<td>2016</td>
<td>Korea</td>
<td>24, 28</td>
<td>24, 28</td>
<td>50.62 (16–89), 47.57 (27–82)</td>
<td>15/9, 18/10</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Patients upto Grade II were included</td>
<td>24.58 ± 6.76 (6–36), 26.32 ± 7.39 (12–40)</td>
<td></td>
</tr>
</tbody>
</table>

Note: MIPO = Minimally Invasive Plate Osteosynthesis, ORIF = Open Reduction and Internal Fixation, AO/OTA = Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association, RTA = Road Traffic Accident.
Table 2 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Level of evidence</th>
<th>Year</th>
<th>Country</th>
<th>No. of patients enrolled (MIPO, ORIF)</th>
<th>No. of patients followed up (MIPO, ORIF)</th>
<th>Mean age (Overall (MIPO, ORIF))</th>
<th>Male/Female ratio (MIPO, ORIF)</th>
<th>Mode of injury (MIPO/ ORIF)</th>
<th>Fracture types (MIPO, ORIF)</th>
<th>Fracture location (proximal/ middle/ distal)</th>
<th>Open fracture (Gustilo Anderson Grade I/II/ IIIA)</th>
<th>Associated Injuries</th>
<th>Follow-up duration (months) (Overall (MIPO, ORIF))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ko et al. [23]</td>
<td>Retrospective</td>
<td>III</td>
<td>2017</td>
<td>Korea</td>
<td>27,23</td>
<td>27,23</td>
<td>55.9±10.8, 56±10.0</td>
<td>18/9, 16/7</td>
<td>NA</td>
<td>NA</td>
<td>NA Transverse/ Oblique/ Spiral- 16/5/6, 11/5/7</td>
<td>NA None</td>
<td>Patients with any nerve injury were excluded</td>
<td>19.1±3.0, 18.5±4.3</td>
</tr>
<tr>
<td>Kulkarni et al. [24]</td>
<td>Retrospective</td>
<td>III</td>
<td>2017</td>
<td>India</td>
<td>34, 34</td>
<td>34, 34</td>
<td>39.55 (18–70)</td>
<td>N/A</td>
<td>90% patients had RTA followed by domestic accidents</td>
<td>NA</td>
<td>18/10/6, 24/8/2</td>
<td>MIPO- 3 cases of Preoperative Radial nerve palsy ORIF- 4 cases of Preoperative Radial nerve palsy</td>
<td>None</td>
<td>Minimum of 6 months</td>
</tr>
<tr>
<td>Sri et al. [25]</td>
<td>RCT</td>
<td>II</td>
<td>2019</td>
<td>India</td>
<td>15, 15</td>
<td>15, 15</td>
<td>37.53±8.1, 36.93±7.4</td>
<td>9/6, 10/5</td>
<td>RTA- 11/9, Falls- 4/6</td>
<td>10/3/2, 9/4/2</td>
<td>NA</td>
<td>NA None</td>
<td>Patients with proximal and distal humeral fractures, associated ipsilateral limb fractures, patients with radial nerve injury were excluded</td>
<td>24 months</td>
</tr>
<tr>
<td>Wang et al. [26]</td>
<td>RCT</td>
<td>II</td>
<td>2019</td>
<td>China</td>
<td>30, 30</td>
<td>30, 30</td>
<td>38.21±2.3, 43.16±2.67</td>
<td>12/18, 17/13</td>
<td>NA</td>
<td>7/12/11, 8/13/9</td>
<td>NA</td>
<td>NA NA</td>
<td>NA</td>
<td>6–24 months</td>
</tr>
</tbody>
</table>

*MIPO minimally invasive plate osteosynthesis, ORIF open reduction and internal fixation, AO/OTA- The AO Foundation/Orthopaedic Trauma Association, RTA road traffic accident, NA not available*
<table>
<thead>
<tr>
<th>Study</th>
<th>Postoperative clinical functional scores (MIPO, ORIF)</th>
<th>Union time (Weeks) (MIPO, ORIF)</th>
<th>Duration of surgery (Minutes) (MIPO, ORIF)</th>
<th>Blood loss (ml) (MIPO, ORIF)</th>
<th>Radiation exposure (Seconds) (MIPO, ORIF)</th>
<th>Surgical approach used (MIPO, ORIF)</th>
<th>Complications (MIPO, ORIF)</th>
<th>Reoperation for non-union/delayed union/infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>An [15]</td>
<td>UCLA-34.76 ± 0.56(33–35), 34.38 ± 1.41(30–35) MEPS-99.41 ± 2.43(90–100), 99.69 ± 1.25(95–100) ROM-132.94 ± 10.01(100–140), 136.5 ± 5.10(120–140)</td>
<td>15.29 ± 4.01(8–24), 21.25 ± 13.67(10–58)</td>
<td>92.35 ± 57.68(70–195), 103.12 ± 31.08(60–160)</td>
<td>NA</td>
<td>NA</td>
<td>MIPO-Anterior, ORIF-Anterolateral (5 cases) Posterior (11cases)</td>
<td>0, 0</td>
<td>0, 1</td>
</tr>
<tr>
<td>Oh [16]</td>
<td>UCLA-34.3, 33.8 MEPS-97.6, 97</td>
<td>17.3, 16.7</td>
<td>110, 169</td>
<td>NA</td>
<td>201 (MIPO)</td>
<td>MIPO-Deltobicipital + Anterior, ORIF-Anterior/ Anterolateral (Primary autogenous iliac bone grafting was done in 5 cases of ORIF)</td>
<td>1, 3</td>
<td>NA</td>
</tr>
<tr>
<td>Wang [18]</td>
<td>Constant scores-93.5 ± 5.9, 95.3 ± 4.3 ASES-94.9 ± 6.2, 96.9 ± 5.5</td>
<td>125.2 ± 23.880–185), 113.0 ± 24.9(65–170)</td>
<td>NA</td>
<td>NA</td>
<td>MIPO-Deltobicipital + Anterolateral, ORIF-Anterolateral/ Posterior</td>
<td>1, 2</td>
<td>Rotational malalignment (in degrees)-18.2 ± 15.4, 7.4 ± 4.4</td>
<td>1, 3</td>
</tr>
<tr>
<td>Kim [19]</td>
<td>UCLA-33.1, 33.9 MEPS-96.4, 98.9 [P = 0.798]</td>
<td>14.6, 15.8 [P = 0.588]</td>
<td>105, 116</td>
<td>NA</td>
<td>68 (MIPO)</td>
<td>MIPO-Deltobicipital + Anterior, ORIF-Anterolateral</td>
<td>0, 0</td>
<td>0, 1</td>
</tr>
<tr>
<td>Hadhoud [20]</td>
<td>UCLA-32.2 ± 2.4, 30.9 ± 3.8 MEPS-90.3 ± 8.3, 87.7 ± 10</td>
<td>15.3, 16.5</td>
<td>80.7 ± 7.8(65–90), 125.3 ± 8.3(110–140)</td>
<td>92.7 ± 15.3 (70–120), 366.8 ± 52.3 (300–450)</td>
<td>72 ± 7.7 (60–90), 12 ± 6.03 (10–15)</td>
<td>MIPO-Deltobicipital + Anterior, ORIF-Anterolateral (for proximal shaft fractures)/ Posterior (for midshaft and distal fractures)</td>
<td>0, 1</td>
<td>1, 0</td>
</tr>
</tbody>
</table>
Table 3 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Postoperative clinical functional scores (MIPO, ORIF)</th>
<th>Union time (Weeks) (MIPO, ORIF)</th>
<th>Duration of surgery (Minutes) (MIPO, ORIF)</th>
<th>Blood loss (ml) (MIPO, ORIF)</th>
<th>Radiation exposure (Seconds) (MIPO, ORIF)</th>
<th>Surgical approach used (MIPO, ORIF)</th>
<th>Complications (MIPO, ORIF)</th>
</tr>
</thead>
<tbody>
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<tr>
<td>Esmaeilehaj [21]</td>
<td>UCLA- 33.1 ± 1.5(29–35), 32.8 ± 1.1(30–35)</td>
<td>17.38 (13.03–26.07), 21.73 (13.03–47.8)</td>
<td>93.9 ± 23.9(48–151), 106.5 ± 27.2(58–173)</td>
<td>NA</td>
<td>NA</td>
<td>MIPO- Deltopectoral + Anterior, ORIF- Anterolateral (29 cases)/ Posterior (4 cases) based on the fracture site</td>
<td>1,3 NA 1.4 0 2 NA</td>
</tr>
<tr>
<td></td>
<td>MEPS- 96.6 ± 5.1(80–100), 96.9 ± 6.8(80–100)</td>
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<tr>
<td>Lee [22]</td>
<td>MEPI- 99.41 ± 2.43(90–100), 99.69 ± 1.25(95–100)</td>
<td>13.29 ± 3.07(10–24), 14.04 ± 3.44(10–24)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>MIPO- Anterior (proximal incision) + Between Brachioradialis and biceps (distal incision), ORIF- Not mentioned</td>
<td>NA NA NA 0 4 NA</td>
</tr>
<tr>
<td></td>
<td>ROM- 123.13 ± 8.32(100–135), 122.5 ± 8.68(100–135)</td>
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<tr>
<td>Ko [23]</td>
<td>UCLA- 32.4 ± 3.2, 31.0 ± 1.4</td>
<td>12.0 ± 3.3, 14.8 ± 2.0</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>MIPO- Anterolateral, ORIF-Anterolateral</td>
<td>0 0 NA 0 0 1 2 0 3 0 0</td>
</tr>
<tr>
<td></td>
<td>ASES- 91.0 ± 1.6, 89.4 ± 0.9</td>
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<tr>
<td>Kulkarni [24]</td>
<td>UCLA- Good/fair-33/1, 26/8</td>
<td>14.55, 13.58</td>
<td>131.71, 150.58</td>
<td>NA</td>
<td>NA</td>
<td>MIPO- Deltpectoral + Anterior, ORIF- Anterior (12 cases), Posterior (22 cases)</td>
<td>0 5 NA 1 0 2 1 0 5</td>
</tr>
<tr>
<td></td>
<td>MEPS—Excellent/Good/Fair-28/5/1, 21/12/1</td>
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<tr>
<td>Sri [25]</td>
<td>DASH Score (3 months)— 19.5 ± 27.4, 21.4 ± 28.2</td>
<td>15.5, 16.1</td>
<td>70.7 ± 8.1, 123.5 ± 7.9</td>
<td>84 ± 10.3, 270 ± 10.4</td>
<td>90 (60–96) (MIPO)</td>
<td>MIPO- Not mentioned, ORIF- Anterior</td>
<td>0 0 0 0 0 1 0 1 0 0</td>
</tr>
<tr>
<td></td>
<td>DASH Score (1 year)— 8.3 ± 5.8, 8.9 ± 6.4</td>
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<tr>
<td>Wang [26]</td>
<td>DASH Score (1 year)— 11.3 ± 4.8, 11.6 ± 5.0</td>
<td>11.1 ± 2.5, 16.2 ± 2.8</td>
<td>90.0 ± 9.5, 120.0 ± 12.5</td>
<td>142.5 ± 37.5, 262 ± 80.6</td>
<td>NA</td>
<td>MIPO- Deltopectoral + Anterior, ORIF- Anterolateral</td>
<td>0 1 NA 0 0 0 1 0 1 0 1</td>
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</tbody>
</table>

MIPO minimally invasive plate osteosynthesis, ORIF open reduction and internal fixation, UCLA university of California, Los Angeles shoulder scale, MEPS mayo elbow performance score, ROM range of motion, ASES American shoulder and elbow surgeons score, DASH disabilities of the arm, shoulder and hand score, NA not available
Elbow performance score (MEPS) [35] was also used in seven studies [15, 16, 19–22, 24]. Out of these, Kulkarni et al. described in terms of excellent/good/fair/poor and was thus not suitable for meta-analysis [24]. One of the papers (Oh et al.) did not mention the exact p value and hence could not be used for meta-analysis [16]. Finally, we were left with five studies for each of UCLA and MEPS. There was no statistically significant difference in pooled analysis of either UCLA scores (SMD = 0.19, 95% CI = 0.06 to 0.44, P = 0.14; I² = 29%; P = 0.23) or MEPS (SMD = −0.05, 95% CI = −0.03 to 0.20, P = 0.72; I² = 0%; P = 0.91) between MIPO and ORIF. The effect estimates of randomized clinical trials and
observational studies were similar for both UCLA (test for subgroup difference: $P = 0.13; I^2 = 56.5\%$) and MEPS (test for subgroup difference: $P = 0.58; I^2 = 0\%$). Two RCTs [25, 26] mentioned the Disabilities of the Arm, Shoulder and Hand (DASH) Score [36] ($SMD = -0.07$, $95\% CI$ $-0.49$ to $0.34$, $P = 0.73; I^2 = 0\%$; $P = 0.94$) while two observational studies [18, 23] mentioned American Shoulder and Elbow Surgeons (ASES) score [37] ($SMD = 0.42$, $95\% CI$ $1.07$ to $1.92$, $P = 0.58; I^2 = 92\%; P = 0.0004$) and both of them also didn’t show any significant difference between MIPO and ORIF (Fig. 4).

Union Time and Non-Union Rate

Nine studies [15, 16, 19, 21–26] mentioned union time in their studies out of which six could be used for the purpose of pooling the results [15, 19, 21–23, 26]. Union time in MIPO plating was significantly lesser than ORIF. ($MD = -3.12$, $95\% CI$ $-4.91$ to $-1.34$, $P = 0.0006$; $I^2 = 71\%$; $P = 0.004$). No significant difference was noted between RCTs and observational studies (test for subgroup difference: $P = 0.11; I^2 = 61.3\%$). As far as union rate is concerned, all the studies mentioned the number of fractures

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**UCLA**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>MD</th>
<th>95% CI</th>
<th>P</th>
<th>I²</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Randomised Controlled Trials</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Erasmus 2015</td>
<td>33.1</td>
<td>1.5</td>
<td>32</td>
<td>33.2</td>
<td>11</td>
<td>33</td>
<td>26.9%</td>
</tr>
<tr>
<td>Elsas 2016</td>
<td>34.7</td>
<td>0.8</td>
<td>34</td>
<td>34.7</td>
<td>3</td>
<td>34</td>
<td>27.2%</td>
</tr>
<tr>
<td>Hahndorf 2015</td>
<td>34.7</td>
<td>0.8</td>
<td>34</td>
<td>34.7</td>
<td>3</td>
<td>34</td>
<td>27.2%</td>
</tr>
<tr>
<td>Kim 2015</td>
<td>33.1</td>
<td>2.2</td>
<td>36</td>
<td>33.9</td>
<td>29</td>
<td>32</td>
<td>27.0%</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>80</td>
<td>66.8%</td>
<td>0.05</td>
<td>0.266, 0.36</td>
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<tr>
<td>Heterogeneity: Chi² = 3.11, df = 2 (P = 0.21), I² = 36%</td>
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<tr>
<td>Test for overall effect: Z = 0.32 (P = 0.70)</td>
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</table>

**MEPS**

<table>
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<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>MD</th>
<th>95% CI</th>
<th>P</th>
<th>I²</th>
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<tbody>
<tr>
<td>1.1 Randomised Controlled Trials</td>
<td></td>
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<tr>
<td>Erasmus 2015</td>
<td>96.6</td>
<td>5.1</td>
<td>32</td>
<td>96.9</td>
<td>6.0</td>
<td>33</td>
<td>26.3%</td>
</tr>
<tr>
<td>Elsas 2016</td>
<td>93.0</td>
<td>0.3</td>
<td>15</td>
<td>97.7</td>
<td>10</td>
<td>15</td>
<td>12.0%</td>
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<tr>
<td>Hashdor 2015</td>
<td>93.4</td>
<td>40.4</td>
<td>36</td>
<td>93.9</td>
<td>40.4</td>
<td>33</td>
<td>27.4%</td>
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<tr>
<td>Kim 2015</td>
<td>83.1</td>
<td>8.3</td>
<td>83</td>
<td>83.5</td>
<td>8.3</td>
<td>83</td>
<td>83.5%</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>121</td>
<td>65.8%</td>
<td>0.00</td>
<td>0.03, 0.031</td>
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<tr>
<td>Heterogeneity: Chi² = 0.07, df = 2 (P = 0.72), I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 0.63 (P = 0.53)</td>
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**DASH**

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<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>MD</th>
<th>95% CI</th>
<th>P</th>
<th>I²</th>
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<td>1.1 Randomised Controlled Trials</td>
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</tr>
<tr>
<td>Erasmus 2015</td>
<td>8.3</td>
<td>5.8</td>
<td>15</td>
<td>8.9</td>
<td>8.4</td>
<td>15</td>
<td>33.3%</td>
</tr>
<tr>
<td>Elsas 2016</td>
<td>11.3</td>
<td>4.8</td>
<td>36</td>
<td>11.6</td>
<td>5</td>
<td>39</td>
<td>66.7%</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>45</td>
<td>45.0%</td>
<td>0.00</td>
<td>0.03, 0.03</td>
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<tr>
<td>Heterogeneity: Chi² = 0.01, df = 1 (P = 0.94), I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 0.34 (P = 0.73)</td>
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**ASES**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>MD</th>
<th>95% CI</th>
<th>P</th>
<th>I²</th>
</tr>
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<tbody>
<tr>
<td>1.1 Randomised Controlled Trials</td>
<td></td>
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</tr>
<tr>
<td>Erasmus 2015</td>
<td>84.9</td>
<td>8.2</td>
<td>22</td>
<td>84.9</td>
<td>5.4</td>
<td>23</td>
<td>56.1%</td>
</tr>
<tr>
<td>Elsas 2016</td>
<td>84.9</td>
<td>8.2</td>
<td>22</td>
<td>84.9</td>
<td>5.4</td>
<td>23</td>
<td>56.1%</td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.97, CHi² = 12.47, df = 1 (P = 0.0004), I² = 52%</td>
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<tr>
<td>Test for overall effect: Z = 0.56 (P = 0.59)</td>
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*Fig. 4* Forest plot showing University of California, Los Angeles (UCLA) Shoulder Scale, Mayo Elbow performance score (MEPS), Disabilities of the Arm, Shoulder and Hand (DASH) Score and American Shoulder and Elbow Surgeons (ASES) score.
which went on to unite till the last follow-up in each of the individual studies. However, the cut off time, when they declared a fracture to have gone into non-union varied from 6 months to an year or even beyond. We took either 9 months follow-up as cut off period or the requirement of secondary operative intervention to label a fracture to have gone into non-union. And hence, for the purpose of meta-analysis, one case of delayed union mentioned in each of An et al. [15] and in Kim et al. [19] was counted as non-union since the fractures went on to unite at 17 and 22 months, respectively. Also, union was considered as union/presence of bridging callus in 3 out of 4 cortices on standard antero-posterior and lateral radiographs with clinical absence of pain at the fracture site across all studies. There was overall just three cases of non-union in MIPO group amongst all studies (282 patients). As regards to ORIF, six studies mentioned [16, 18–21, 24, 26] one or more cases of non-union, amounting to 7 in total out of 281 patients. The pooled results showed clear superiority of MIPO over ORIF in achieving union if we look at the incidence of non-union. (OR = 0.27, 95% CI 0.10–0.70, \(P = 0.007\); \(I^2 = 0\%\); \(P = 0.99\)). The effect estimates of randomized clinical trials and observational studies were similar (test for subgroup difference: \(P = 0.78\); \(I^2 = 0\%\)) (Fig. 5).

**Duration of Surgery, Intraoperative Blood Loss, Radiation Exposure**

Data of seven studies [15, 16, 18–21, 24–26] were compiled to compare the surgical duration between MIPO and ORIF and it was significantly shorter in MIPO group with a mean difference of –22.89 min (95% CI –37.74 to –8.04, \(P = 0.003\); \(I^2 = 95\%\); \(P < 0.00001\)). Test for difference between RCTs and observational studies was significant (\(P = 0.004\), \(I^2 = 87.7\%\)). Intraoperative blood loss (in ml) was mentioned in three RCTs [20, 25, 26] and was significantly smaller in MIPO group. (MD = –193.68, 95% CI –260.08 to –127.27, \(P < 0.0001\); \(I^2 = 96.0\%\); \(P < 0.0001\)) (Fig. 6). Although intraoperative fluoroscopy is an integral part of MIPO, exact radiation exposure was mentioned for MIPO group in four studies [16, 19, 20, 25] where it ranged from 68 to 201 seconds. For ORIF, it was used for only one study [20].

**Other complications—iatrogenic Radial Nerve Palsy, Infection, Mal-union, Reoperation**

All 11 studies [15, 16, 18–26] mentioned about iatrogenic radial nerve palsy. Its rate was significantly lower in the MIPO group (2%) as compared to ORIF (8.6%) (OR = 0.31, 95% CI 0.14–0.67, \(P = 0.003\); \(I^2 = 0\%\); \(P = 0.92\)). Test for subgroup differences did not show any significant difference between RCTs and observational studies (\(P = 0.99\), \(I^2 = 0\%\)). Seven out of 11 studies mentioned infection as one of the complications [16, 20, 21, 23–26]. However, most of the infections were superficial and low grade in nature. Pooled data clearly showed an absence of infection in all but one of the MIPO groups [24] while it was found to varying extents in ORIF groups. (\(OR = 0.31, 95\% CI 0.09–0.86, P = 0.03\); \(I^2 = 0\%\); \(P = 0.98\)). Test for subgroup differences between RCTs and observational studies were not significant (\(P = 0.99, I^2 = 0\%\)) (Fig. 7). About mal-union, the criteria used varied across studies. Only two studies described it in detail. Esmailiejah et al. mentioned incidence of varus deformity of more than five degrees in six out of 32 cases of MIPO and two out of 33 cases of ORIF [21]. Wang et al. [18] studied CT scan based Humeral Retroversion Angle to assess the degree of postoperative rotational malalignment and found it to be significantly higher in MIPO group as compared to ORIF (18.2° ± 15.4° vs. 7.4° ± 4.4°, respectively; \(P = 0.017\)). Reoperation for complications like non-union, delayed union or infection was mentioned in three studies [20, 24, 26], accounting for eight cases, all of which belonged to ORIF group. However, it is important to mention here that few retrospective studies [22] had mentioned requirement of reoperation as an exclusion criteria for enrolling patients (Table 3).

**Publication Bias**

Funnel plots for a few major parameters—functional outcomes (UCLA and MEPS), union time and non-union rate showed no substantial asymmetry, indicating no significant risk of publication bias (Fig. 8).

**Discussion**

This meta-analysis clearly shows the superiority of MIPO over ORIF in terms of union rate, union time and incidence of three major complications—non-union, iatrogenic radial nerve palsy and infection. Surgical duration was significantly shorter and intraoperative blood loss lesser in MIPO as compared to ORIF. However, there was no significant difference in terms of functional outcome.

MIPO has gained wide popularity in recent times. There were six systematic reviews/meta-analysis published till 2017 on this topic [8–11, 38, 39]. At the time of registering for the review, there were two more RCTs (published in 2019) [25, 26] and two more non-randomised comparative studies (published in 2017) [23, 24] not included amongst these studies. Recently, a systematic review was published specifically comparing MIPO with ORIF by Beerse et al. [40] However, it was not a registered one and has not included the two RCTs published in 2019. Out of these seven reviews, six have compared MIPO with both ORIF and IMN.
2 amongst these six have done network meta-analysis [11, 39]. Also, no subgroup analysis between RCTs and non-randomised studies has been done. Our study, which was done after proper registration, includes five RCTs and six observational studies and has subgroup analysis corresponding to the type of studies.

The pooled results did not show the superiority of either MIPO or ORIF when functional outcome in terms of shoulder function (UCLA), elbow function (MEPS), both shoulder and elbow (ASES) or whole upper limb (DASH) is concerned. Previous meta-analyses have shown similar pooled results. Since the main endpoint of interest, functional outcome, is not sufficient to say which one is a better procedure, Hohmann et al. mentioned the importance of looking at the incidence of complications in such a case as an alternative treatment effect [8, 41]. However, it must be seen that the functional outcome scores across most of the individual studies have excluded the cases which required

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**Fig. 5** Forest plot showing union time (weeks) and incidence of non-union
secondary procedures for one or more of the complications. Also, since none of the two methods involve either shoulder or elbow joints, the scores are not expected to be much different [40].

For intraoperative parameters like duration of surgery, amount of blood loss and radiation exposure, MIPO has got clear superiority. All except one of the studies showed lesser operative duration in MIPO [18]. ORIF works on the principle of absolute stability and hence perfect anatomical restoration is sought for. On the other hand, MIPO works on relative stability and gross restoration of length, rotation and alignment is required. This fact coupled with smaller incisions and lesser surgical dissection reduces the operative duration and also the blood loss [42].

If there is one factor which goes highly in favour of MIPO, it is relatively low incidence of non-union and iatrogenic radial nerve palsy. Amongst the long bone diaphyseal fractures treated operatively, humerus is highly notorious for non-union. Historically, if conservative management of humeral shaft fractures has yielded good results, it is due to the preservation of osseous vascularity and the fracture haematoma. But, mal-union was highly common. Even non-union was seen due to inadequate immobilization [2–4]. A recently published RCT (Matsunaga et al.) between MIPO (bridge plating) and conservative management by functional brace had a significantly more favourable non-union rate for MIPO (0% versus 15%) [43]. Xue et al., in a cadaveric study showed that MIPO technique is superior to ORIF in terms of preserving the vascular integrity of the mid-distal humeral shaft [44]. It also preserves fracture haematoma, at least partly, and thus seems to aid or assist what nature is trying to do [42]. One thing that nature does not do on its own is proper alignment and that is the exact thing we are trying to provide from our end in MIPO. That can be achieved with IMN also, but it jeopardizes medullary blood supply, damages rotator cuff and leads to shoulder impingement, if nail is protruding out [8–11]. Most of the studies in our review had all types of humeral diaphyseal fractures (AO Type A, B and C), which shows that MIPO works equally well for all of them.

Iatrogenic radial nerve palsy in conventional open plating may range from 5.1% to 17.6% [45, 46]. In our review, its incidence was 2% for MIPO and 8.6% for ORIF. However, most of them were transitory and recovered within weeks to months. Few studies have shown that there is a pad of brachialis muscle between plate and the radial nerve in cases operated by MIPO from anterior aspect [15, 47]. Danger zone for the radial nerve is around three-eighths (37.5%) to

Fig. 6 Forest plot showing duration of surgery (minutes) and intraoperative blood loss (ml)
five-eighths (62.5%) of the humeral length when measured from the tip of the acromion process to the lateral epicondyle. Keeping the forearm in supination takes radial nerve away from the surgical field and thus MIPO should be done in this very position [48]. Whether that can lead to postoperative rotational malalignment or not may be a topic for
future CT-based studies, somewhat similar to that of Wang et al. [18].

Incidence of infection was low in both the groups. However, chances of infection increases as the degree of surgical dissection is increased. Compared to ORIF, MIPO causes iatrogenic devascularisation of bone and soft tissues to a lesser extent and hence reduces the chances of infection [23, 41, 43]. Above all, since the infection tends to be limited in the plate and soft tissues due to intact periosteum, postoperative infections after MIPO are less aggressive and easier to manage [23]. Comparative analysis of postoperative malrotation in both the groups was adequately dealt with in just one of the included studies [18]. Conventionally, up to 15° of internal rotation has been considered to be acceptable. Analysis of rotational malalignment in both the groups on the basis of CT scan based Humeral Retroversion angle, as described by Boileau et al. and to what extent it affects the functional outcome in short term and incidence of shoulder arthritis in long term should be looked for in the future studies [48].

The strengths of the study was the systematic approach we adopted for performing the review, the fact that majority of the team consisted of surgeons who had enough experience in orthopaedic trauma and the critical review of all the included studies to assess the quality of various outcome measures and other parameters for recommendation of one procedure over the other. The major limitation of the present study was the quality of the original studies. Out of the 11 comparative studies comprising of 5 RCTs, only 1 was an RCT without any risk of bias which described the process of randomization in detail [22]. The second limitation was the variation in terms of types of fractures across studies. Some studies included up to Gustilo Anderson grade 2B open fractures [16, 19, 21, 22, 24] while others did not. And thirdly,

![Figure 8: Funnel plots for few major parameters of the study—functional outcomes (UCLA and MEPS), union time and union rate.](image)

**UCLA**

**MEPS**

**Union Time**

**Non-union Rate**

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**Subgroups**

- Randomised controlled Trials
- Observational Studies

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UCLA University of California, Los Angeles shoulder scale, MEPS mayo elbow performance score, SMD standard mean difference, SE standard error, OR odd’s ratio
the postoperative outcome assessment scoring systems used were different across studies. Although UCLA and MEPS was commonly used in majority of the studies, few studies measured DASH [25, 26] and other scores [18], and thus the results of all the studies could not be pooled together. Also some studies mentioned only the mean scores and not the exact p value [16], due to which we were not able to calculate standard deviation for those studies and hence could not be included in the meta-analysis for some of the parameters.

Conclusions

This systematic review and meta-analysis shows that MIPO has got similar functional outcome as compared to ORIF and causes significantly less blood loss, requires less operative duration, has lesser incidence of major complications like non-union, iatrogenic radial nerve palsy, and infection. But, high-quality RCTs will be required to address the question of whether it becomes a standard of care for humeral shaft fractures. We recommend that future studies should compare not only MIPO and ORIF but also MIPO and conservative treatment by functional arm brace.

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Declarations

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Ethical This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent For this type of study, informed consent is not required.

References


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Articular Femoral Head Fracture Management: A Meta-analysis of Literature

Giulia Bettinelli1· Giacomo Placella2· Désirée Moharamzadeh2· Alberto Belluati3· Vincenzo Salini1,2

Abstract
Purpose Articular fractures of the proximal femur are seldom encountered and there are few studies in literature regarding this topic. To date, only a few large series have adequate follow-up and exhaustive description of treatment and outcome, which, however, often result incomplete and do not allow a comparison. Since there are still uncertainties and debates on which the treatment gold standard should be, the goal of the present study is to carry out a meta-analysis on type I and II Pipkin fracture management to establish the best treatment according to EBM.

Methods Studies regarding acetabular fractures of the femur head were identified from Google Scholar, Cochrane Library, Medline, ScienceDirect and PubMed; gray studies were searched from the included references’ literature, and using general search engines and Social media; the query to be temporally extended from 1996 to 2020. Only comparative studies were included; we ruled out case-reports, case series, author’s opinion, register databases.

Results Comparing conservative and surgical treatment, we found evidence of a better outcome choosing surgical treatment. We found a significant better outcome with open reduction internal fixation, instead of fragment excision. Comparing failure rate of surgical approaches, we found no statistically significant difference.

Conclusion Our study proves that there is evidence in favor of operative treatment rather than conservative in complete or displaced Pipkin fracture Type I + II; open reduction internal fixation should be preferred rather than fragment excision, whenever possible.

Level of Evidence III. Therapeutic.

Keywords Pipkin · Femoral head fracture · Hip fracture · Hip dislocation

Background

Articular fractures of the femoral head are rare, and usually are associated to traumatic dislocations in about 12% of cases. More often fractures are consequent to a traumatic posterior hip dislocation; less frequent are fractures caused by an anterior hip dislocation (11% of hip dislocations) or isolated femoral head articular fractures [1–3].

In 1869 John Birkett performed an autopsy in a 35yo woman, who died after a fall from a window: he was the first ever to describe an articular femoral head fracture [4].

These fractures occur mostly due to high energy traumas, mainly car accidents when seated with hips in flexion and adduction which determines the maximum laxity of coxofemoral joint [5].

Based on the position of the hip and the direction of the force applied, different fracture patterns can occur, usually classified according to Pipkin [6].
Pipkin’s classification comprises four types: type I if the fracture involves a non-weight bearing cartilage surface (below the round ligament insertion), type II if it involves a weight-bearing area (above the round ligament insertion); type III is associated to a femoral neck fracture; type IV if associates to acetabular fractures [7].

Although Pipkin classification is the most frequently used, it is not the only available option.

Chiron classification describes the fragment size to classify the fractures in one of the five types with prognostic value but requires a CT scan to be reproducible [8]. Other useful proposals of classification are the AO method, the Yoon’s modification of Pipkin Classification and Brumback’s classification, but these are less used in clinical practice [7].

Treatment can vary from conservative, prior immediate reduction to restore the femoral head’s blood supply, to total hip arthroplasty (THA), based on the fracture pattern. Often surgeons have to balance between benefits and harms of one treatment compared to another.

Since it is an uncommon finding, and since it is an articular fracture localized in a deep joint, the final treatment results challenging also for an expert traumatology surgeon. Despite the best treatment option choice, some consequences can eventually develop, due to the trauma: Heterotopic Ossifications (HO), Avascular Necrosis (AVN) and Osteoarthritis [6].

In March 2020 we performed an electronic research in PubMed Clinical Queries, entering the term “Pipkin”; we discovered there is only one systematic review regarding this topic, dated 2009 (Giannoudis) [6]. Similarly, only one meta-analysis exists, dated 2016 (Wang), comparing anterior vs posterior approach in Pipkin I and II fracture management reporting only a statistically significant decreased risk of heterotopic ossification in posterior approach compared to anterior approach [9].

Our purpose with the present meta-analysis is to gather all the novel literature that compares different management strategies, to extrapolate best practices when facing an articular fracture of the proximal femur.

Methods

A systematic review and meta-analysis of comparative studies was performed in April 2019; this was in accordance with the guidelines of meta-analysis of observational studies in epidemiology (MOOSE) [10].

Customized structured electronic searches were performed by two independent reviewers in Google Scholar, Cochrane Library, Medline, ScienceDirect and PubMed.

We identified all orthopedic studies regarding articular fractures of the femur head; gray studies were searched from the included references’ literature, and using general search engines and Social media (Researchgate, Google, Yahoo); if the article was not available, we tried to contact the authors. We wanted the query to be temporally extended from 1996 to 2020.

The following keywords were used: “femoral head fracture” OR “Pipkin fracture” OR “31C AO”, also in combination with the Boolean operator AND; no language restrictions were applied: if languages other than English and Italian were detected, internal translator support was requested.

Reference lists of eligible studies were also analyzed. It was often possible to exclude a citation immediately on the basis of information in the title and abstract. If the citation could not be excluded immediately, articles to be included were identified by full-text review. Studies meeting the inclusion criteria were evaluated in detail, and study characteristics were extracted using a standardized approach. Quantitative and qualitative characteristics of the studies were summarized.

Only comparative studies were included; we ruled out case-reports, case series, author’s opinion, register databases.

Articles were considered not eligible for this review if they met the following listed exclusion criteria.

Exclusion criteria: case report, study dealing exclusively Pipkin’s fracture type III–IV, data collection concluded before 1996 and with less than 12 month follow-up.

Inclusion criteria: comparative articles published between 1996 and 2020, dealing with femoral articular head fracture; presence of outcome measurements’ report with regard to fracture management and post-operative complications.

The same two reviewers performed the screening process; disagreements about relevance/eligibility were resolved by discussion.

Although useful for bibliography and to gather general knowledge regarding the topic, out of 112 studies retrieved relevant we eventually identified a total of 15 articles after further selection procedures.

An institutional review board approval was not sought neither obtained as all data were extracted from previously published studies. No external funding was received for the completion of this study.

As first outcome, we compared conservative vs surgical treatment. We included 9 articles [11–19]. The subordinate issues to be developed among this first outcome were the appearance of post-treatment complications (ANV, HO).

Our second outcome was to compare failure in surgical treatment: excision and Open Reduction Internal Fixation (ORIF); to answer this question, we included 7 articles [11, 13, 17, 19–22]. Once again, as subordinate outcomes we
evaluated the possible development of ANV and HO with one or the other surgical strategy.

As third outcome we compared failure of different surgical approaches. ANV and HO development were once again our secondary outcome, for each of the three groups. To develop this topic, we used 6 articles [11, 17, 20, 23–25].

For the score of each point, we collected data regarding Merle D’Aubigne score or Thompson and Epstein classification.

Two researchers independently extracted the data on the included literature. The following data were extracted: first author’s name, year of publication, intervening measures, epidemiological data, comparable baseline, sample size, outcome measurements and duration of follow-up. Other relevant parameters were also extracted from individual studies. Pooling of the data was performed and analyzed using RevMan software, version 5 (The Cochrane Collaboration, Oxford, United Kingdom). Heterogeneity was estimated depending on the values of $P$ and $I^2$ using the standard chi-square test. To indicate significant heterogeneity, $I^2 > 50\%$, $P < 0.1$ were required. Therefore, the random-effects model was applied for data analysis.

Risk differences (RDs) and 95% confidence intervals (CIs) are presented for dichotomous data in first outcomes group. For second and third Outcomes groups were calculated RDS and 90% CIs for dichotomous data. No continuous data were reported in this meta-analysis.

**Risk of Bias**

Two different reviewers evaluated and assessed all studies’ methodology quality using MINORS (methodological index for non-randomized studies) to establish their potential bias in our protocol research.

A minimum follow-up of 12 months was considered as an appropriate period for results monitoring, accordingly to the evidence reported in literature (Table 1).

**Statistical Analysis**

The meta-analysis was performed using RevMan V.5.0.18.33 to calculate pooled summary estimates and generate forest plots. Forest plots were used to present the results of the individual studies.

Moreover, publication bias was assessed using funnel plot for all papers and for each aforementioned subgroup.

**Results**

This meta-analysis included 274 cases from 15 studies. Mean age of patients is 36.4 years (sex ratio 3:1 male to female). Motor vehicle accidents contribute to 78% of cases, followed by fall from height in 14% cases.

In Fig. 1, we report the flowchart we used to extrapolate relevant articles (Table 2).

**Choice of Treatment Strategy**

Our first outcome is a comparison of conservative and surgical management in Pipkin type I and II fractures; 9 articles met the inclusion criteria and were considered relevant to develop this issue. The Merle D’Aubigne or Thompson and Epstein scale were applied to assess hip function: as in papers included in the present article [11–21, 23–25] we considered as “event” a post-treatment score of poor or fair.

The Funnel plot (Fig. 2) referred to the included studies is reported, no publication bias is detectable.

No significant heterogeneity was found, and a fixed model was used ($\chi^2 = 4.41, df = 8, P = 0.82, I^2 = 0\%$). The following forest plot (Fig. 3) shows a significant difference between the two groups (RR = 2.77, 95% CI 1.34–5.74, $Z = 2.74, P = 0.006$) in favor of surgical treatments.

When comparing surgical vs conservative treatment, we also analyzed the development of AVN and HO at the end of FU as secondary endpoints. Considering post-treatment development of HO during FU, we obtained a result in favor of conservative treatment, but these results are not reliable, because there is heterogeneity in the two groups (HO conservative vs surgical: $\chi^2 = 3.49, df = 6, P = 0.74, I^2 = 0\%$; AVN conservative vs surgical: $\chi^2 = 6.89, df = 5, P = 0.23, I^2 = 27\%$) (Figs. 4, 5).

**ORIF vs Excision**

The second outcome was to determine if there is a better outcome choosing ORIF or excision as surgical management of Pipkin I and II fractures. Seven articles were considered eligible to develop this issue.

We found a significant better outcome in patients who underwent ORIF ($\chi^2 = 3.52, df = 5, P = 0.62, I^2 = 0\%$) (Fig. 6).

In terms of HO formation, the Forest plot shows a slightly better outcome with excision than with ORIF, although this result is not significant ($\chi^2 = 1.53, df = 3, P = 0.68, I^2 = 0\%)$.

Regarding AVN complication, excision had a non-significant better result ($\chi^2 = 1.15, df = 2, P = 0.56, I^2 = 0\%$).
<table>
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<td>1</td>
<td>1</td>
<td>14/24</td>
<td>14/24</td>
<td>high</td>
</tr>
<tr>
<td>Stannard, 2000</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>11/24</td>
<td>11/24</td>
<td>high</td>
</tr>
<tr>
<td>Guimaraes, 2010</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>10/24</td>
<td>10/24</td>
<td>high</td>
</tr>
<tr>
<td>Wang, 2019</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>14/24</td>
<td>14/24</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Surgical Approaches Comparison

Number of available studies useful for a statistical analysis is too scarce; it was unluckily not possible to make a comparison of surgical approaches.

Discussion

It is difficult to predict outcome and response to treatment of Pipkin fractures as the fragment can be variable in size, shape and localization.
Most of the literature on the topic has been described in the last three decades; our decision to use the database from 1996 to date was made, because the mainly modern synthesis tools have been marketed during this period.

As previously stated, we decided to focus our efforts on Pipkin types I and II. Type III is the least common, accounting 8.6% of all Pipkin fractures, and requires operative treatment without any doubt, specifically THA; it is shared knowledge they have the worst prognosis [26].

Eventually Pipkin IV are more severe and with a poorer prognosis than the previous three types, for the addiction of the acetabular fracture and require always ORIF [6].

The predictive value of Pipkin classification is largely shared by previous studies [6] especially for the two sub-group Pipkin types I + II and the second grouping types III + IV.

The first subgroup has a more favorable outcome than the second, which often requires hip replacement. In the I + II Pipkin fracture group nowadays there is no gold standard treatment.

Our study proves that there is evidence in favor of operative treatment rather than conservative in complete or displaced Pipkin fracture Type I + II; the risk of having poor or fair score is higher with conservative treatment. To us, non-operative treatment in these patients is unjustifiable. Each grade of injury has a risk of developing arthritis, and free
1. Hip dislocations need urgent reduction to restore the blood supply to the femoral head; once osteochondral fragments from the femoral head must be reduced and fixed [27].

2. Among operative choices, there is not yet statistical evidence between the different surgical approaches neither in terms of better outcomes nor prevention of AVN and HO development.

3. We believe that using an approach which exposes the dislocation’s direction may offer advantages in terms of vascular supplies and stability. If a posterior dislocation occurs, we recommend the use of a posterolateral approach; if an anterior dislocation occurs, the lateral or antero-lateral or anterior approaches are preferred.

4. Intuitively the use of the opposite way can weaken the capsule, decrease the vascular supply, and reduce the safe range of motion for rehabilitation.
As a matter of fact, after the development of hip arthroscopic surgery in the recent years, it is now possible to manage Pipkin fractures types I and II arthroscopically. Hip arthroscopy yields less morbidity, causes minimal soft-tissue damage, and allows early rehabilitation [28, 29]. Furthermore, it allows debridement and washout of small fragments, which were previously neglected, and may determine a premature OA. This technique is minimally invasive and is expected to prevent the development of osteoarthritis after hip trauma [30].

Furthermore, since hip arthroscopy is much less invasive and muscle-sparing when compared to all other surgeries, HO is less likely to develop. Despite there seem to be good results in favor of the new arthroscopic trends to avoid HO and AVN, nowadays too few studies are present and mainly consists in case reports [29]. Arthroscopic mosaicplasty may provide satisfactory results, as a couple of short to mid-term studies proved; this permits successful joint preservation after significant trauma in the treatment of femoral head osteochondral lesions especially in young patients with good bone stock [31, 32].

According to Gagala, osteochondral autologous transfer is a reasonable option in the fixation of Pipkin fractures in selected patients [33].

The second statistically significant results we found in our Metanalysis regards the better outcomes of the ORIF solution compared to fragment excision. This result, however, is not very precise as in the studies examined the size of the fragments removed or reinserted is almost never specified, leaving the choice to the surgeons in most cases. Our opinion according to Giannoudis et al. is that whenever the fragment is large enough to be fixed (bigger than 2 cm) it must always be fixed [6].

With regards to the synthesis tools, the treatment of internal fixation with Herbert screws is effective for Pipkin type I and type II femoral head fracture [34]. The biodegradable pin option allows a good fixation of the fracture fragments to prevent displacement, avoiding metal artifacts during radiologic imaging. Magnetic resonance also can be performed with such implants, making earlier detection of head necrosis possible. Postoperative exercises and 6-week postoperative partial weightbearing are generally well tolerated, with no development of fragment displacement [35].

Developing the main goal of the present meta-analysis we found out that surgical strategy should be the gold standard to treat articular femoral head fracture type I and II according to Pipkin classification. As the matter of fact, patients who had underwent a conservative treatment showed significant lower satisfaction and a poor-fair outcome at FU in terms of Merle D'Aubigne or Thompson and Epstein scale.

Our results were also statistically favorable to ORIF instead of limiting the surgical procedure to just fragment excision. This is probably due to the precise reduction of the chondral articular plane allowed by an ORIF procedure; this permits an anatomical restoration as close as possible to the original.

Lastly our study did not highlight any statistically significant difference in terms of HO formation and AVN development following excision rather than ORIF or using different surgical approaches; however, more studies are needed.

It would be of great interest to deepen the research on arthroscopic technique for Pipkin fracture repair, which could prove to be an excellent solution in these cases.

### Declarations

**Conflict of interest** The authors declare that they have no competing interests.

**Ethical statement** The study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki.

**Informed consent** For this type of study informed consent is not required.
References


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The MeNT-OS Score for Orthopaedic Surgery: An Objective Scoring System for Prioritisation of Orthopaedic Elective Surgeries During a Pandemic

Sumanth Madhusudan Prabhakar1 · Joshua Decruz1 · Remesh Kunnasegaran1

Introduction

The reintroduction of elective Orthopaedic surgery during the COVID-19 pandemic is likely to occur in phases, dictated by resource limitations and loco-regional pandemic status. Guidelines providing a general framework for the prioritisation of surgery have largely been based on surgical urgency, while scoring systems such as the MeNTS score may have limited applicability in the setting of Orthopaedic Surgery. We, therefore, propose an Orthopaedic-specific algorithm (‘MeNT-OS’), based on a modification of the MeNTS scoring system, that may be used to objectively triage and prioritise Orthopaedic cases during the COVID-19 pandemic.

Methods

We developed a scoring algorithm modified from the Medically Necessary Time-Sensitive Procedure (MeNTS) score with 13 unique variables, reflecting human and physical resource utilisation, surgical complexity, functional status of patients, as well as COVID-19 transmission risk. This score was then trialled in a sample of 118 cases, comprising 69 completed and 49 postponed cases. A higher overall score was intended to correlate with lower surgical prioritisation.

Results

The use of our scoring system resulted in higher average scores for postponed cases compared to completed cases, as well as higher median, 25th and 75th percentile scores. These results were statistically significant and showed concordance with the ad hoc decisions made before the scoring system was used, with the lower scores for completed cases suggesting a more favourable risk–benefit ratio for being performed as compared to the postponed cases.

Conclusion

The utility of the proposed ‘MeNT-OS’ scoring system has been assessed using data from our institution and offers an objective and systematic approach that is geared towards Orthopaedic procedures. We believe this scoring tool can provide Orthopaedic surgeons a safe and equitable approach to making difficult decisions on prioritisation of surgery during the COVID-19 period, and possibly other resource-limited settings in the future.

Keywords COVID · Triage · Algorithm · Arthroplasty · Pandemic

Introduction

The global COVID-19 pandemic has caused a paradigm shift on the delivery of surgical care worldwide, with a large proportion of non-emergency or elective surgeries deferred to divert our limited healthcare resources to deal with the pandemic [1]. Orthopaedic procedures have been among the most disrupted aspects of surgical care, causing a significant number of patients to experience profound impacts on their functionality and overall quality of life [2].

As the COVID-19 pandemic continues to evolve, and countries begin gradually easing restrictions on elective surgeries in accordance with the local circumstances, plans for the resumption of elective surgeries are being made [3]. As the reintroduction of elective surgery is likely to occur in a phased manner, accounting for limitations in re-deployment of skilled manpower, availability of consumables for surgery, and other limited healthcare resources, it is likely that a return to pre-pandemic levels of surgical services may not be as quick as initially anticipated [4]. To this end, a number of guidelines for prioritisation of surgery have been issued by professional surgical societies, including the American College of Surgeons [5] (ACS) and the Royal College of
Surgeons [6] (RCS). However, while these guidelines offer a broad framework for the prioritisation of cases, based on surgical urgency, they often do not account for multiple other dynamic factors which may influence scheduling of surgery.

The Medically Necessary, Time-Sensitive (MeNTS) tool [7] proposed by the University of Chicago is a comprehensive scoring tool that suggests prioritisation of cases based on a detailed consideration of procedure, disease, and patient-related variables (Fig. 1). However, this tool is based on a structure that does not include Orthopaedic specialty-specific criteria or a consideration of functional status. It includes variables that are difficult to quantify objectively, and contains variables that may be more relevant to general surgery and other non-Orthopaedic surgical specialties. In addition, there has been no validation of the MeNTS scoring for Orthopaedic cases to date.

The use of a scoring system with variables unique to Orthopaedic surgery should allow for more objective prioritisation of Orthopaedic procedures. We, therefore, propose an Orthopaedic-specific algorithm, based on a modification of the MeNTS scoring system, that may be used to objectively triage and prioritise Orthopaedic cases during the COVID-19 pandemic. To our knowledge, this is the first tool designed specifically for use in the context of Orthopaedic surgery.

### Table 1. Procedure Factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR time, min</td>
<td>&lt;30</td>
<td>31–60</td>
<td>61–120</td>
<td>121–180</td>
<td>&gt;181</td>
</tr>
<tr>
<td>Estimated LOS</td>
<td>Outpatient</td>
<td>&lt;23 h</td>
<td>24–48 h</td>
<td>2–3 d</td>
<td>&gt;4 d</td>
</tr>
<tr>
<td>Postoperative ICU need, %</td>
<td>Very unlikely</td>
<td>&lt;5</td>
<td>5–10</td>
<td>11–25</td>
<td>&gt;25</td>
</tr>
<tr>
<td>Anticipated blood loss, cc</td>
<td>&lt;100</td>
<td>100–250</td>
<td>250–500</td>
<td>500–750</td>
<td>&gt;751</td>
</tr>
<tr>
<td>Surgical team size, n</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>&gt;4</td>
</tr>
<tr>
<td>Intubation probability, %</td>
<td>≤1</td>
<td>1–5</td>
<td>6–10</td>
<td>11–25</td>
<td>&gt;25</td>
</tr>
</tbody>
</table>

GL, gastrointestinal; LOS, length of stay; MIS, minimally invasive surgery; OHNS, otorhinolaryngology; H&N, head & neck surgery; OR, operating room.

### Table 2. Disease Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonoperative treatment option effectiveness</td>
<td>None available</td>
<td>Available, &lt;40% as effective as surgery</td>
<td>Available, 40% to 60% as effective as surgery</td>
<td>Available, 61% to 95% as effective as surgery</td>
<td>Available, equally effective</td>
</tr>
<tr>
<td>Nonoperative treatment option resource/exposure risk</td>
<td>Significantly worse/not applicable</td>
<td>Somewhat worse</td>
<td>Equivalent</td>
<td>Somewhat better</td>
<td>Significantly better</td>
</tr>
<tr>
<td>Impact of 2-wk delay in disease outcome</td>
<td>Significantly worse</td>
<td>Worse</td>
<td>Moderately worse</td>
<td>Slightly worse</td>
<td>No worse</td>
</tr>
<tr>
<td>Impact of 2-wk delay in surgical difficulty risk</td>
<td>Significantly worse</td>
<td>Worse</td>
<td>Moderately worse</td>
<td>Slightly worse</td>
<td>No worse</td>
</tr>
<tr>
<td>Impact of 6-wk delay in disease outcome</td>
<td>Significantly worse</td>
<td>Worse</td>
<td>Moderately worse</td>
<td>Slightly worse</td>
<td>No worse</td>
</tr>
</tbody>
</table>

### Table 3. Patient Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>1</th>
<th>2–40</th>
<th>41–50</th>
<th>51–65</th>
<th>&gt;65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>&lt;20</td>
<td></td>
<td></td>
<td></td>
<td>&gt;65</td>
</tr>
<tr>
<td>Lung disease (asthma, COPD, CF)</td>
<td>None</td>
<td></td>
<td></td>
<td>Minimal (inhaler)</td>
<td>&gt; Minimal</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
<td>Not present</td>
<td></td>
<td></td>
<td>Mild/moderate/CPAP</td>
<td>On CPAP</td>
</tr>
<tr>
<td>CV disease (HTN, CHF, CAD)</td>
<td>None</td>
<td>Minimal (no meds)</td>
<td>Mild (1 med)</td>
<td>Moderate (2 med)</td>
<td>Severe (≥3 meds)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>None</td>
<td></td>
<td></td>
<td>Moderate (PO meds only)</td>
<td>&gt; Moderate (insulin)</td>
</tr>
<tr>
<td>Immunocompromised*</td>
<td>No</td>
<td>Moderate</td>
<td></td>
<td></td>
<td>Severe</td>
</tr>
<tr>
<td>ILI symptoms (fever, cough, sore throat, body aches, diarrhea)</td>
<td>None (Asymptomatic)</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Exposure to known COVID-19 positive person in past 14 days: No, Probably not, Possibly, Probably, Yes

*Hematologic malignancy, stem cell transplant, solid organ transplant, active/current cytotoxic chemotherapy, anti-TNFα or other immunosuppressants, >20 mg prednisone equivalent/day, congenital immunodeficiency, hypergammaglobulinemia, severe immunodeficiency, AIDS, CAD, coronary artery disease; CF, cystic fibrosis; CHF, congestive heart failure; COVID-19, novel coronavirus; CPAP, continuous positive airway pressure; CV, cardiovascular; HTN, hypertension; ILI, influenza-like illness; med, medication; PO, by mouth.

Fig. 1 The Medically Necessary, Time-Sensitive (MeNTS) procedures scoring tool
Methods

We developed a scoring tool ‘MeNT-OS’ (Medically Necessary and Time-Sensitive—Orthopaedic Surgery) consisting of variables that would reflect human and physical resource utilisation, surgical complexity, functional status of patients, as well as COVID-19 transmission risk (Fig. 2). A total of 13 unique variables were included and stratified into Surgical Factors and Disease Factors, scored on a three or five-point scale, for a total score range of 13–51 points. Higher numeric values were assigned to factors that would reflect greater resource utilisation, increased surgical morbidity, increased risk of COVID-19 transmission, and less adverse functional impact on patients. A higher overall score is, therefore, designed to correlate with lower surgical prioritisation.

Modifications from the MeNTS Score

The original MeNTS tool proposed by Prachand et al. consists of 21 variables stratified into three categories of Procedure, Disease and Patient factors, with each scored on a five-point scale to yield a cumulative score range of 21–105 points. Higher scores reflected lower prioritisation of cases as they signified poorer peri-operative patient outcomes, high resource utilisation and increased risk of COVID-19 transmission to the healthcare team. In the development of our Orthopaedic-specific scoring tool, we retained some variables present in the original MeNTS tool while excluding those that were impractical in the Orthopaedic setting. The rationale for exclusion of certain factors is detailed below.

Factors Excluded, Modified, and Added

Amongst Procedure Factors, we omitted ‘Intubation Probability’ as we found it to be challenging to determine objectively with the arbitrarily assigned answer stems. However, we recognised the effects of intubation on increased aerosolisation of airway secretions [8], as well as its potential effects on post-operative respiratory function. We felt this was represented adequately with ‘Type of Anaesthesia Used’ instead, with highest scores associated with the use of general anaesthesia involving intubation.

Our algorithm introduced another factor to evaluate the risk of COVID-19 transmission to the surgical team, based on the potential for aerosol generation. The use of certain surgical tools—namely, use of diathermy, pulse lavage, ultrasonic tools, and power tools or high speed burrs—has been shown to increase aerosol generation [9, 10]; hence, higher scores were assigned to procedures which were predicted to require the use of these tools.

‘Surgical Site’ was removed from our scoring tool as none of the anatomical categories described were relevant for commonly performed Orthopaedic surgeries. In contrast to general surgical procedures, Orthopaedic procedures do not typically involve manipulation of the upper aerodigestive tract or the thorax, which are risk factors for airway secretion aerosolisation. In general, there have been no strong correlations between Orthopaedic surgical site (which are often in the peripheral joints) and post-operative respiratory function, with the notable exception of spine surgeries involving the prone position [11]. Even so, we felt that these risks were evaluated sufficiently with the other existing variables in our scoring system.

The variable ‘Post-Operative ICU need’ was better modified to ‘Type of Inpatient Bed Required’, with the assumption that admission to the high dependency ward or ICU would entail greater resource consumption.

Disease Factors were modified to be more specialty-centered. We proposed to estimate the impact of delayed surgery on ‘functional outcome’ rather than ‘disease outcome’ proposed originally, as functional outcomes are generally more clearly defined in the Orthopaedic setting, in addition to being a key practical consideration in the listing of most Orthopaedic surgeries (with the possible exception of oncologic surgeries). For ease of scoring, less variability was introduced in the scoring of these categories with a three-point scale rather than a five-point scale.

Other modifications were made in the category of Patient Factors. We chose to use the ASA classification to serve as a surrogate measure for patient comorbidities and severity of systemic disease, thus removing the need to individually score age, cardiorespiratory diseases, diabetes, and immunocompromised status. This reduced the complexity of the scoring system while also ensuring that the principle of selecting patients with a higher likelihood of tolerating surgery was not compromised.

Two other Patient Factors—presence of influenza-like illness (ILI) symptoms, and exposure to known COVID-19-positive persons within a 14-day period, were considered redundant and excluded as the presence of any of the above would have likely resulted in the cancellation of the surgery at our institution.

Factors Retained

We retained the other factors of Time in Operating Room, Anticipated Blood Loss, Surgical Team Size, and Estimated Length of Stay to serve as surrogate measures of anticipated...
resource consumption. The Impact of Delay in Surgical Difficulty/Risk was also retained.

We then proceeded to test this scoring system retrospectively, with both postponed and completed Orthopaedic cases during the early COVID-19 pandemic period from February to May 2020. Scores were calculated and compared for a total of 69 completed and 49 postponed cases from sub-specialties of Adult Reconstruction, Spine, Sports, Foot and Ankle and Musculoskeletal Oncology (Tumour). A smaller sample of cases was used to evaluate the utility of the MeNTS score as a prioritisation tool for Orthopaedic surgeries.

## Results

Our MeNT-OS scoring system identified a total of 13 factors that would contribute to triage and prioritisation of Orthopaedic procedures in the setting of the COVID-19 pandemic.

---

### Surgical Factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating room time, min</td>
<td>≤ 30</td>
<td>31-60</td>
<td>61-120</td>
<td>121-180</td>
<td>≥ 181</td>
</tr>
<tr>
<td>Estimated blood loss, ml</td>
<td>≤ 100</td>
<td>101-250</td>
<td>250-500</td>
<td>500-750</td>
<td>≥ 751</td>
</tr>
<tr>
<td>Type of anaesthesia</td>
<td>Local anaesthesia</td>
<td>Regional anaesthesia</td>
<td>General anaesthesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical team size</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>&gt;4</td>
</tr>
<tr>
<td>Estimated length of stay</td>
<td>Day surgery</td>
<td>≤23hrs</td>
<td>24-48 hrs</td>
<td>48-72 hrs</td>
<td>≥ 4 days</td>
</tr>
<tr>
<td>Type of bed required</td>
<td>Day surgery</td>
<td>General ward</td>
<td>High dependency</td>
<td>ICU</td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Equipment used (1 point for each)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>- Diathermy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Pulse lavage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ultrasonic tools</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Power tools/high speed burrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Disease Factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative treatment effectiveness</td>
<td>Non available</td>
<td>Available, not as effective as surgery</td>
<td>Available, effective as surgery</td>
</tr>
<tr>
<td>Impact on function with 2 month delay in surgery</td>
<td>Significantly worse</td>
<td>Moderately worse</td>
<td>Slightly worse or equal</td>
</tr>
<tr>
<td>Impact on surgical difficulty/risk with 2 month delay</td>
<td>Significantly worse</td>
<td>Moderately worse</td>
<td>Slightly worse or equal</td>
</tr>
<tr>
<td>Impact on function with 6 month delay in surgery</td>
<td>Significantly worse</td>
<td>Moderately worse</td>
<td>Slightly worse or equal</td>
</tr>
<tr>
<td>Impact on surgical</td>
<td>Significantly worse</td>
<td>Moderately worse</td>
<td>Slightly worse or equal</td>
</tr>
</tbody>
</table>

---

Fig. 2  Modified MeNTS scoring tool for Orthopaedic Surgery—the “MeNT-OS” score
These factors were divided into Surgical Factors (8 Factors) and Disease Factors (5 Factors).

A total of 118 Orthopaedic cases, consisting of 69 completed cases and 49 postponed cases, were used in the trial of our MeNT-OS scoring system. These cases were all performed at a single institution in Singapore during a 4-month period of the COVID-19 pandemic, from February to May 2020. The cases were drawn from the caseload of five surgeons from the Orthopaedic sub-specialties outlined above. A breakdown of cases by subspecialty is provided (Fig. 3), with Sports, Spine, and Foot and Ankle accounting for a higher proportion of completed cases, and Adult Reconstruction a higher proportion of postponed cases.

The application of the modified scoring system to the completed cases resulted in scores ranging from 19 to 38, with a mean of 31.3 and a median of 31. The scores for postponed cases ranged from 25 to 41, with a mean score of 32.6 and a median of 35 (Fig. 4a, b). Mann–Whitney U test was used to assess the scoring system to compare scores of completed and postponed cases, and returned a statistically significant p value of 0.0003.

Among the Orthopaedic sub-specialties, higher mean scores for both completed and postponed cases were observed for cases from Adult Reconstruction and Spine, while scores for surgeries from Foot and Ankle, Sports, and Oncology were lower in comparison (Fig. 4c). Postponed surgeries from Adult Reconstruction, Foot and Ankle, and Spine sub-specialties had higher scores compared to completed cases from the same specialty, whereas scores for Oncology and Sports were marginally lower for postponed cases. Using the Mann–Whitney U test, our scoring system was further validated for Spine and Adult Reconstruction subspecialty cases with p values of 0.006 and 0.003, respectively. We were not able to obtain statistically significant p values for the sub-specialties of Sports, Foot and Ankle and Tumour.

A sample of 26 cases, consisting of 9 completed and 17 postponed cases from a single surgeon were also evaluated using the MeNTS tool for a trial of validation. Scoring with the MeNTS tool resulted in a mean score of 58.3 for completed cases and 55.2 for postponed cases, with a p value of 0.112 rendering it statistically not significant at a 95% confidence interval.

Attempts were made to study reliability of our dataset using Cronbach’s Alpha, with computed values of 0.58 from data for completed cases, and 0.64 for postponed cases suggestive of moderate internal consistency of data.

Discussion

The resumption of elective Orthopaedic surgery during the COVID-19 period is likely to occur in a phased manner, and will require surgeons to prioritise procedures in order to account for manpower and resource limitations that will lower surgical capacities. Surgeons, hospitals, and healthcare systems have not approached this uniformly, with many continuing to rely on individual judgement to decide which surgeries should be performed. Our institution, which is incidentally at the epicenter of the response to the COVID-19 pandemic in Singapore, has employed a department-focused approach that prioritises cases based on surgical indication and urgency. In specific, surgical departments are asked to prioritise their delayed cases and submit them to a multi-disciplinary committee for approval; once approved, surgeons/ departments are granted time to perform these surgeries in pre-allocated operating theatres.
Fig. 4  a Comparison of MeNT-OS scores illustrating higher mean and median scores for postponed cases. b Distribution of scores for postponed and completed surgeries, and identification of potential cut-off point based on current data. c Comparison of average MeNT-OS scores between Orthopaedic sub-specialties
Our aim was to introduce a measure of objectivity into this process with the development of a specialty-centric scoring system.

The use of our MeNT-OS scoring system resulted in higher mean scores for postponed cases compared to completed cases, as well as higher median, 25th and 75th percentile scores (Fig. 4a). These differences were statistically significant and were internally validated using a sample of 69 completed and 49 postponed cases. These results showed concordance with the ad hoc decisions made before the scoring system was used, with the lower scores for completed cases suggesting a more favourable risk–benefit ratio for being performed as compared to the postponed cases.

Among the Orthopaedic surgery sub-specialties, statistically significant differences were observed in the comparison of scores for completed and postponed cases from adult reconstruction and spine surgery. As these two sub-specialties account for most Orthopaedic patients requiring inpatient admission after elective surgeries (74% of inpatient admissions amongst completed cases in our cohort), the MeNT-OS shows promise in helping surgeons prioritise cases appropriately to ensure optimal utilisation of hospital resources.

Although marginally lower scores for postponed cases were observed in the sub-specialties of Sports and Tumour, these differences were not proven to be statistically significant with p-values of greater than 0.05.

While we noted there to be a wide distribution of overlapping scores for both completed and postponed cases, we observed a mean score of 31.3 for completed cases and 32.6 for postponed cases, and median scores of 31 and 35, respectively. With an arbitrary cut-off score of 34 derived from these values (above which cases are recommended to consider deferment of surgery) (Fig. 4b), we were able to identify 67% of postponed cases and 78% of completed cases retrospectively. Although the accuracy of such a cut-off point is limited by the number of overlapping scores, we believe that such a threshold would be dynamic, and should be adjusted based on local considerations, especially for cases with scores close to the cut-off point.

A number of other scoring systems and algorithms have been proposed to guide decision making for prioritisation of surgeries during the COVID-19 period. These include broadly applicable tools such MeNTS [7], designed for use on a wide range of surgical specialties, as well as specialty-specific tools such as the Johns Hopkins Gynaecologic Prioritisation System [12] (JH-GPS). The Spine Urgency Score is another such tool [13], jointly developed by neurosurgeons and Orthopaedic spine surgeons for prioritising spine surgery cases in resource-limited settings. A modification of the MeNTS score for use in the paediatric population has also been described [14].

However, our attempted validation of the MeNTS scoring tool for Orthopaedic Surgery, with retrospective scoring of postponed and completed cases, suggested that the score would have limited applicability for Orthopaedics in its original format. This was evidenced by the fact that completed cases were assigned higher overall scores than postponed cases, a result that contradicted the notion that patients assigned lower scores should be prioritised for surgery. Although our sample size was small and not statistically significant, these preliminary results further highlighted the need for a scoring system tailored for Orthopaedic use.

From our preliminary evaluations, we were able to identify a number of advantages of our scoring system as compared to the MeNTS tool. Our ‘MeNT-OS’ system was designed to be specialty-centric with the inclusion of several factors that were more relevant to Orthopaedic practice, including considerations for the use of aerosol-generating tools commonly used in Orthopaedics, as well as the impact of delayed surgery on the functional status of the patient. Conversely, factors that were considered less applicable for use in Orthopaedic practice were excluded as detailed.

These purported advantages were validated in our evaluations with both our own scoring system as well as a trial of the MeNTS tool for Orthopaedic surgery.

The MeNT-OS scoring tool has several limitations. As with the MeNTS tool and other similar scoring systems published for this purpose, equal weighting was given to all factors in our scoring. It is thus inevitable that certain factors may be assigned disproportionate weightage; this may need to be revised once more data is available on peri-operative outcomes in the COVID-19 pandemic. Despite efforts to design a scoring tool that was as objective as possible, there may still be significant subjectivity in scoring certain factors such as the functional impact of delayed surgery, or the effectiveness of conservative treatment. These factors were also identified as possible contributors to the higher scores seen for completed surgeries, compared to postponed surgeries, in the Sports and Tumour services.

As a preliminary study involving a relatively arbitrary modification of the MeNTS scoring system, our study was primarily aimed at assessing the relative concordance of the ad hoc review process, and was not intended to be an in-depth study to assess validity and reliability of the MeNT-OS score in a true sense. Reliability analysis of our data with Cronbach’s Alpha revealed a sub-optimal level of internal consistency within our data for completed and postponed cases, with values of 0.58 and 0.64, respectively. These values reflect a moderate degree of reliability at best, and may be explained by (a) heterogeneity of factors in the scoring system, with a mixture of quantitative and qualitative factors and (b) polytomous response options for qualitative factors, and (c) poor
inter-relatedness between items in the scoring tool, all which may have led to underestimation of the true reliability of the MeNT-OS scoring data. Overall reliability may be improved in future studies by identifying factors with a low correlation to the final outcome and excluding them from the scoring tool.

Lastly, we were unable to ensure equal representation of all subspecialty cases, and were also limited to the cases of five surgeons at our institution, which reduced our overall sample size and ability to utilise more robust methods (such as ROC curve analysis/logistic regression modelling) to determine a ‘cut-off score’ for the MeNT-OS tool. Future studies involving larger sample sizes are planned for this purpose; such techniques would also enable the identification of more influential factors within the MeNT-OS tool, and facilitate further refinement of the scoring system by assigning appropriate weightage to these factors.

**Conclusion**

As the global COVID-19 pandemic continues to evolve, planning for the resumption of elective surgeries is underway in many countries. However, a return to pre-pandemic volumes of elective surgeries is unlikely for a significant period of time, pressuring hospitals and healthcare systems to select surgeries judiciously, to ensure the most efficient use of limited resources, reduce risk of COVID-19 transmission, while also maximising surgical benefits for patients.

We propose the use of a scoring system (‘MeNT-OS’), based on a modification of the MeNTS tool, for triage and prioritisation of Orthopaedic surgeries to be performed during the COVID-19 pandemic period. A trial of the MeNT-OS system, using data from our institution, has offered promising preliminary results, and offers an objective and systematic approach that is geared towards Orthopaedic procedures. We believe this scoring tool can provide Orthopaedic surgeons a safe and equitable approach to making difficult decisions on prioritisation of surgery during the COVID-19 period, and possibly, other resource-limiting situations in the future.

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**Compliance with Ethical Standards**

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Dorsal or Lateral Approach for Intramedullary Nailing Using Kirschner Wire in Pediatric Radius Diaphyseal Fractures: Does it really matter?

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Abstract

Background Intramedullary nailing is the most preferred fixation method for diaphyseal radius and ulna fractures in the young age group. The aim of this study was to compare the dorsal and lateral entry points in the context of entry site-related complications, fracture union and functional results.

Methods This retrospective comparative study included pediatric patients who underwent surgery for isolated diaphyseal radius or both bone forearm fractures with intramedullary nailing using Kirschner wire between January 2013 and January 2019. K-wire was introduced from the distal radius through dorsal entry (Group A) in 19 patients and lateral entry (Group B) in 18 patients. The mean follow-up was 37 months. Complications were noted and functional outcomes were evaluated according to the CHOP criteria.

Results All fractures were healed. The functional results were determined to be excellent for 30, fair for 4, and poor for 3 patients. The overall complication rate was 18.9%, including distal radius fracture, mild pain in the wrist, and minor loss in ROM. No statistically significant differences were determined between the groups in respect of functional results and complication rates.

Conclusion Good functional results and similar complication rates can be obtained with both dorsal and lateral entry approaches. Stainless steel K-wire is an inexpensive intramedullary fixation implant option, which provides strong stabilization. Distal radius fracture is a newly reported complication for forearm intramedullary nailing. Leaving the implant out of the skin seems safe with the benefit of avoiding a further surgical intervention to extract the implant.

Keywords Pediatric forearm fractures · Intramedullary nailing · Dorsal or lateral approach

Introduction

Diaphyseal radius and ulna fractures, which are common in childhood and adolescence, can usually be successfully treated with closed reduction and casting [1]. Open fractures, skeletally mature patients, inadequate reduction of fracture, associated ipsilateral humeral fracture, neurovascular injury and unacceptable displacement during follow-up after conservative treatment are commonly accepted surgical indications [2].

Intramedullary nailing (IMN) is the most preferred fixation method for diaphyseal radius and ulna fractures in the young age group, allowing minimally invasive treatment of these fractures with great success [2, 3]. However, complications are still reported for surgical treatment of pediatric forearm fractures with IMN [4–6].

The preferred entry points for radius IMN are dorsally near Lister tubercle and directly lateral of distal radius. Good
results have been reported for both entry points separately, although there are not sufficient data to guide surgeons in the choice of which one of these entry points to use [5, 7–9].

To the best of our knowledge, there has been no previously published study which has compared the results of pediatric forearm fractures treated with IMN according to the entry points. The aim of this study was to compare the two entry points in respect of entry site-related complications, fracture union, and functional results.

**Patients and Methods**

This retrospective study was approved by the Local Ethics Committee. The orthopedic trauma registry of a level 1 trauma center was searched for pediatric and adolescent patients who underwent surgery for isolated diaphyseal radius or both bone forearm fractures between January 2013 and January 2019. The inclusion criteria were as follows:

Patients who

1. had sustained a traumatic isolated diaphyseal radius or both bone forearm fracture,
2. underwent surgery with IMN,
3. age < 14 years, and
4. were followed up for at least 12 months after surgery.

Exclusion criteria were pathological fractures, previous fracture and surgery of the involved bone and the use of extramedullary implants for internal fixation.

In the specified time period, a total of 52 patients were identified who had been treated surgically for a traumatic isolated diaphyseal radius or both bone forearm fracture. After exclusion of 15 patients, the study was completed with the remaining 37 patients (Fig. 1), comprising 30 males and 7 females with an average age at the time of surgery of 10.5 years. Patient files were examined in terms of age, injury mechanism, additional fractures, presence of any open fracture or neurovascular injury, fracture side and the surgical approaches. For patients who required a change of implant choice because of a complication, initial choice for entry point was taken into account.

**Preoperative Evaluation**

All patients were evaluated initially in the Emergency Room. Physical examinations including neurovascular examination were performed. Appropriate conventional antero-posterior (AP) and lateral radiographs were obtained for all patients. Closed reduction and long-arm casting under sedation was attempted for all patients as initial treatment. The reduction was evaluated again with AP and lateral radiographs.

Failed closed reduction was accepted as > 15° angulation in any plane for girls ≤ 8 years and boys ≤ 10 years and > 10° angulation for girls > 8 years and boys > 10 years after closed reduction and casting. Bayonet apposition > 1 cm was also accepted as surgical criteria for all age groups [2, 3].

**Surgical Procedure**

All surgical procedures were performed under general anesthesia and a tourniquet was prepared for all patients for use if needed. Fluoroscopy was used in all steps throughout the surgery. Mini open fracture reduction was performed after three attempts of failed closed reduction and pin passage to the proximal fragment. Closed reduction and intramedullary fixation was achieved in 16 patients, whereas a mini open approach was used for 21 patients. Stainless steel Kirschner (K) wires of different sizes (1.2–2.5 mm) were used for all patients for IMN.

The implant was introduced from the distal radius through dorsal entry (Group A) in 19 patients and lateral entry (Group B) in 18 patients. The blunt end of the pin was slightly pre-contoured for easy medullary entry. For dorsal entry, a 2 cm of longitudinal incision was made over the Lister tubercle. After protecting the extensor pollicis longus and extensor carpi radialis brevis tendons with retractors, the bone was drilled with a 2.7 mm of drill proximal to the physeal line, under fluoroscopic guidance. For radial entry, a 2 cm longitudinal incision was made over radial styloid between the 1st and 2nd extensor compartments. After dissecting and protecting the dorsal branch of the radial nerve, bone was drilled proximal to the physeal line under
fluoroscopic guidance. Pin was advanced manually with a help of a hammer if needed. Pin tips were left outside the skin.

**Postoperative Period**

Oral antibiotics for one week were prescribed to all patients to prevent pin site infection, and the pin site dressing was changed every second day.

The mean follow-up period was 37 months (range 12–64 months). All patients were evaluated with physical examination, and AP and lateral radiographs at every follow-up visit. The first two follow-up examinations were made at 2 and 4 weeks postoperatively, then at 4-week intervals until the 3rd month and every 3 months thereafter until the end of one year. After one year, all patients were examined once a year. Changes to follow-up visit dates were made if necessary, according to the availability of patients and families.

Radiographic examination was performed at all follow-up examinations. Callus formation in at least 3 of 4 cortices on AP and lateral radiographs was accepted as union. Delayed union and nonunion were defined as fracture healing beyond 3 months and 6 months, respectively [10]. Pins were removed under local anesthesia during the same clinic visit when fracture union was recorded.

Complications were noted and functional outcome was evaluated according to the Flynn Children’s Hospital of Philadelphia (CHOP) criteria at the final follow-up examination by an examiner independent of the surgical intervention. This outcome classification is based on range of motion (ROM) and perioperative complications [8]. Functional outcomes, entry site-related complications, and time to bone union (pin removal) were compared between the two groups. Complications which were not related to the entry site, such as re-fracture, were excluded from the statistical analysis.

**Statistical Analysis**

Data were analyzed using NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA). For evaluation of study data descriptive statistical analysis (mean, standard deviation, median, first quartile, third quartile, frequency, percentage, minimum, maximum) were used. Relevance of qualitative data to normal distribution was tested via Shapiro–Wilk test and graphical examination. Comparison of quantitative data with normal distribution and without normal distribution between two groups was made with independent sample t-test and Mann–Whitney U test, respectively. Pearson chi-squared test, Fisher’s exact test and Fisher-Freeman-Halton test were used for comparing qualitative data. Level of significance was accepted as $p < 0.05$.

### Results

#### Timing for Surgery and Postoperative Stay in Hospital

The mean time from trauma to surgery was $9.11 \pm 8.33$ days (range 0–31 days). There was no statistically significant difference between the groups ($p = 0.55$).

The mean postoperative stay in hospital was 2.81 days (range 1–8 days).

#### Fracture Union and Implant removal

The mean time to fracture union was 47.5 days.

Fracture union was achieved at mean 52.5 days for Group A, and at mean 42.2 days for Group B. The difference was statistically significant ($p = 0.04$). (Table 1).

The mean fracture union time was found 54.5, 50.2, 37.7, and 44.4 days for dorsal mini-open, dorsal closed, lateral closed, and lateral mini-open reduction subgroups, respectively.

There was no relationship between surgical delay and fracture ($p = 0.694$).

All implants were removed after fracture union.

| Table 1 Comparative statistical analyses for complications, fracture reduction, union, and functional score |
|-------------------------------------------------|--------|--------|--------|
| Complication                                    | Dorsal | Lateral | $p$   |
| (-)                                             | 16 (84.2) | 14 (77.8) | $^b0.693$ |
| (+)                                             | 3 (15.8) | 4 (22.2) |       |
| Minor                                           | 1 (5.3) | 3 (16.7) | $^c0.589$ |
| Major                                           | 2 (10.5) | 1 (5.6) |       |
| Fracture reduction                              |        |        |       |
| Open                                            | 9 (47.4) | 12 (66.7) | $^d0.236$ |
| Close                                           | 10 (52.6) | 6 (33.3) |       |
| Fracture union (day)                            | $52.47 \pm 16.31$ | $42.17 \pm 12.71$ | $^e0.040^*$ |
| Functional score                                |        |        |       |
| Poor                                            | 2 (10.5) | 1 (5.6) | $^c0.589$ |
| Fair                                            | 1 (5.3) | 3 (16.7) |       |
| Excellent                                       | 16 (84.2) | 14 (77.8) |       |

$^a p < 0.05$

$^b$Independent sample $t$ test

$^c$Fisher’s exact test

$^d$Fisher-Freeman-Halton exact test

$^e$Pearson $\chi^2$ test
Functional Assessment

According to the Forearm Fracture Fixation Outcome Classification of the Childrens Hospital of Philadelphia, 30 (81.1%) patients were classified as excellent, 4 (10.8%) patients as fair, and 3 (8.1%) patients as poor.

There was no statistically significant difference between groups ($p > 0.05$) (Table 1).

Complications and Unplanned Interventions

The overall complication rate was found to be 18.9% ($n = 7$), with minor complications at 10.8% ($n = 4$), and major complications of 8.1% ($n = 3$). Distal radius fracture occurred in two patients in Group A (Fig. 2a, b) and one patient in Group B during entry of the K-wire. There were 4 minor complications determined as mild pain in the wrist ($n:3$) and minor loss in range of motion (ROM) ($n:1$). All minor complications persisted at the final clinic visit. One patient had sustained both mild pain and minor loss in ROM during daily activities such as writing. Another patient with mild pain had also a weakness on thumb extension, during follow-up, which resolved following physiotherapy.

No statistically significant difference was determined between the groups according to complications ($p > 0.05$) (Table 2).

There was no patient with pin tract infection even though the K-wire was left outside the skin. No growth disturbance was observed at the final follow-up examination. Re-fracture occurred in one patient due to a fall 8 months after implant removal, which was not considered to be related to the entry point.

Discussion

Diaphyseal radius fractures in the pediatric and adolescent age groups are seen as isolated or more commonly as part of a forearm fracture. Conservative treatment is preferred, while surgical interventions can be performed for open fractures, floating elbow injuries and unacceptable fracture reduction [2, 3]. At rates similar to those in literature, 1015 of 1098 (92.5%) patients admitted to our Emergency Department due to both bone or isolated radius diaphyseal

![Fig. 2 a, b Early postoperative AP (a) and lateral (b) view X-rays after initial operation for both bone diaphyseal forearm fracture. A distal radius fracture occurred during dorsal entry of K-wire, which was fixed through trans-ulnar K-wire](image)
fractures during the specified time period were successfully treated with conservative treatment (Fig. 1).

IMN using titanium elastic nails (TEN) through a closed or mini open approach is the most preferred fixation implant for these fractures in the pediatric age group. Similar functional results and complication rates have been reported with the use of K-wires [11]. The lower cost and higher strength could be reasons for choosing K-wire rather than TEN, especially for older children [12–14]. In the present study, K-wires were used for all patients as the internal fixation implant because of low cost and continuous availability in our public health system. While using K-wires, the biomechanical principle was not 3-point cortical contact like TEN but filling the intramedullary cavity with arelative stiff implant to prevent displacement.

In the lateral entry group, the fixation was achieved with closed maneuvers 33% of patients. We used a mini-open approach in 66% of these patients, while in the dorsal entry group, 47% of the patients needed an open reduction, which might suggest with the lateral entry point is more difficult to get a successful reduction or fixation with closed methods, even if the difference was statistically insignificant. We think that the difference for achieving closed reduction between two groups could due to different surgeons performing surgical interventions.

Dorsal and lateral entry points have been described for diaphyseal radius fractures, and overall good results have been reported for both approaches [5, 7–9]. In the current study, the functional outcome was evaluated with the CHOP classification, which is based on complications and range of motion. Similar to previous findings in literature, no statistically significant difference was determined between the two groups of the current study in respect of functional results. It has been reported that the incision made over the Lister tubercle for the dorsal approach or over the lateral cortex of the radial styloid for the lateral approach might put underlying structures at risk of iatrogenic injury [5].

IM nailing of pediatric diaphyseal radius fracture is not without problems, with reported complication rates ranging from 17 to 42% [2]. In a current systematic review of 22 published articles by Nørgaard et al. [5] minor and major complications were compared according to lateral and dorsal surgical approaches. The rates of major complications were reported as 5.6% and 8.9% and minor complications as 6.4% and 12.9% for the lateral and dorsal approach, respectively. Most common minor complication in this review was transient nerve palsy for lateral entry group and EPL compromise for dorsal entry group. The overall complication rate in the present study was 18.9%, which was similar to findings in previous studies. No statistically significant difference was determined between the surgical approaches in respect of complication rates.

Normal healing of closed pediatric forearm shaft fractures occurs at an average of 5.5 weeks [15]. Delayed union has been defined as healing exceeding 12 weeks after injury and is accepted as a minor complication, which could be seen in both dorsal and lateral approach groups [3, 5]. In the current study, all the fractures were healed at mean 47.5 days, which was within the reported time interval. The mean time for fracture healing was found to be 52.5 days and 42.2 days for the dorsal and lateral approach groups, respectively. The time to fracture union was significantly shorter in the lateral entry group. Even though, we do not think the entry point as a reason for delayed bone healing. We did not find any relation between surgical delay and fracture union groups. A faster bone consolidation was determined with closed reduction for both group. This difference may also cause by variations of follow-up visit dates, as we accepted the date of the X-ray with bone union as bone healing time.

Complications could show differences according to the approach used. In literature, extensor pollicis longus (EPL) tendon rupture has been reported in the dorsal approach at rates of up to 18% [7, 8, 16–19]. Technical errors such as inadequate visualization during insertion, a sharp cut of the nail and leaving the nail in the extensor compartment have been blamed for this complication. Prolonged irritation of the tendon by the nail could be another reason, and the mean time for diagnosis of EPL tendon rupture has been reported to be 10.4 weeks (range 2–34 weeks) [4]. In the current study, all pins were left over the skin and were removed at mean 6.7 weeks (range 4–12 weeks), which could explain the lack of EPL tendon rupture in the current study. Weakness of thumb extension was detected in one patient, who was referred to the Hand Surgery Unit. It was reported as mild tendon adhesion without rupture and followed up with physiotherapy.

To the best of our knowledge, distal radius fracture during nail insertion has been never reported in previous studies, and this was seen in two patients with the dorsal approach and in one patient with the lateral approach in the current study. As the K-wire is stiffer than a titanium elastic nail [13], the combination of this stiffness and the introduction of the K-wire close to the meta-diaphyseal junction could be the reason for distal radius fracture. Fractures during dorsal pin entry occurred because of applying extreme force for wrist flexion to introduce the inadequate contoured K-wire to the medullary canal even though the K-wire was not oversized compared to medullary canal. One of these complications was treated by adding an extra K-wire across DRUJ because the iatrogenic instability and changing the entry point to lateral, whereas the other fracture did not require a change of entry point or extra fixation. To avoid this complication, we think, drilling the bone entry, pre-contouring the implant and gentle pushing during insertion are essential points of surgical technique. There is no need to flex the
wrist to make insertion easier if we pay attention to these points. The patient in Group B with fracture was a distal 1/3 diaphyseal fracture, which intramedullary fixation was not the best treatment choice. During pin insertion, the short lateral cortex was not able to resist the force of the manipulation. This patient was treated by changing the K-wire for a low-profile plate applied through a lateral approach. All three patients were followed up for mean 46 (23, 52, and 63) months and healed without any ROM limitation or wrist pain. Preoperative X-rays of these patients were re-evaluated for an overlooked occult distal radial fracture. After this re-evaluation, fractures were confirmed to be iatrogenic.

There are concerns that leaving the pins outside the skin could cause potential complications such as infection, skin irritation. However, studies have reported no significant difference in complications whether the implant is left exposed or embedded beneath the skin [20, 21]. There are also secondary benefits such as avoiding any additional surgical intervention and thereby reducing costs [21]. In the current study, no entry site infection was observed that required additional debridement or antibiotics.

Four minor complications in three patients were determined comprising mild pain in the wrist [3] and minor loss of ROM [1] all these complications persisted at the final clinic visit. Transient or permanent nerve palsy of the sensory radial branch has been reported in many studies, at rates of 2.9% and 0.3%, respectively. This complication has been reported especially with the use of the lateral approach [5]. No palsy in the dorsal sensorial branch of the radial nerve was determined in any of the current study patients where the intramedullary implant had been introduced through the lateral approach.

This study had some limitations, primarily the low number of patients. The follow-up clinic visit times showed some variability because of the retrospective nature of the study, and although the time to union showed a statistically significant difference between the groups, this variability weakens the result. There is need for further, prospectively designed studies of larger patient populations. Also, a prospective randomized study which compare the use of stainless-steel K-wire and titanium elastic nail could give valuable information.

In conclusion, good functional results and similar complication rates can be obtained with both the dorsal and lateral entry approaches. Stainless steel K-wire is an inexpensive intramedullary fixation implant option for pediatric diaphyseal forearm fractures, which provides strong stabilization until the fracture heals. Fracture of the distal radius is a newly reported complication of the application of intramedullary nailing for pediatric forearm fractures. It is remarkable that this complication is reported with K-wire as an implant, while TEN with higher elasticity might be a better choice, especially when precise surgical tips of forearm IMN application is overlooked. Leaving the implant outside the skin seems to be safe with the benefit of avoiding further surgical intervention to extract the implant.

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**Ethical standard statement** This article does not contain any studies with human or animal subjects performed by any of the authors.

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Projection of the A1-Pulley of the Thumb onto Superficial Anatomical Landmarks: An Anatomical Study and a Useful Guide to Surgeons

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Abstract
Background The aim of our study was to project the A1-pulley of the thumb onto the total thumb length to enable its complete division with and without direct sight.

Materials and Methods The study involved 50 hands from adult human cadavers. The proximal and distal borders of the A1-pulley were measured with reference to the first metacarpophalangeal joint (MCPJ). The length of the thumb was defined as the interval between the first carpometacarpal joint (CMCJ) and the apex of the thumb. The length of the pulley is calculated proportionally with reference to the line between the first CMCJ and apex of the thumb.

Results Approximated by computing 95% confidence intervals, the pulley can be expected to lie in an area between 34.0% (proximal border) and 57.8% (distal border) alongside this line.

Conclusion Percutaneous and minimally-invasive division of the A1-pulley needs to be performed between 34.0 and 57.8% of the length between the first CMCJ and apex of the thumb.

Keywords Trigger thumb · A1-pulley · Minimally invasive surgery · Anatomical landmarks

Introduction
The trigger thumb or stenosing tenosynovitis at the A1-pulley represents one of the most common pathologies in hand surgery [1–3]. Following exhaustion of conservative treatment methods, open surgical release, enabling the surgeon direct visualization, is the gold standard treatment including high success rates [4]. As alternative, blind percutaneous A1-pulley release was first reported by Lorthior in 1958 [5] and has been evaluated including satisfactory outcomes since then [1, 2, 6, 7]. However, incomplete division of the pulley, laceration of the flexor pollicis longus tendon as well as injury to the adjacent neurovascular structures represent potential complications of this procedures due to lack of direct visualisation [2, 3, 8, 9]. Therefore, the aim of our study was to project the extension of the A1-pulley onto the length of the thumb to enable its complete division with and without direct sight.
Materials and Methods

Specimens

The study involved 50 hands (31 left and 19 right) from adult human cadavers of Caucasian origin embalmed by use of Thiel’s method [10]. Our sample consisted of 30 (60%) extremities from female and 20 (40%) from male cadavers. Their age ranged from 39 to 105 years with a median of 78. The mean height was 165.7 cm (SD 9.8; range 150–183). Body donors had given their written informed consent during their lifetime to participate in anatomical studies. Prior to the implementation, specimens with obvious signs of prior surgeries or pathologies in the area of interest were excluded.

Dissection and Measurement Protocol

Hands were placed in the supine position. The skin and soft tissues of the thumb and thenar region were removed while care was taken not to manipulate the first proper palmar digital nerve’s (FPPDN) original course. After the depiction of the A1-pulley, its proximal and distal borders were measured with reference to the first metacarpophalangeal joint (MCPJ). Additionally, the ulnar and radial intersection points of the nerve and the flexor pollicis longus tendon were evaluated with reference to the joint. The proximity of the FPPDN to the A1-pulley distal to the radial crossing point of the nerve and the flexor pollicis longus tendon was measured with regard to the ligament’s radial border. The length of the thumb was defined as the interval between the first carpometacarpal joint (CMCJ) and the apex of the thumb. For a schematic depiction, see Fig. 1.

Data Analysis

All measurements were taken in millimetres using a digital calliper rule. Descriptively, continuous variables are summarized using mean, standard deviation (SD), median, minimum and maximum while frequencies and percentages are displayed for categorical variables.

To project the A1-pulley onto the superficial landmarks, common methodology such as linear regression and related techniques were deemed to be inadequate, because comparing the location using absolute values (i.e., millimetres in this case) can be misleading since different hand sizes might lead to different absolute lengths while proportions remain constant. Therefore, the locations of the proximal and distal borders of the A1-pulley are represented as proportions (compositional data) with regard to the line between the first CMCJ and the apex of the thumb. This segment was divided into three parts: (1) From the CMCJ to the proximal border of the pulley, (2) the width of the pulley and (3) from the distal border of the pulley to the apex of the thumb.

Compositional data have some characteristics (e.g., values in a bounded interval from 0 to 1 that must add up to 1, i.e., 100%, for each observation and hence cause redundancy of the variables) that require special statistical techniques such as Dirichlet regression models [11] which were employed here with the mean/dispersion parameterization. All data analyses were carried out in the statistical software R [12] using the DirichletReg package.
Results

Concerning absolute values, the proximal border of the pulley was at a mean of 1.3 mm (SD 1.9) distal to the first MCPJ. This localisation was found either proximal or distal to the joint (range 2.8 mm proximal–7 mm distal). The ligament’s distal border was on average height of 5.1 mm (SD 2.1; range: 0–10.6) distal to the MCPJ. The FPPDN crossed the flexor pollicis longus tendon at its ulnar margin at a mean of 22.5 mm (SD 6.4; range 9.3–42) and at its radial border at an average height of 11.2 mm (SD 6.9; range 0–34.9) proximal to the first MCPJ. In 66% of all cases, the FPPDN lay directly on the pulley’s radial side distal to its radial intersection point with the flexor pollicis longus tendon (see Fig. 2). In the further cases, the distances between the structures were at a mean of 2.0 mm (SD 1.2; range 0.3–4.3). The A1-pulley had a mean length of 6.4 mm (SD 1.6; range 2.8–10.6). The mean distance between the first CMCJ and the apex of the thumb was 92.6 mm (SD 7.1; range 75.9–112.0).

The Dirichlet regression model failed to detect any significant predictors (side, height, sex, thumb length) for the proportional location of the pulley along with the thumb. Therefore, we can assume that the investigated anatomical structures are proportionally constant (see Fig. 3) and can be predicted to be located at 42.3% (proximal border) and 49.3% (distal border) of the reference length (from the first CMCJ to the apex of the thumb), starting from the CMCJ. Accounting for uncertainty, the pulley can be expected to lie in an area between 34.0 (proximal border) and 57.8% (distal border) along with the finger (this interval was approximated by computing 95% confidence intervals of the marginal beta
distributions with the model’s parameters and taking the lower/upper endpoint for the proximal/distal border). These proportions can be transformed back to absolute values which will then, of course, be larger as the reference length (i.e., thumb size) increases (see Fig. 3).

Discussion

The main aim of the study was to project the A1-pulley of the thumb onto superficial landmarks. As a reference line, we opted for the interval between the first CMCJ and the apex of the thumb. The pulley had a mean length of 6.4 mm (SD 1.6; range 2.8–10.6) and the mean distance between the first CMCJ and the apex of the thumb was 92.6 mm (SD 7.1; range 75.9–112.0). The proximal border of the A1-pulley was located at a mean of 42.3% and its distal margin on average at 49.3% of the reference line, starting from the first CMCJ. Approximated by computing 95% confidence intervals of the marginal beta distributions, the A1-pulley can be expected to lie between 34.0% (proximal border) and 57.8% (distal border) alongside this line. The FPPDN crossed the flexor pollicis longus tendon at its ulnar margin at a mean of 22.5 mm and at its radial border at an average height of 11.2 mm proximal to the first MCPJ. In 66% of all cases, the FPPDN lay directly on the pulley’s radial side distal to its radial intersection point with the flexor pollicis longus tendon.

Annular pulleys enable the efficient transmission of muscle forces by stabilizing the tendons and fixing them to the phalanges during flexion [13]. The pulley system can be impaired due to swelling and thickening of the tendons by various influences, resulting in impingement at the level of the hypertrophic A1-pulley, inhibiting tendon movement and causing the respective finger to snap and lock during extension [14, 15]. This trigger thumb phenomenon occurs ten times more often when compared to the trigger pathology of the long fingers [16], that include a lifetime risk of 2–3% [4].

The primary treatment options usually involve immobilization, anti-inflammatory drugs and local steroid injections. If these approaches fail, operative revision is indicated [17]. Open surgical release is considered as the gold standard including reported high success rates [4]. However, it includes complications as scar tenderness, joint contractures, stiffness and flexor tendon bowstringing [18, 19]. Therefore, blind percutaneous A1-pulley release was first reported by Lorthior in 1958 as alternative treatment technique [5]. The method includes a shorter recovery time, decrease of pain sensation and avoidance of scar tenderness when compared to the open approach [4, 20–22]. However, the lack of direct visualisation includes an increased risk of the incomplete division of the pulley, lesions of the adjacent neurovascular structures and damage to the flexor tendons [19, 20]. To overcome these problems, ultrasonography-guided percutaneous A1 pulley release has been postulated by various authors recently [4, 23–26].

Concerning the use of superficial landmarks for identification of the A1-pulley, Watkins et al. [27] used the intercrease line, a transverse line between the radial edge of the proximal palmar crease and the ulnar edge of the distal palmar crease, to identify the pulleys of the long fingers in a cadaveric study. Grinčuk et al. [19] identified the A1-pulley through palpation combined with location via superficial landmarks in a sample including fourteen fresh frozen cadaveric thumbs and 56 fingers. Authors performed percutaneous release followed by dissection of the specimens. In 42.8%, longitudinal lacerations of the flexor pollicis longus tendon were observed and in three thumbs, incomplete A1-pulley release had occurred. A mean A1-pulley length of 5.7 mm (SD 0.6) was reported, which is comparable to our sample (mean 6.4 mm; SD 1.6). Gnanasekaran et al. [18] projected the pulley system of the thumb onto the palmar thumb creases in a sample of fifty-five fresh frozen specimens. These were named the proximal-proximal crease (at the first MCPJ), the distal–proximal crease (superficial to the middle of the proximal phalanx) and the distal crease (at the interphalangeal joint). Authors reported a mean A1-pulley length of 5.1 mm (SD 0.9) and a fusion of the A1- and A2-pulleys in ten cases, which could not be observed in our sample. The proximal margin of the A1-pulley was located 2.0 mm proximal and the distal border 3.1 mm distal to the proximal-proximal thumb crease (respectively the MCPJ), which is not comparable to our sample (proximal: 1.3 mm distal to MCPJ; distal: 5.1 mm distal to MCPF), probably due to the variety of the cutaneous landmarks. Hazani et al. [16] evaluated thirteen cadaveric hands with palmar creases as superficial landmarks. Here, three creases were identified and in 85.6% of the cases, at least two creases were located at the level of the MCPJ. The most proximally situated crease corresponded anatomically to the A1-pulley and showed the least variability when compared to the other creases. The average length of the pulley was 6.1 mm (SD 1.7), which is well comparable to our sample (mean 6.4; SD 1–63). Though very convenient, the palmar thumb creases might be insufficient as superficial landmarks due to their variability.

A limitation of our study is that, in the cadaver model pathological changes of the flexor tendons and the pulley system are probably differing to the in-vivo situation. Therefore, length changes of the A1-pulley may occur.

We conclude, based on our results that splitting of the A1-pully between 34 and 57.8% at the line between the first CMCJ and the apex of the thumb results in complete division of the pulley, which is especially important during percutaneous techniques. Additionally, the proximity of the FPPDN needs to be kept in mind, since this lies directly on
the pulley’s radial side distal to its radial intersection point with the flexor pollicis longus tendon in 66% of all cases.

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ORIGINAL ARTICLE

Novel Radiographic Indexes for Elbow Stability Assessment: Part A—Cadaveric Validation

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Abstract

Introduction   Elbow bony stability relies primarily on the high anatomic congruency between the humeral trochlea and the ulnar greater sigmoid notch. No practical tools are available to distinguish different morphotypes of the proximal ulna and herewith predict elbow stability. The aim of this study was to assess inter-observer reproducibility, evaluate diagnostic performance and determine responsiveness to change after simulated coronoid process fracture for three novel elbow radiographic indexes.

Methods   Ten fresh-frozen cadaver specimens of upper limbs from human donors were available for this study. Three primary indexes were defined, as well as two derived angles: Trochlear Depth Index (TDI); Posterior Coverage Index (PCI); Anterior Coverage Index (ACI); radiographic coverage angle (RCA); olecranon-diaphysary angle (ODA). Each index was first measured on standardized lateral radiographs and subsequently by direct measurement after open dissection. Finally, a type II coronoid fracture (Regan and Morrey classification) was created on each specimen and both radiographic and open measurements were repeated. All measurements were conducted by two orthopaedic surgeons and two dedicated musculo-skeletal radiologists.

Results   All three indexes showed good or moderate inter-observer reliability and moderate accuracy and precision when compared to the gold standard (open measurement). A significant change between the radiographic TDI and ACI before and after simulated coronoid fracture was observed [TDI: decrease from 0.45 ± 0.03 to 0.39 ± 0.08 (p = 0.035); ACI: decrease from 1.90 ± 0.17 to 1.58 ± 0.21 (p = 0.001)]. As expected, no significant changes were documented for the PCI. Based on these data, a predictive model was generated, able to identify coronoid fractures with a sensitivity of 80% and a specificity of 100%.

Conclusion   New, simple and easily reproducible radiological indexes to describe the congruency of the greater sigmoid notch have been proposed. TDI and ACI change significantly after a simulated coronoid fracture, indicating a good responsiveness of these parameters to a pathological condition. Furthermore, combining TDI and ACI in a regression model equation allowed to identify simulated fractures with high sensitivity and specificity. The newly proposed indexes are, therefore, promising.

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tools to improve diagnostic accuracy of coronoid fractures and show potential to enhance perioperative diagnostic also in cases of elbow instability and stiffness.

Level of evidence  Basic science study.
Clinical relevance  The newly proposed indexes are promising tools to improve diagnostic accuracy of coronoid fractures as well as to enhance perioperative diagnostic for elbow instability and stiffness.

Keywords  Elbow joint · Radiographic study · Cadaveric study · Ulna · Olecranon

Abbreviations
GSN  Greater sigmoid notch
TDI  Trochlear Depth Index
PCI  Posterior Coverage Index
ACI  Anterior Coverage Index
RCA  Radiographic coverage angle
ODA  Olecranon–diaphysary angle
SD  Standard deviation
ICC  Intra-class correlation coefficient

Introduction

Elbow stability is guaranteed by primary and secondary constraints [1–4]. The ulnohumeral articulation is the most important primary stabilizer of the elbow joint [5–7]. Bony stability relies primarily on the high anatomic congruency between the humeral trochlea and the ulnar greater sigmoid notch (GSN). This structure has a C-shaped concavity, extending between two bony processes, the olecranon and the coronoid [2, 8].

The coronoid process is the most important bony constraint against posterior elbow dislocation, together with the radial head [9–13]. With a loss of 50% or more of coronoid height, major translational, rotational and valgus–varus instability appears [14, 15].

The radiographic classification proposed by Regan and Morrey [16], inspired by this principle, aimed to define a simple diagnostic–therapeutic algorithm to approach coronoid fractures [17, 18].

Later on, O’Driscoll proposed a CT-based classification [19], which is anatomically more accurate, and is considered particularly useful for surgical planning and evaluation of complex fracture patterns [18].

Both classifications have strengths and limitations. Among the latter, the complete C-shaped olecranon morphology is not adequately examined and, the anatomic congruency between the proximal ulna and the distal humerus is neglected, although it also plays a role in preventing elbow dislocation. Moreover, both classifications focus on the coronoid process only, giving no importance to the olecranon process as a possible factor affecting elbow joint stability.

The association between olecranon fractures and elbow dislocation or subluxation suggests a potential role of this anatomical structure in antero-posterior elbow stability [1, 20]. On the other hand, the olecranon is believed to play only a minor role in rotational and valgus–varus stability [21, 22].

Several scientific reports investigated the anatomical and biomechanical properties of the GSN and its contribution to elbow stability; however, without providing a practical application of this precious knowledge [23, 24].

Furthermore, simple, reliable and predictive parameters to describe the anatomical morphology of the proximal ulna are not available yet. The only accepted evidence is that the height of the coronoid process directly correlates with its resistance against posterior elbow dislocation [25, 26]. The creation of reliable, accurate radiographic parameters to describe GSN elbow coverage could provide clinicians with practical tools to determine the intrinsic osseous stability of the elbow and to describe different morphotypes of the proximal ulna, possibly predicting elbow stability.

The aim of this study was to assess the anatomical accuracy of three new elbow radiographic indexes that may be used to quantify the intrinsic osseous stability by comparing radiographic with open anatomical measurements on cadaveric specimens. The secondary aims of this study were to evaluate the inter-observer reproducibility of the indexes, their diagnostic performance and their responsiveness to change in case of a simulated coronoid fracture.

Materials and methods

Ten fresh-frozen upper limbs cadaveric specimens from human donors including the complete middle third of the humerus and the entire hand were available for this study. Before investigation, care was taken to evaluate the specimens for visible signs of previous trauma, gross instability or deformity.

Plain radiographs in anteroposterior and lateral projections were then taken to visualize integrity of bony structures and joint congruency.

To perform the radiographic study of the elbow, standardized medio-lateral digital radiographs were obtained holding the joint in 90° of flexion (Figs. 1A-B, 2A-B). The quality of the radiographic projection was considered appropriate
when the contours of the throcir sulcus, of the capitellum and of the medial throcila were seen as three concentric circles or circular segments [27, 28].

Subsequently, a medial approach centered on the medial epicondyle was performed on each specimen; the common flexor origin was identified, released from the humeral epicondyle and reflected distally. Similarly, the medial collateral ligament was identified and released, allowing dislocation of the ulno-humeral joint. The proximal ulna anatomical bony landmarks were finally identified by open dissection (TDI = BD/AC). Box plots (c) illustrating the comparison between the radiographic and open TDI in native elbows and after coronoid osteotomy (*p value <0.05). Data represent minimum, maximum (box) and mean (line). RX Radiographic

After measurement of normal anatomy on the intact specimen, a horizontal coronoid process osteotomy was performed with a chisel to simulate a Regan and Morrey type II coronoid fracture, since this type of lesion has been shown to entail a clinically significant loss of joint stability [16]. The osteotomy line was placed on a coronal plane at half of the distance between the coronoid tip and the bare area of

Fig. 1 Digital elbow radiographs in lateral projection of the same elbow, depicted in its native state (a) and after simulated coronoid fracture (b). The Trochlear Depth Index (TDI) is the ratio between the distance from the olecranon to the coronoid tip (AC) and the distance between this line and the deepest point of the throcila (TDI = BD/AC). Box plots (c) illustrating the comparison between the radiographic and open TDI in native elbows and after coronoid osteotomy (*p value <0.05). Data represent minimum, maximum (box) and mean (line). RX Radiographic
the proximal ulna trochlear notch, as described in previous studies [29, 30]. After the osteotomy, a graduated sliding calliper was used to repeat the anatomical measurements relevant for the radiographic study. All linear measurements were performed by two observers reaching consensus on the obtained value by mutual agreement.

Finally, the fractured elbows were reduced manually, and a second medio-lateral digital radiograph was obtained for each specimen, with the same technical characteristics and quality criteria described above.

A single expert surgeon with extensive experience in elbow surgery performed all surgical procedures (P.A.). Institutional approval of the study protocol was obtained by the Nicola’s Foundation & ICLO Research Centre (ID 19506).

Radiographic Study

All digital radiographs were exported as digital image files (.BMP) and analysed independently by four observers, not blinded to the performed procedure: two orthopaedic surgeons not involved in the surgical procedures (F.L., E.R.) and two dedicated musculoskeletal radiologists (A.Z., M.C.). The software GeoGebra Classic 5 Version 5.0.426.0

Fig. 2 Digital elbow radiographs in lateral projection of the same elbow, depicted in its native state (a) and after simulated coronoid fracture (b). The Anterior Coverage Index (ACI) is the ratio between HC and H (ACI = HC/H); the Posterior Coverage Index (PCI) is the ratio between HA and H (PCI = HA/H). Box plots (c) illustrating the comparison between radiographic and open ACI in native and fractured elbows (**p value < 0.01). Data represent minimum, maximum (box) and mean (line). RX radiographic
(GeoGebra GmbH, Altenbergerstraße 69, 4040 Linz, Austria) was used to mark radiographic landmarks and measure linear distances. Since all described parameters are ratios between linear measurements on the same radiograph, standardized scaling of the radiographic digital images was not necessary.

The following points and lines were identified on each radiograph:

- A: tip of the olecranon process;
- B: midpoint of the segment AC;
- C: tip of the coronoid process (or the most posterior point of the superior surface of the coronoid process in case of a simulated fracture);
- D: deepest point of the greater sigmoid notch (determined by the intersection of a line perpendicular to AC and passing through the point B and the greater sigmoid notch profile of the ulna);
- r: posterior olecranon cortex line.

The segments AC and BD were measured and the minimal trochlear height (HD, or simply H), the olecranon height (HA) and the coronoid height (HC) were determined as the linear distances between the points D, A, C and the posterior olecranon line.

Using these linear measurements, three primary indexes were developed:

1. **Trochlear Depth Index (TDI)**: defined as the ratio between proximal ulna trochlear notch depth (BD) and olecranon–coronoid distance (AC). \( TDI = BD/AC \), where AC indicates the distance between coronoid and olecranon tips and BD indicates the shortest distance from AC to the deepest point of trochlear notch) (Fig. 1).

2. **Posterior Coverage Index (PCI)**: defined as the ratio between the olecranon height (HA) and the minimal proximal ulna trochlear height (H). \( PCI = HA/H \), where HA indicates the shortest distance between olecranon tip and the posterior olecranon cortex and H indicates the height of the deepest trochlear portion) (Fig. 2).

3. **Anterior Coverage Index (ACI)**: defined as the ratio between the coronoid height (HC) and the minimal proximal ulna trochlear height (H). \( ACI = HC/H \), where HC indicates shortest distance from coronoid tip to the posterior olecranon cortex and H indicates the height of the deepest trochlear portion) (Fig. 2).

Furthermore, two derived angles were described:

1. **Radiographic Coverage Angle (RCA)**: defined as the dorsally opened angle subtended by the circular segment AC of the GSN. \( RCA = 4 \cdot \arctan \left( \frac{2 \cdot BD}{AC} \right) \), where AC indicates the distance between coronoid and olecranon tips and BD indicates the shortest distance from AC to the deepest point of trochlear notch)

2. **Olecranon–Diaphysis Angle (ODA)**: defined as the angle between the ulnar diaphysis and the line passing through AC. \( ODA = \arcsen \left( \frac{HC-HA}{AC} \right) \), where HC indicates shortest distance from coronoid tip to the posterior olecranon cortex, HA indicates the shortest distance between olecranon tip and the posterior olecranon cortex and AC indicates the distance between coronoid and olecranon tips)

The three aforementioned primary indexes were measured on the radiographs, before and after coronoid osteotomy. Evaluation of the derived angles was outside the scope of the current study, as they can be derived by mathematical operations and they are not measurable ex vivo.
Finally, the above-described radiological parameters were calculated also from the linear measurements obtained after open cadaveric dissection. These measurements, defined as “open TDI”, “open ACI”, “open PCI” to distinguish them from their radiographic counterparts, were considered as gold standard for the subsequent statistical evaluation.

### Statistical Analysis

Statistical analyses were performed using R software (R Core Team, Wien, Austria). The Shapiro–Wilk test was used to evaluate data distribution. Interclass correlation was assessed using \( \text{icc} \) function from \( \text{irr} \) package. Accuracy for each parameter was reported as mean % error compared to the gold standard (open measurements with graduated caliper). For each sample, Δ accuracy was obtained as the difference between the mean of values reported by all observers and the value obtained by open measurement, normalized for the value of open measurement:

\[
\Delta \text{accuracy} = \frac{\text{mean value in RX} - \text{open measurement}}{\text{open measurement}}
\]

The mean value from all samples was calculated to define the mean % error for each index.

Then, precision for each measurement was calculated as the ratio between the standard deviation (SD) and mean of the measurements provided by the four raters:

\[
\text{precision} = \frac{\text{standard deviation among observers}}{\text{mean of measurement among observers}}
\]

The Student’s \( t \) test was used to assess differences between measurements in fractured and native samples for each parameter.

The mean measurements obtained by the four observers for each sample were used for the analysis.

Effect sizes were calculated as Cohen’s \( d \), comparing indexes from native and fractured elbows:

\[
d = \frac{\text{native mean value} - \text{fractured mean value}}{\text{pooled standard deviation}}.
\]

Cohen’s \( d \) values above 0.8 were considered as large effect sizes [31].

A generalized linear model was developed to evaluate the effect of TDI and ACI on the presence of fractures. The ACI effect was significant, and the addition of TDI improved the fitness of the model. Model fitting was measured by Akaike Information Criterion [32].

Sensitivity of the test was calculated as the ratio between true positives and the sum true positives + false negatives.

Specificity was calculated as the ratio between true negatives and the sum true negatives + false positives. Data were presented as mean ± SD. A \( p \) value < 0.05 was considered statistically significant.

A receiver operating characteristic (ROC) curve for the different threshold values was drawn and the area under curve was calculated [33] to evaluate the test performance.

### Results

Complete sets of radiographic and linear measurements were obtained for all ten cadaveric specimens (median age at death 59.3 years [47–69]; females: 50%, left elbow: 30%). No difficulties were encountered during the dissections and the measurements and two lateral digital radiographs of adequate quality were obtained for each specimen, before and after coronoid osteotomy.

### Reliability and Diagnostic Performance

The indexes showed a moderate or good inter-observer reliability. The overall inter-observer ICC (Intra-class correlation coefficient) was 0.524 (CI 95%: 0.304–0.738) for TDI; 0.793 (CI 95%: 0.646–0.9) for ACI; 0.504 (CI 95%: 0.283–0.724) for PCI.

The indexes had a moderate accuracy. The measurement performed observing radiographic images showed a mean % error with respect to the gold standard represented by the open measurements (Δ accuracy) of −18.9% (CI 95%: −28.5% to −9.4%) for TDI; +13.5% (CI 95%: 2.3–24.6%) for ACI; +5.3% (CI 95%: 0.2–10.3%) for PCI.

The Δ accuracy (where Δ equal to 0 represents the perfect accuracy) reported in the subgroup of orthopaedic surgeons was -15.5% (CI −24.8% to −6.2%) for TDI, +12.3% (CI 95%: 2.1–22.4%) for ACI and +4.9% (CI 95% 1.4–8.4%) for PCI. The accuracy reported in the subgroup of musculoskeletal radiologists was −22.5% (CI −32.0% to −13.0%) for TDI, +14.7% (CI 95 3.8–25.6%) for ACI and +5.6% (CI 95% 1.4–12.7%) for PCI. Only for the TDI a statistically significant difference in accuracy between orthopaedic surgeons and musculoskeletal radiologists was observed (Fig. 4).

The precision was calculated as the mean error of the measurements on digital radiographs with respect to open measurements, and it resulted ±12% (95% CI 7.7–16.3%) for TDI, ±6% (95% CI 3.5–8.5%) for ACI and ±6% (95% CI 1.0–11%) for PCI.

### Responsiveness: Comparison Between Native Elbows and Simulated Coronoid Fracture

The mean radiographic TDI was 0.45 ± 0.03 (range 0.40–0.51) in native elbows and 0.39 ± 0.08 (range 0.29–0.51) after simulated coronoid fracture (\( p = 0.035 \)). The mean open TDI was 0.60 ± 0.09 (range 0.48–0.73) in native
elbows and 0.48 ± 0.14 (range 0.31–0.73) after simulated coronoid fracture (p = 0.02) (Fig. 1C).

The mean radiographic ACI was 1.90 ± 0.17 (range 1.66–2.22) in native elbows and it resulted 1.58 ± 0.21 (range 1.22–1.89) after simulated coronoid fracture (p = 0.001). The mean open ACI was 1.76 ± 0.25 (range 1.14–1.88) in native elbows and 1.39 ± 0.27 (range 0.90–1.88) after simulated coronoid fracture (p = 0.001) (Fig. 2C).

The mean radiographic PCI was 1.36 ± 0.08 (range 1.24–1.48) in native elbows and 1.32 ± 0.16 (range 0.92–1.48) after simulated coronoid fracture (p = 0.387). The mean open PCI was 1.28 ± 0.14 (range 1.05–1.56) in native elbows and 1.28 ± 0.14 (range 1.05–1.56) after simulated coronoid fracture (p = 1). As expected, no significant changes between native and fractured specimens were observed in this index measuring posterior coverage.

The effect size (Cohen’s d) based on the open measurements (gold standard) was 0.981 for TDI and 1.394 for ACI. For what concern the effect size based on the radiographic measurements, it resulted 1.057 for TDI and 1.684 for ACI. These values correspond to large or very large effect sizes [31], suggesting that these indexes are effective in the identification of differences between native and fractured elbows. Since PCI did not vary between fractured and native elbows (effect size = 0) it was not considered for the linear model development.

**Predictive Potential: ACI and TCI as Indicators of Fracture**

Since ACI and TDI demonstrated to significantly change in fractured elbows compared to native elbows, these two parameters were considered as possible indicators of fractures. The variable “fracture” was set as a dependent categorical variable (fractured = 1; native = 0) in a generalized linear model using radiographic ACI and TDI values (mean of all observers) as independent variables (or “predictors”). The multiple regression analysis showed that only ACI was able to significantly influence the result (p < 0.05); nevertheless, TDI was maintained in the model even if not significant since it allowed for an improvement of model fitting. The model equation (18.473-ACI*9.289-TDI*5.409) was able to identify a fracture with a sensitivity of 80% and a specificity of 100%. The area under the relative ROC curve (AUC) was 0.88, confirming the good performance of the test.

The application of the model test using the open measurements (study gold standard) resulted in a 90% sensitivity and 90% specificity.

**Discussion**

The main finding of this study is that all the proposed radiological indexes demonstrated a good–moderate inter-observer reliability, accuracy and precision, well reproducing the open measurements considered as gold standard. ACI was the most reliable parameter to be used in the discrimination of native and fractured elbows, and the use of radiographs for its determination was reliable.

Since the calculation of the indexes of interest is determined by measurement obtained from radiographic images, the quality of these measure represents an important step in the validation of their use.

Interclass correlation among observers resulted moderate for TDI and PCI (> 0.5) and good for ACI (> 0.7), confirming the reliability of these measures, in particular for ACI.

ACI also demonstrated good mean precision (± 6%) and better accuracy compared to TDI (+ 13.5% vs. − 18.9%). PCI also demonstrated good precision (± 6%) and the best accuracy among the evaluated indexes (+ 5.3%) but, as expected, it was also the only index not changing significantly between native and fractured elbows. On the contrary, TDI and ACI decreased significantly after simulated coronoid fracture, with this result being confirmed both by gold standard open measurements and by radiographic measurements, supporting the effectiveness of these evaluations in the identification of fractures. Large and very large effect sizes were observed for TDI and ACI, respectively, when comparing native and fractured elbow with both radiographic and open measurements, suggesting that these indexes are effective in the identification of fractures.

The moderate interclass correlation reported for TDI and PCI may be due to the difficulty of obtaining an adequate standard plane in lateral view X-rays, and a consequent difficulty in identifying the reference points. The use of...
3D-images (CT, MRI) could solve this problem in a trauma setting. Elbow fracture diagnosis can be challenging; detection rate has been reported to be different between orthopaedic surgeons and radiologists, attesting the elbow as the most overlooked site among the upper limb [34, 35]. Standard elbow views are not always enough to avoid missed diagnoses [36, 37]. In a recent X-ray and CT comparison study, 12% of patients with positive extension test and normal radiography had an occult fracture [38].

Even though X-rays are suitable to be interpreted by a wide range of clinicians, objective and reliable indexes are mandatory to better assess the functional morphology of the elbow and to raise suspicion of coronoid fracture. Furthermore, such indexes of congruency between the GSN and the distal humerus could be helpful in defining elbow morphology at risk of acute and chronic instability, as well as to plan tailored treatment of elbow stiffness. Measurements of olecranon and coronoid height and GSN congruency on plain radiographs have already been proposed decades ago, yet as isolated reports and without undergoing a strict validation process [39]. Subsequent studies focussed mainly on the role of the coronoid process, with the anatomy of the GSN as a whole structure fading to the background, until a recent MRI-based investigation by Giannicola et al. defined the normal values of the “ulnar greater sigmoid notch coverage angle” as a parameter to evaluate the GSN congruency [40].

The linear measurements collected in our study permit to evaluate the GSN anatomy with the angle RCA, which can be derived by a mathematical operation \[ RCA = 4 \arctan (2 \ BD/AC) \]. Being linear measurements simpler and more reproducible than angular measurements, we discourage a direct angular measurement of the GSN, provided the aforementioned reference points are well identifiable on standardized plain lateral radiographs. Herewith, the ACI, the PCI and the TDI could be implemented in the radiographic workflow of posttraumatic elbow and in the evaluation of joint instability risk factors involving the coronoid process. These indexes correlate with the height of the coronoid process and inversely with the depth of the GSN; in this way, they completely define the containing capacity of the proximal ulna. In case of instability, these indexes could be associated with other, already described, radiological signs such as the “vacuum sign” visible on stress radiographies [41].

Further studies will define how the new elbow radiographical indexes proposed in this study perform in describing the functional elbow anatomy, allowing early recognition of patients with elbow instability risk factors in clinical practice.

These indexes could also play a key role in degenerative elbow pathology; in this context, they could simplify the surgical decision-making by identifying those patients with anatomical risk factor for developing stiffness. In the search for a test able to identify fractures, a formula obtained combining the values of ACI and TDI indexes in a generalized linear model demonstrated good performances, identifying fractures with a sensitivity of 80% and a specificity of 100%. Despite the good performance of the test, it suffers of several limitations. The use of the same measurements for model development and test assessment represents the main bias. In addition, the low number of cases, as well as the lack of significance in the TDI parameter of the model, does not allow for the generalization of the test application.

Equivalent radiographic indexes have been used to evaluate the continence of concave joints in other anatomical districts [42–45]. Currently, no radiological index is commonly used in the evaluation of intrinsic stability, except for dynamic ultrasound stress tests [46]. Though, plain films are still unable to guarantee the benefits of dynamic investigation, several dynamic stress while performing X-rays were performed without clinically relevant results [47, 48]. Thank to the rigorous ex vivo anatomical validation, this study paves the way to the application of the described indexes and angles in vivo (Part B, [49]) and in the clinical setting, anticipating also a possible future description on CT and MRI images reconstructed in a sagittal trochlear plane.

Several limitations should be considered for this study. First, this is a no blinded study with a small sample size, which could amplify bias related to technical procedural aspects and anatomical variants. Furthermore, the contribution of muscle tone to elbow stability could not be investigated in an ex vivo study [50]. To minimize bias, care was taken in evaluating the specimens for visible signs of gross instability, deformity and previous trauma and specimen moisture and temperature were maintained at constant levels throughout the whole study.

Despite these limitations, this is the first study that used the anatomical measurements as gold standard for the validation of a radiographic study of elbow functional anatomy. These indexes are mainly making it easy to diagnose a coronoid fracture. However, elbow instability depends on a complex interplay between soft tissues and bony structures, of which the coronoid fracture plays a key role. The inclusion of the angles described in the manuscript may add more value to the regression equation or calculations. Future studies are needed to clarify the clinical implications of these indexes.

**Conclusion**

Three new, simple and easily reproducible radiological indexes to describe the congruency of the greater sigmoid notch have been proposed. TDI and ACI change significantly
after a simulated coronoid fracture, indicating a good responsiveness of these parameters to a pathological condition. Furthermore, combining TDI and ACI in a regression model equation allowed to identify simulated fractures with high sensitivity and specificity.

The newly proposed indexes are, therefore, promising tools to improve diagnostic accuracy of coronoid fractures and show potential to enhance perioperative diagnostic also in cases of elbow instability and stiffness.

Author Contribution  FL: Study design, data collection, original draft preparation, and anatomical illustrations; DC: manuscript correction; ER: data collection and original draft preparation; CEZ: data collection and manuscript correction; MV: statistical analysis and manuscript correction; LdG: statistical analysis and manuscript correction; AZ: data collection and manuscript correction; MBG: data collection and manuscript correction; PA: manuscript correction; PSR: manuscript correction.

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Ethical Approval  Nicola’s Foundation & ICLO Research Centre (ID 19506).

Study Guarantor  Francesco Luceri, M.D.

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Novel Radiographic Indexes for Elbow Stability Assessment: Part B—Preliminary Clinical Study

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Abstract

Introduction The coronoid process plays a key-role in preserving elbow stability. Currently, there are no radiographic indexes conceived to assess the intrinsic elbow stability and the joint congruency. The aim of this study is to present new radiological parameters, which will help assess the intrinsic stability of the ulnohumeral joint and to define normal values of these indexes in a normal, healthy population.

Methods Four independent observers (two orthopaedic surgeons and two radiologists) selected lateral view X-rays of subjects with no history of upper limb disease or surgery. The following radiographic indexes were defined: trochlear depth index (TDI); anterior coverage index (ACI); posterior coverage index (PCI); olecranon–coronoid angle (OCA); radiographic coverage angle (RCA). Inter-observer and intra-observer reproducibility were assessed for each index.

Results 126 subjects were included. Standardized lateral elbow radiographs (62 left and 64 right elbows) were obtained and analysed. The mean TDI was 0.46 ± 0.06 (0.3–1.6), the mean ACI was 2.0 ± 0.2 (1.6–3.1) and the mean PCI was 1.3 ± 0.1 (1.0–1.9). The mean RCA was 179.6 ± 8.3° (normalized RCA: 49.9 ± 2.3%) and the mean OCA was 24.6 ± 3.7°. The indexes had a high-grade of inter-observer and intra-observer reliability for each of the four observers. Significantly higher values were found for males for TDI, ACI, PCI and RCA.

Conclusion The novel radiological parameters described are simple, reliable and easily reproducible. These features make them a promising tool for radiographic evaluation both for orthopaedic surgeons and for radiologists in the emergency department setting or during outpatient services.

Level of evidence Basic Science Study (Case Series).

Clinical relevance The novel radiological parameters described are reliable, easily reproducible and become handy for orthopaedic surgeons as well as radiologists in daily clinical practice.

Keywords Coronoid process · Elbow instability · Proximal ulna · Opening angle · Congruency · Olecranon · Radiographic study

Abbreviations

GSN Greater sigmoid notch
TDI Trochlear depth index
PCI Posterior coverage index
ACI Anterior coverage index
RCA Radiographic coverage angle
OCA Olecranon–coronoid angle
SD Standard deviation
ICC Intra-class correlation coefficient

Introduction

The elbow joint is a complex hinged joint that includes the distal end of the humerus in the upper arm and the proximal ends of the ulna and radius in the [1, 2]. The combination of an osseous buttresses and a soft-tissue
envelope provides static and dynamic stability to the joint. Elbow stabilizers are classified into primary and secondary depending on their relative contribution to joint stability [3, 4].

Among the bony constraints, the ulnohumeral joint plays a primary stabilizing role, whereas the radio-humeral joint has only a secondary function. The biomechanical role of the coronoid process, which acts mainly as anterior support against posterior displacement of the ulna and forearm, has been thoroughly studied [4–7].

The role of the anatomical congruency between the greater sigmoid notch (GSN) and the humeral trochlea has been established by assessing specific contribution of olecranon and coronoid process to stability. A linear correlation between progressive olecranon resection and varus-valgus and rotational instability was reported [8]. The height of the coronoid process plays a key-role against posterior, rotational and varus-valgus laxity and a bone loss of more than 50% is associated to major elbow instability [5, 9].

Regan and Morrey stratified the coronoid fractures based on the percentage of coronoid involvement [10]: Type I describes an avulsion of the coronoid tip. Type II indicates a single or comminuted fragment involving less than 50% of the coronoid; when the fracture involves more than 50% of the coronoid process it is classified as a type III fracture. A modification was later added for fractures without dislocation (A), and fractures with an associated dislocation (B).

The Regan and Morrey classification system is widely used, but a limitation of this classification system, already described [11], is the lack of a specific thresholds to define Types I and II fractures with potential overlap between the two types. This classification does not fully describe the progressive loss of joint congruence in a fracture setting and does not give any precise information about the intrinsic stability of the elbow, especially in those cases in which the clinicians do not have pre-trauma radiographs available.

Currently, we have a huge theoretical knowledge of the anatomy of the GSN, but simple radiological tools to evaluate the intrinsic elbow stability in a clinical setting are lacking. The plain radiography is the basic tool to study elbow joint. Practical and reliable radiographic indexes, able to describe the ulnar congruency, could be helpful in regular clinical practice and in the emergency service.

The aim of this study was to introduce new radiological indexes for lateral plain radiographs that may help quantify the functional anatomy of the elbow joint and to evaluate their inter-observer and intra-observer reproducibility. The secondary goal of this study was to define the normal values of these indexes in a healthy population without the history of trauma or instability.

Materials and Methods

Patients

All elbow radiographs performed on patients younger than 18 years and older than 75 years referring to the Emergency Department of our Institution for elbow pain of any origin during 2018 (12 months) were considered for inclusion in the study. To select only radiographs without evidence of any elbow pathology, the clinical records were reviewed to exclude patients with local or systemic bone or joint disease, history of trauma or signs of instability at the clinical evaluation. Radiographs were considered eligible for further evaluation if the criteria reported were fulfilled:

Inclusion Criteria

1. Skeletally mature subjects aged between 18 and 75 years old
2. Standard lateral elbow radiographs, which fulfilled the following quality criteria: - 90° elbow flexion with concentric trochlear sulcus contour [12]

Exclusion Criteria

1. Congenital or developmental anomaly of elbow, arm or forearm
2. Systemic disease/local pathological abnormality of the bony anatomy
3. History of previous elbow fracture or dislocation
4. Elbow osteoarthritis
5. History of elbow surgery
6. Radiographs not fulfilling aforementioned quality criteria

Radiological Evaluation

On each included lateral radiograph, the tip of the olecranon (A), the tip of the coronoid tip (B), the center (O) of the GSN and its deepest point (D) as well as a line tangent to the posterior cortex surface of the proximal ulna and the ulnar diaphysis were identified as radiographic landmarks. These landmarks were used to define three primary indexes and two angles (Fig. 1–5): trochlear depth index—TDI; posterior coverage index—PCI; anterior coverage index—ACI; radiographic coverage angle—RCA and olecranon-coronoid angle—OCA [13]. The RCA was then normalized to the value of 360°, representing the whole circumference of the GSN.
A digital software (IMPAX Agfa HealthCare) was used to mark all radiographic landmarks and to generate semi-automatically linear and angular measures. All investigated indexes and angles are not affected by the bias linked to the radiographic projection magnification.

Examiners

All radiographs were evaluated and measured by four independent observers with extensive experience in the field of musculoskeletal radiology or orthopaedic surgery (more than 10 years): two of them were dedicated musculoskeletal radiologists (Examiner 1 and Examiner 2) and two of them were orthopaedic surgeons (Examiner 3 and Examiner 4).

All four observers evaluated each X-ray twice, with a 15-day delay between first and second assessments to perform an internal validation.

The University Hospital Centre Review Board approved the study protocol (Comitato Etico Milano Area 2, 595_2019bis). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Statistical Analysis

Statistical analysis was performed by one investigator (A.M.) using GraphPad Prism v.6.0 software (GraphPad Software Inc) and with SPSS v.15.0 (SPSS Inc., an IBM Company, Chicago, IL, USA). The Shapiro–Wilk normality test was used to evaluate the distribution of the sample [14]. Continuous variables were expressed as mean ± standard deviation (SD) or as median and first and third quartiles [Q1–Q3] as, appropriate; dichotomous variables were expressed in numbers of cases and frequencies.

The inter-observer reproducibility of the radiographic indexes was evaluated with intra-class correlation coefficient (ICC), which were derived from one-way random-effect analysis of variance. Intra-observer ICC estimates were calculated based on the single measurements, using an absolute-agreement, two-way mixed-effects model. Inter-observer ICC estimates were calculated based on the mean value between the two measurements of each observer. The ICC was considered moderate if between 0.500 and 0.749, good if between 0.750 and 0.899 and excellent if ICC > 0.90.

Correlations between different measurements were investigated using Pearson coefficient (“r”) for normally distributed variables and Spearman coefficient (“ρ”) for non-normally distributed variables. The same parameters were used to evaluate correlation between measurements and age of the subjects. Correlations between indexes and categorical variables (side, sex) were evaluated using Student’s t test for normally distributed indexes, Mann–Whitney test was used for non-normally distributed variables [15]. For all analyses, the significance level was set at P value lower than 0.05.

Results

237 consecutive standard lateral radiographs were screened for eligibility. 126 lateral radiographs of the elbow (62 left and 64 right elbows) fulfilled the inclusion criteria and were analysed.

The study population encompassed 126 subjects (62 females and 64 males), with a mean age of 44.9 ± 15 years (18–75 years).

The mean TDI was 0.46 ± 0.06 (0.3–1.6); the mean ACI was 2.0 ± 0.2 (1.6–1) and the mean PCI was 1.3 ± 0.1 (1.0–1.9). The mean RCA was 179.6 ± 8.3° (normalized RCA: 49.9 ± 2.3°) and the mean OCA was 24.6 ± 3.7°.

With the sole exception of the RCA, all indexes had good inter-observer and intra-observer reliability. Inter-observer ICC was 0.727 (0.641–0.797) for TDI; 0.709 (0.616–0.783) for ACI; 0.724 (0.636–0.795) for PCI, 0.522 (0.372–0.643) for RCA and 0.843 (95% CI 0.679–0.912) for OCA (Table 1).

Intra-observer reliability values for the four observers were also moderate to excellent (Table 2).

No significant correlation was found between the radiological indexes and the age of the patients. There was statistically significant difference between males and females in terms of TDI, ACI, PCI and normalized RCA but not OCA (Figs. 1, 2, 3, 4, 5); Higher values for all indexes were reported for males (TDI: males: 0.47 ± 0.06; females: 0.45 ± 0.06; p = 0.047—ACI: median in males: 2.09 [1.92–2.09]; median in females: 1.92 [1.84–1.98], p < 0.001—PCI: median in males: 1.35 [1.27–1.43]; median in females: 1.31 [1.26–1.36], p = 0.029—RCA: males: 50.35% ± 2.2%; females: 49.4% ± 2.3% p = 0.022).

Several correlations were measured between the different indexes. Strength of correlation was moderate for OCA–PCI, RCA–TDI, RCA–PCI, TDI–PCI and ACI–PCI and weak for OCA–ACI, RCA–ACI, TDI–ACI and OCA–RCA, thus excluding redundancy between the evaluated indexes (Fig. 6). Interestingly, the strength of the correlation between the measured RCA and TDI, which are geometrically linked by the equation \( RCA = 4 \cdot \arctan(2 \cdot TDI) \) was by far lower than expected (r = 1), herewith suggesting low reliability of the angular measurement RCA.
Discussion

The main finding of this study is that all radiological indexes and angles investigated, with the exception of the RCA, have a good inter- and intra-observer reliability when measured in a healthy population.

A tendency for a more congruent anatomy was observed in males as compared to females.

No relevant redundancy between the parameters TDI, ACI, PCI and OCA was reported, with only moderate or weak correlations existing between them. This study revealed also that an angular measurement of the GSN coverage is less reproducible than linear measurements, therefore, encouraging the use of the latter, which also permits to calculate the RCA angle through mathematical operations.

TDI may be useful to quantify the anatomical congruency of the elbow joint and to highlight possible elbow instability predisposition in case of trauma setting. ACI and PCI may be extremely helpful in clinical practice to define the stabilizing role of the anterior and posterior walls. These parameters may also help the clinicians to better define different patients’ subgroups according to the increasing degree of expected elbow stability.

The anatomy of the proximal ulna has been widely studied in the setting of reconstructive as well as replacement surgery [16–18]. Simple radiological landmarks, such as the posterior cortex of proximal ulna and tips of olecranon and coronoid processes, have been used to better describe the elbow anatomy in its complexity [13, 17].

Despite the elbow joint being the second most commonly dislocated joint in adult, the exact mechanism that can cause this event with or without fracture is nowadays still a subject of debate and no consensus has been reached on the reason why some elbows experience a simple and other a complex dislocation [19].

O’Driscoll et al. [4] described a sequential soft-tissue disruption starting from the lateral side, whereas other more recent studies proposed that the soft-tissue injury could begin from the medial side [20].

Micro-trauma is another clinical scenario that can lead to symptomatic chronic instability, both affecting the medial and the lateral side. Patient with symptomatic minor instabilities complain of chronic elbow pain and limitation in daily activities, which makes demanding and time consuming the process necessary to reach a proper diagnosis and indicated adequate treatment [21–23].

These numerous pathological entities and clinical variables, in addition to the complexity of functional elbow anatomy, make it extremely challenging to identify and quantify intrinsic elbow stability with simplified imaging parameters.

Regan and Morrey stratified the coronoid fractures based on the percentage of coronoid involvement and created a classification system, which is still currently widely used [10]. Herewith, contribution of the coronoid process against posterior, rotational and varus–valgus laxity could be quantified, suggesting that more than 50% height loss is associated with major elbow instability [5, 9].

Nevertheless, static radiographic parameters have inherent limitations, as they cannot fully describe the complex joint stability status: for example, the rotation axis of the elbow is not a static constant, as it significantly shifts throughout the range of motion of the joint. The common limitation of radiographic classifications is its inability to accurately describe the three-dimensional fracture pattern and help in surgical planning. To overcome these limitations, O’Driscoll et al. [24] proposed a CT classification system

Table 1 Inter-observer reliability of the investigated parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ICC</th>
<th>95% IC</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDI</td>
<td>0.727</td>
<td>0.641–0.797</td>
</tr>
<tr>
<td>ACI</td>
<td>0.709</td>
<td>0.616–0.783</td>
</tr>
<tr>
<td>PCI</td>
<td>0.724</td>
<td>0.636–0.795</td>
</tr>
<tr>
<td>RCA</td>
<td>0.522</td>
<td>0.372–0.643</td>
</tr>
<tr>
<td>OCA</td>
<td>0.843</td>
<td>0.679–0.912</td>
</tr>
</tbody>
</table>

Table 2 Intra-observer reliability of the investigated parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ICC</th>
<th>95% IC</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDI1</td>
<td>0.792</td>
<td>0.717–0.849</td>
</tr>
<tr>
<td>TDI2</td>
<td>0.818</td>
<td>0.749–0.869</td>
</tr>
<tr>
<td>TDI3</td>
<td>0.532</td>
<td>0.394–0.646</td>
</tr>
<tr>
<td>TDI4</td>
<td>0.833</td>
<td>0.758–0.884</td>
</tr>
<tr>
<td>ACI1</td>
<td>0.717</td>
<td>0.620–0.793</td>
</tr>
<tr>
<td>ACI2</td>
<td>0.807</td>
<td>0.737–0.861</td>
</tr>
<tr>
<td>ACI3</td>
<td>0.620</td>
<td>0.499–0.716</td>
</tr>
<tr>
<td>ACI4</td>
<td>0.841</td>
<td>0.776–0.888</td>
</tr>
<tr>
<td>PCI1</td>
<td>0.597</td>
<td>0.471–0.699</td>
</tr>
<tr>
<td>PCI2</td>
<td>0.899</td>
<td>0.860–0.928</td>
</tr>
<tr>
<td>PCI3</td>
<td>0.487</td>
<td>0.343–0.609</td>
</tr>
<tr>
<td>PCI4</td>
<td>0.782</td>
<td>0.703–0.841</td>
</tr>
<tr>
<td>RCA1</td>
<td>0.630</td>
<td>0.512–0.724</td>
</tr>
<tr>
<td>RCA2</td>
<td>0.933</td>
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<tr>
<td>RCA3</td>
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<td>RCA4</td>
<td>0.795</td>
<td>0.720–0.851</td>
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<tr>
<td>OCA1</td>
<td>0.712</td>
<td>0.612–0.789</td>
</tr>
<tr>
<td>OCA2</td>
<td>0.911</td>
<td>0.876–0.937</td>
</tr>
<tr>
<td>OCA3</td>
<td>0.867</td>
<td>0.816–0.905</td>
</tr>
<tr>
<td>OCA4</td>
<td>0.943</td>
<td>0.907–0.963</td>
</tr>
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</table>

Observers: two dedicated musculoskeletal radiologists (Examiner 1 and Examiner 2) and two orthopaedic surgeons (Examiner 3 and Examiner 4)
for coronoid fractures, which provides also indications for the surgical decision-making [18, 25].

Although the role of the coronoid process is elbow stability indisputable, a further aspect to be considered is role of the olecranon height in generating the anatomical congruency between the GSN and the humeral trochlea: progressive olecranon resection has been correlated with increasing varus–valgus and rotational instability, suggesting that olecranon and coronoid processes both play a relevant role in determining elbow stability [8]. This raised interest in creating indexes for the olecranon height and in measuring the proximal ulna and the GSN as a whole, and several radiographic parameters were reported in adolescent and young adults [13, 26, 27].

The trochlear depth index used in this study was inspired by the acetabular depth index (depth–width ratio) and its importance in defining the joint stability for developmental dysplasia hip [28, 29]. This matches width and depth of the trochlear notch, giving a concise description of ulnar elbow coverage. Ndou and Scheparz [30] described GSN width using the same landmarks, measuring the depth as the distance from the deepest point of GSN to a line connecting olecranon and coronoid tips; however, to our knowledge, a depth–width ratio has never been proposed as a radiological parameter to assess the stability of the elbow joint.

Fig. 1 Box-and-whiskers plot (a) illustrating the trochlear depth index (TDI) comparison between males and females ($p < 0.05$). Schematic representation (b) and measurement on a lateral radiograph (c) of TDI: the ratio between the distance from the olecranon tip to the coronoid tip (AC) and the distance between this line and the deepest point of the trochlea (TDI = BD/AC).
An advantage of the combination of two linear measurements as opposed to the use of an angular measurement (such as the RCA) is the lower risk of measurements errors, mainly attributable to the imprecision in determining the centre of the GSN necessary to calculate the RCA. This was confirmed in our study by the moderate ICC for the RCA measurements and the low strength of the correlation between TDI and RCA (expected $r$ value $= 1$). The authors recommend, therefore, to rely on linear measurements and, if needed, to obtain derived angles to describe GSN coverage or sigmoid notch opening by mathematical operations, such as $RCA = 4 \cdot \arctan \left( \frac{2 \cdot BD}{AC} \right) = 4 \cdot \arctan \left( 2 \cdot TDI \right)$ and sigmoid notch opening angle $= \frac{RCA}{2}$ [31].

Simple, practical and reliable radiographic indexes to assess elbow stability, such as those introduced in this study,
may have an important role in the decision-making process, already from the first clinical consultation after injury.

These radiographic parameters are extremely promising, since they permit to obtain a practical and quick measurement of the constitutional elbow congruency, can be easily reproduced in an emergency service without the need of a CT and are applicable in both trauma and non-trauma patients.

Comparing the values obtained in the current study to previously published normal data, OCA highlights the role of the coronoid in relation to posterior dislocation. Goldfarb et al. measured a mean value of 23°, and the results are almost correlating with our results. OCA and RCA resulted to be in line with previous studies [13, 26].

ACI and PCI have never been described in the scientific literature. For coronoid, olecranon and notch height we used the same landmarks applied by Beşer et al. [17]. The strength of correlation measured between the radiographically determined ACI and PCI in the current study is similar to that obtained by Beşer et al. for the non-normalized anatomical counterparts of these two parameters measured in anatomical specimens. Interestingly, we found a moderate correlation between the PCI and OCA, whereas the mentioned anatomical study did not reveal any correlation between ulnar angles and the posterior olecranon height.
These data suggest that ACI and PCI may be very helpful in clinical practice to define the stabilizing role of the anterior and posterior walls. These parameters may also help the clinicians to better define different patients’ subgroups according to the increasing degree of expected elbow stability. The hope is that these indexes will allow selecting patients with joint instability/stiffness risk factors or to better guide second level imaging after acute trauma or in post-traumatic elbow sequelae. The relatively small sample size was the most important limitations of this study. Moreover, the two-dimensional radiographic elbow images do not take into account of the complexities of bony anatomy and its fundamental role in joint stability, which was visible in some differences emerging when comparing the results with the anatomical study by Beşer et al. [17]. Finally, this radiographic study was limited to a single plane view for a primary constraint of elbow joint, and the evaluation of structures potentially affecting stability in other planes was outside the scopes of this study. CT and MRI have also been

Fig. 4 Box-and-whiskers plot (a) illustrating the radiographic coverage angle (RCA) comparison between males and females ($p<0.05$). Schematic representation (b) and measurement on a lateral radiograph (c) of the RCA, defined as the dorsally opened angle between a line passing through the centre of a circle tangent to GSN surface and the olecranon tip and a line passing through the centre of the same circle and the coronoid tip (i.e. the angle subtended by the circular segment AOC). Alternatively, the RCA can be alternatively derived by mathematical operations from the linear measurements illustrated in Fig. 1 as $RCA = 4 \cdot \arctan(2 \cdot BD / AC)$.  

\[
RCA = 4 \cdot \arctan(2 \cdot BD / AC)
\]
used to measure joint stability, taking into account both its bony and cartilaginous contribution; however, the high costs and limited availability of MRI in a trauma setting limit its use as a second level examination for selected patients [26]. Nevertheless, the authors encourage the use of standardized reconstructions in the sagittal plane and the measurements of the presented indexes, for whom a validation in CT and MRI is expected.

**Conclusion**

Novel radiographic indexes to describe the congruency of the greater sigmoid notch and the anatomy of the proximal ulna have been evaluated in a healthy population: TDI, ACI, PCI and OCA demonstrated a good inter- and intra-observer reliability and showed no relevant redundancy. A tendency for a more congruent anatomy was observed in males as compared to females. These parameters can be used to...
Fig. 6 Dispersion plots showing correlations between radiological indexes (*: $p < 0.01$)
simply and effectively describe elbow joint functional bony anatomy; on the other hand, an angular measurement of the GSN coverage proved to be less reproducible than linear measurements.

Author Contributions FL: Study design, data collection, original draft preparation, and anatomical illustrations; DC: Manuscript correction; ER: Data collection and original draft preparation; CEZ: Data collection and manuscript correction; AM: Statistical analysis and manuscript correction; AZ: Data collection and manuscript correction; MC: Data collection and manuscript correction; MBG: Data collection and manuscript correction; PA: Manuscript correction; PSR: Manuscript correction.

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Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent For this type of study informed consent is not required.

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Is Revision Bankart Repair with Remplissage a Viable Option for Failed Bankart Repair in Non-contact Sports Person Aiming to Return to Sports?

Skand Sinha1 · Nitin Mehta1 · Rakesh Goyal1 · Ankit Goyal1· Deepak Joshi1 · R. K. Arya1

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Abstract

Purpose Failure of a well-executed Bankart repair in non-contact athletes is difficult to predict and its management is a lesser investigated area with uncertain outcome in terms of return to sports (RTS). This study analyses effectiveness of revision Bankart repair with remplissage for failed Bankart repair in non-contact athletes, focusing on time and level of RTS.

Materials and Methods Fifty-five consecutive non-contact athletes with evidence of instability after primary arthroscopic Bankart repair having glenoid loss < 25% and off-track Hill-Sachs lesion were included in the study according to algorithm mentioned. All cases underwent revision arthroscopic Bankart repair with remplissage and followed-up for 24 months. Rowe, UCLA, WOSI and Quick-DASH scores were recorded preoperative and at 24 months. RTS was allowed after unilateral seated shot-put test.

Results Out of 55 cases, 6 were excluded because of poor tissue quality, 7 were lost to follow-up. Forty-two cases with a mean age of 28.2 ± 5.2 years were included. Mean duration between primary surgery and failure was 7.3 ± 1.4 months with a mean 1.9 redislocations. The mean Rowe, WOSI, UCLA, Quick-DASH scores improved from 37 to 89, 39.3 to 83.7%, 18.4 to 30.5, 45.3 to 18.7 at 24 months. Thirty-five cases could RTS in a mean time 15.4 ± 1.4 months. Out of seven cases who could not RTS, four had instability, one had pain and two voluntarily quit sports.

Conclusion Revision Bankart repair with remplissage is a feasible option for failed primary Bankart repair in non-contact athletes who have glenoid bone loss < 25% with off-track Hill-Sachs.

Level of evidence Level IV.

Keywords Failed Bankart · Non-contact sports · Revision Bankart repair with remplissage · Return to sports

Introduction

The arthroscopic Bankart repair has been the most common procedure performed for the management of recurrent anterior instability of shoulder [1, 2]. Despite excellent results at trained hands, failure have also been reported. With increasing cases of failed Bankart repair, causes of failure and their logical treatment options are constantly being evaluated. Under-appreciation of bipolar defects pre and per-operative, recurrent traumatic episodes, younger age, poor surgical techniques, poor quality capsule and failure to recognize capsular laxity remain most important causes of failure [1, 3, 4].

The cases of failed Bankart repair with glenoid loss of more than 25% are classically treated by Latarjet procedure [5]. But in cases having glenoid loss of less than 25% with/without humeral head loss have been treated with various
surgical revision procedures depending upon indications and surgeon preferences of which open/arthroscopic Latarjet, revision arthroscopic Bankart repair and revision arthroscopic Bankart repair with remplissage have been reported [6–9].

Most of the causes of failure of Bankart repair lie in improper case selection or execution but failure of ideally indicated and well-executed Bankart repair in set of non-contact athletes is still a lesser investigated area.

This study analyses outcome of revision Bankart repair with remplissage for failed Bankart repair (glenoid loss < 25% and off-track Hill-Sachs lesion) in non-contact athletes, according to treatment algorithm (Fig. 1). It also investigates time and level of return to sports (RTS) after surgery.

Research Question: Does revision Bankart repair with remplissage for failed Bankart repair (glenoid loss < 25% and off-track/engaging Hill-Sachs lesion) in non-contact sports persons provide satisfactory clinical outcome with same level of return to sports?

Material and Methods

This retrospective analysis of a prospective case series was conducted on 55 consecutive non-contact sports persons who had recurrence of anterior instability after primary arthroscopic Bankart repair, from 2015 to 2017. Informed consent was obtained from all patients.

Thorough clinical examination, MRI (3 T Magnetic Resonance Imaging) and CT scan (64 slice Multidetector Computed Tomography scan with 3-Dimensional reconstruction) was performed.

Inclusion was based on pre-operative, radiological and per-operative assessment (Fig. 1). Cases with subjective and objective (clinico-radiological) evidence of failed arthroscopic Bankart repair, who had suffered ≤ 2 episodes of dislocation (defined as dislocation with spontaneous relocation or dislocation requiring a reduction) were included only after confirmation of glenoid bone loss of less than 25% and an off-track Hill-Sachs lesion [Hill-Sachs Interval (HSI) > Glenoid track (GT)] on CT scan. The method of CT assessment used in this study was the perfect circle method [10, 11] and 3D reconstruction to assess bipolar bone loss [12]. Location of suture anchors of previous Bankart repair were also assessed. The inclusion was further narrowed down per-operatively. If the capsulo-labral quality was found healthy, only then the patients were included. Patients with poor labral tissue quality and non-engaging Hill-Sachs lesion were excluded from the study.

The patients involved in contact sports, treated with a previous open surgery, multi directional instability (Beighton score ≥ 4), glenoid defect of > 25%, HSI < GT, evidence of degenerative arthritis, glenoid dysplasia, concurrent fractures, rotator cuff tears, SLAP (superior labral tear from anterior to posterior) tear, PASTA (partial articular supraspinatus tendon avulsion) lesions and neuromuscular disorder were excluded.

Surgical Technique

All surgeries were performed by the same surgical team in lateral decubitus position. Standard posterior, antero-superior-lateral and antero-inferior portals were established and arthroscopic evaluation was done. During arthroscopic evaluation, the patient’s limb was freed of lateral traction and shoulder flexion, abduction and external rotation was performed for dynamic assessment of Hill-Sachs engagement. Furthermore, assessment of labral tissue was also done. Cases who had poor labral tissue underwent Latarjet procedure in same sitting. Cases with non-engaging Hill-Sachs per-operatively and with a good labral tissue underwent isolated Bankart repair.

An additional posterolateral accessory portal was made by penetrating the capsule and tendon of infraspinatus using outside in technique after ensuring that the needle was perpendicular to the Humeral lesion. Remplissage was done using two single loaded 5.5 mm bioresorbable suture anchors 1 cm apart (Fig. 2a). Before tying mattress sutures for completion of remplissage (Fig. 2b), Bankart lesion was addressed and repair done using minimum of three single loaded 2.3 mm bioabsorbable suture anchors (Fig. 2c, d).

After surgery, follow-up was done every month for first 6 months and thereafter every 2 months till the end of minimum of 24 months. Shoulder immobilizer was given for 3 weeks. Patients were allowed elbow flexion/extension, forearm strengthening, gentle scapular glides and proprioceptive training after pain subsided. The ROM exercises of shoulder were initiated after 4 weeks. From 8 weeks onwards, the aim was to achieve up to 80% of normal ROM. After 3 months of surgical procedure, emphasis was laid on strength and endurance training followed by conditioning to sports at 6 months onwards. Exercises involving the physiological load were instituted after the 6 months and return to training for respective sports was recommended after 8 months. Return to competitive sports was recommended after the 12 months, when they gained full confidence in their shoulder and were pain free. Functional assessment for every patient prior to return to sports was done by unilateral seated shot-put test [13].

Rowe [14], UCLA (University of California Los Angeles) scores [15], WOSI (Western Ontario Shoulder Instability Index) score [16] and Quick-DASH (The Disabilities of the Arm, Shoulder and Hand Score) score [17] and ROM (by goniometer) were recorded preoperative and at 24 months.
Patients with Failed Bankart Surgery

MRI - patient excluded after assessment of SLAP, PASTA, other associated injury

Clinico-Radiological assessment (Apprehension test, Beighton’s score, MRI, CT scan)

CT scan - for assessment of bipolar lesion

Glenoid Bone Loss >25%, HSI>GT

Latarjet Procedure

Labral Tissue Quality - Poor

Glenoid Bone Loss <25%, HSI<GT

Planned for Revision Arthroscopic Bankart repair with Remplissage repair

Intra-operative assessment of labral tissue quality

Labral tissue quality - Good

Arthroscopic Bankart repair

Assessment of Hill-Sachs Lesion

Engaging Hills Sachs lesion

Remplissage done for Hill Sachs Lesion

Meticulous rehabilitation

Assessment of operated shoulder in follow up

Return to Sports

Fig. 1 Treatment algorithm. H/S Hill-Sachs Interval, GT glenoid track
Statistical Analysis

Statistical analysis was carried out by SPSS software (version 13). Chi-square statistical test and Wilcoxin–Mann–Whitney test were applied for comparison of various scores with preoperative and final follow-up values. The continuous data were reported as mean ± standard deviation. The significance level $P$ was less than 0.05.

Results

Demographic characteristics of patients are mentioned in Table 1.

Mean Glenoid Bone loss on 3D CT scan by perfect circle method was 17.6% ± 2.2% (range 12–22%). In our study, 88 percent of the patients had glenoid bone loss less than 20% (Table 2).

The mean Rowe, WOSI, UCLA and Quick DASH scores improved from 37 ± 3.9 to 89 ± 16.9 ($p < 0.05$), 39.3% ± 6.9 to 83.7% ± 10.4 ($p < 0.05$), 18.4 ± 2.1 to 30.5 ± 2.7 ($p < 0.05$) and 45.3 ± 13.1 to 18.7 ± 7.2 ($p < 0.05$), respectively (Table 3).

Although, Stability was achieved in 38 out 42 cases (90.5%) at final follow-up, 7 cases (17%) could not return to sports.

Four (9.5%) out these seven cases complained of subluxation/dislocation and had positive apprehension test after second surgery within the first year of the surgery. Out of these four cases two were later lost to follow-up and the other two quit their respective sports and refused surgery the third time.

Apart from these four cases there were three (7.5%) more cases who could not return to sports due to reasons not related to instability. Two cases had quit their respective sports voluntarily while one developed pain due to internal impingement that did not resolve despite conservative management and he had to quit sports (Table 4). The mean time to return to sports at competitive level was 15.4 ± 1.4 months (range 13–21 months).

At final follow-up, 37 cases had regained full range of motion except external rotation. The mean decrease in external rotation at 90 degrees of abduction was 6.2 ± 2.30 degrees in comparison to normal side. Four cases who had recurrence and one who had pain could not regain full range of motion.

Discussion

The most obvious finding of this study was that when proper case selection is done with ruling out of all causes of potential failure during preoperative work up and surgery, an
arthroscopic revision Bankart repair with remplissage for failed primary Bankart repair in non-contact athletes provides good to excellent results.

Revision Bankart repair with or without remplissage is established treatment of failed Bankart surgery [9]. By addition of remplissage stability can be imparted to failed primary Bankart repair. Stability was achieved in majority of cases in this study (90.5%). For successful outcome case selection according to preoperative clinical and radiological parameters, is paramount. We strictly followed the mentioned treatment algorithm and narrowed down case selection according to existing norms.

Number of dislocations for case selection was restricted to ≤ 2 as the number of dislocations is directly proportional to glenoid bone loss which in turn is related with increased risk of recurrence [18, 19]. Studies have shown that > 2 successive anterior dislocations are associated with higher incidence of recurrence [1, 19].

Soft tissue (capsulo-labral) status is equally important for a successful revision. It may be difficult to accurately evaluate the quality of labrum and capsule on MRI that is why we evaluated it arthroscopically and excluded cases with poor soft tissues. Terry et al. suggested soft tissue quality assessment by correlating to translation of head of humerus under anaesthesia but we depended on arthroscopic assessment only, as translation was found to be increased in most of the cases even when sulcus sign was absent [20].

The edge loading forces on gleno-labral repair are high during abduction and external rotation in cases of glenoid

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### Table 1 Demographic data

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases with failed arthroscopic stabilization procedure</td>
<td>55</td>
</tr>
<tr>
<td>Number of cases excluded due to poor quality labral tissue intraoperative</td>
<td>6</td>
</tr>
<tr>
<td>Number of cases lost to follow-up</td>
<td>7</td>
</tr>
<tr>
<td>Number of cases included in study after completing minimum follow-up of 24 months</td>
<td>42</td>
</tr>
<tr>
<td>Male</td>
<td>26</td>
</tr>
<tr>
<td>Female</td>
<td>16</td>
</tr>
<tr>
<td>Dominant side</td>
<td>32</td>
</tr>
<tr>
<td>Non-dominant side</td>
<td>10</td>
</tr>
<tr>
<td>Mean age at second surgery ± SD (range) in years</td>
<td>28.2 ± 5.2 (20–40)</td>
</tr>
<tr>
<td>Mean number of dislocations after primary surgery</td>
<td>1.9</td>
</tr>
<tr>
<td>Mean interval between first surgery and re-dislocation ± SD (range) in months</td>
<td>7.3 ± 1.4 (5–13)</td>
</tr>
<tr>
<td>Mean follow-up after surgery ± SD (range) in months</td>
<td>30.2 ± 2.8 (24–36)</td>
</tr>
<tr>
<td>Reduction of dislocation</td>
<td></td>
</tr>
<tr>
<td>Health care professional</td>
<td>35 (83.3%)</td>
</tr>
<tr>
<td>Self-reduction/spontaneous</td>
<td>7 (16.7%)</td>
</tr>
<tr>
<td>Median anchors used, n (range)</td>
<td>4.8 (4–5)</td>
</tr>
</tbody>
</table>

### Table 2 Percentage of Glenoid bone loss on 3D CT scan by perfect circle method

<table>
<thead>
<tr>
<th>Percentage of glenoid bone loss</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–&lt;15%</td>
<td>9</td>
</tr>
<tr>
<td>15–&lt;20%</td>
<td>28</td>
</tr>
<tr>
<td>20–&lt;25%</td>
<td>5</td>
</tr>
</tbody>
</table>

### Table 3 Functional outcome scores at 24 months

<table>
<thead>
<tr>
<th>Functional score</th>
<th>Pre-operative</th>
<th>24 months Postoperative</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rowe score (mean ± SD)</td>
<td>37 ± 3.9</td>
<td>89 ± 16.9</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>UCLA score (mean ± SD)</td>
<td>18.4 ± 2.1</td>
<td>30.5 ± 2.7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>WOSI score (mean% ± SD)</td>
<td>39.3 ± 6.9</td>
<td>83.7 ± 10.4</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Quick-DASH score (mean ± SD)</td>
<td>45.3 ± 13.1</td>
<td>18.7 ± 7.2</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

### Table 4 Time and level of return to sports

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meantime of return to sports ± SD (range) in months</td>
<td>15.4 ± 1.4</td>
</tr>
<tr>
<td>Number of cases returning to same competitive level as before primary surgery</td>
<td>20</td>
</tr>
<tr>
<td>Number of cases returning to higher Competitive level than prior to primary surgery</td>
<td>15</td>
</tr>
<tr>
<td>Number of cases not able to return to prior Competitive level</td>
<td>7</td>
</tr>
</tbody>
</table>
bone deficiency. These stresses can be even higher in athletes. The edge loading is reduced by remplissage as the filling of Hill-Sachs defect exteriorizes the engaging area.

Revision Bankart repair is a fairly successful procedure with low recurrence rates and addition of remplissage for Hill-Sachs makes it more secure. We had only 4 cases out of 42 who had recurrence of instability that is comparable to results of other reported studies. Barnes CJ reported a success rate of 94% in cases of revision Bankart repair without Remplissage but all subjects were not athletes [21]. The recurrence rate following revision Bankart repair reported was 3 out of 16 by Arce et al. [22], 3 out of 11 cases Neri et al. [23], 3 out of 23 by Buckup et al. [24], 6 out of 56 by Bart et al. [25] and 5 out of 23 by Kim et al. [26]. A high failure rate of 8 out of 21 was reported by O’Neill et al. in a set of 21 cases of revision Bankart procedure but they had done remplissage in only 8 cases and 19 cases were contact athletes [27]. In contrast to O’Neill, this study has low failure rate because remplissage was added to all cases and only non-contact sports person were selected.

Success of this procedure is depicted by return to sports. In this series, 83% of cases returned to same or higher level of competitive sports they were involved in prior to first surgery that is substantial considering the study population comprised only of sports persons. The reported rate of return to sports was 76% by Bartl et al. [25]. Out of 67 cases of Cordasco et al., 75% could return to same or higher competitive level in a mean time of 7.1 months [28]. Out of 20 cases, Buckup et al. reported 70% return to sports [24].

The mean time of RTS in this study was 15.4 ± 1.4 months but it could be because the patients were allowed RTS only after they were confident about their shoulder, regained near complete ROM, had cleared unilateral seated shot-put test and were pain free.

The improvement post-surgery was established by statistically significant improvement in mean Rowe, WOSI, UCLA and Quick-DASH scores that is comparable to reported by various authors [7–9, 22, 25, 28].

As it is associated with remplissage, there was slight restriction of ER in abduction (6.2 ± 2.30 degrees) but had no impact on outcome or RTS. To minimize restriction of ER, we had inserted anchors in centre of width of Hill-Sachs, avoiding being close to articular margin. Also, all these cases were put to supervised rehab only.

Using the algorithm mentioned, patients having risk of failure are excluded, thus improving the outcome of surgery.

Limitation of Study

There was no control group because it is difficult to get high number of failed Bankart cases that too in a small subset of non-contact athletes.

Conclusion

Revision Bankart repair with remplissage is a feasible option for failed primary Bankart repair in non-contact athletes who have glenoid bone loss < 25% with off track lesion. This allows return to competitive sports with minimal risk of failure but slight limitation of external rotation.

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Author Contributions Conceptualization: SS, DJ; methodology: DJ, RG; formal analysis and investigation: NM, AG; writing—original draft preparation: AG, NM; writing—review and editing: SS, RG; supervision: RKA.

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Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval The study was in compliance with the ethical standards of our institutional ethical committee.

Informed Consent Informed consent was obtained from all the participants in the study.

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MRI-Based Morphometric Study Regarding Operative Windows of Oblique Lumbar Interbody Fusion in Indian Population

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Abstract

Background  The novel Oblique lumbar interbody fusion [OLIF] technique has been proposed as a solution to approach related complications of anterior lumbar interbody fusion [ALIF] and lateral lumbar interbody fusion [LLIF]. There exists no study concerning morphological evaluation of retroperitoneal oblique corridor for the Oblique lumbar interbody fusion (OLIF) technique in the Indian population. The aim of our study was (a) to measure magnetic resonance imaging (MRI) based anatomic parameters concerning OLIF operative windows from L2–L3 to L4–L5 level (b) to determine the feasibility of this technique following MRI-based morphometric evaluation in the Indian population.

Material and methods  We did retrospective MRI analysis of 307 consecutive patients following our exclusion criteria. Bare window, psoas major window and psoas major width were measured from axial T2 MRI image taken at mid disc level from L2–L3 to L4–L5 levels.

Results  The mean bare window size was largest at L2–L3 (1.39 cm) level followed by L3–L4 and L4–L5 level (1.28 and 0.62 cm respectively), and differences between them were statistically significant (P < 0.001). Females had statistically significant larger bare windows at L2–L3 and L3–L4 level than males (P < 0.001). With increasing age, there was a significant increase in bare window size at each level (P < 0.001). The mean psoas major window (PM0) and mean psoas major width (PM1) were largest at L4–L5 level (PM0 = 1.27 cm, PM1 = 3.61 cm) followed by L3–L4 and L2–L3 level (L3–L4: PM0 = 1.19 cm, PM1 = 2.36 cm; L2–L3: PM0 = 0.88 cm, PM1 = 1.39 cm), and differences among each level concerning both parameters were statistically significant (P < 0.001). Both parameters (PM0, PM1) were significantly larger in males than females at each level (P < 0.001).

Conclusion  The OLIF technique is well suited for lumbar interbody fusion at L2–L3 and L3–L4 level in the Indian population irrespective of age and sex. At L4–L5 level, overall 17.9 percent of the study population were unsuitable for this technique due to inaccessible bare window. In our opinion, this level may be better suited for OLIF approach in the elderly Indian population, especially for surgeons who are beginning to attempt this technique in their surgical practice. Preoperative MRI evaluation for the OLIF is important to assess its feasibility, as there exists significant age and gender differences in the Indian population for anatomic parameters concerning OLIF operative windows from L2–L3 to L4–L5 levels.

Keywords  Interbody fusion · OLIF · Indian population · Magnetic resonance imaging

Introduction

Lumbar interbody fusion is a proven treatment strategy for diverse spinal disorders which includes unstable degenerative conditions, trauma, infection and neoplasia [1]. Broadly fusion can be achieved via posterior approaches which include posterior lumbar interbody fusion [PLIF] and transforminal interbody fusion [TLIF], and the anterolateral approaches: anterior lumbar interbody fusion [ALIF], transpsoas lateral lumbar interbody fusion [LLIF]
and oblique lumbar interbody fusion [OLIF]. Posterior approaches have proven acceptable fusion rates but result in disruption of posterior tension band, iatrogenic injury to paraspinal musculature and limited endplate exposure restricted by thecal sac and nerve roots which may cause difficulty in the correction of coronal imbalance and lordosis restoration [1]. The ALIF approach provides excellent exposure of L4–L5 and L5-S1 disc levels allowing better endplate preparation and larger size cage implantation resulting to adequate deformity correction with the restoration of lumbar lordosis. Avoidance of posterior vertebral segments results in lesser postoperative axial pain and reduced possibility of adjacent segment disease. The associated complications include visceral injury, vascular injury, retrograde ejaculation, intestinal adhesions, and abdominal hernia [2]. The LLIF approach aims to overcome these ALIF-related complications by utilizing access to disc via transmuscular interval through psoas. However, this approach results in a potential risk of injury involving lumbar plexus or femoral nerve as they course through psoas muscle and this mandates the procedure to be done under intraoperative neuromonitoring [3]. The “pre-psoas” approach involving oblique corridor between psoas major laterally and aorta or common iliac vessels medially, was first described by Mayer and referred to as OLIF by Silvestre et al. [4, 5]. It is among the latest techniques being proposed as a solution to approach related complications of ALIF and LLIF, which has been demonstrated by promising preliminary results by various studies [6]. Further anatomical research regarding OLIF will guide the surgeons to enhance their skills and help in achieving widespread acceptance of this approach among them [7]. In the present literature there exist few cadaveric and radiological studies involving computed tomography & magnetic resonance imaging, which have described the oblique corridor concerning the OLIF technique in white and Asian population [7–12]. To the best of our knowledge, the present study is the first to evaluate retroperitoneal oblique corridor for OLIF technique in the Indian population. The aim of our study was (a) to measure magnetic resonance imaging (MRI) based anatomic parameters concerning OLIF operative windows from L2–L3 to L4–L5 level and (b) to determine the feasibility of this technique following MRI based morphometric evaluation in the Indian population. This will provide a robust anatomical database to guide future studies about this emerging technique from the Indian subcontinent.

Material and Methods

Approval of the ethical committee at our institute was obtained prior to the study. We collected data of 307 consecutive patients following our exclusion criteria after a retrospective review of MRI scans from September to December 2019, who had presented to our department for treatment regarding low back pain with or without radicular symptoms and required MRI of lumbar spine during their course of treatment. Exclusion criteria included age less than 18 years, traumatic, tumorous or spondylodiscitis cases, prior lumbar or retroperitoneal surgery, any lumbar anterior great vessel abnormality, vertebral abnormalities such as transitional lumbar anomalies, hemivertebrae, spina bifida, and spinal deformities such as scoliosis or kyphosis apart from lumbar degenerative disorders as their cause. MRI scans were taken with a 3 T Philips Achieva system (Philips healthcare, Netherlands) and data measurement was done using Radiant DICOM viewer software (version 72 5.0.0.219060). T2W MRI images in sagittal and axial plane were independently assessed by a senior spinal surgeon and a senior radiologist. First, mid-sagittal T2W view was used to identify disc level on the axial view. Subsequently axial T2W MRI image taken at mid disc level from L2–L3 to L4–L5 levels was used for performing measurements. As per prior published studies in the existing literature, the following operative windows of the OLIF were measured: bare window [bare unobstructed disc portion bounded by abdominal aorta or left iliac vessels medially and left psoas major laterally], psoas major window [left front portion of disc space which is covered by left psoas major from its anterior portion up to middle frontal plane], and psoas major width [width of left psoas major on the middle frontal plane of the intervertebral disc space] (Fig. 1) [7, 9]. The average of measurements obtained by the two reviewers for the operative windows of OLIF at each disc level were recorded.

Fig. 1 Axial T2 MR image at mid-disc level of L3–L4 level. O: approximate intervertebral disc centre; AB: Bare window; BC: Psoas major window; CD: Left psoas major width in the middle frontal plane.
All statistical data analysis was done using IBM SPSS Statistics for Windows, Version 20.0., IBM Corp., Chicago, IL. Descriptive statistics were reported as mean ± SD for continuous variables. The one-way analysis of variance (ANOVA) was used to assess any differences between the bare window of each age group. The unpaired T test was used to compare OLIF operative window parameters between sexes and differences between each level. P value < 0.05 indicated a significant difference for all the statistical data analysis done using ANOVA and unpaired t test.

Results

The study evaluated MRI records of 307 patients, 154 [50.2%] were males and 153 [49.8%] were females. Mean age was 41.07 years [SD 14.37, range 18–78 years].

Bare Window

The bare window represents the unobstructed oblique corridor and its size is critical to perform the OLIF technique safely. All MRI scans showed a clear bare window at L2–L3 and L3–L4 levels. In 55 [17.9%] MRI scans bare window at L4–L5 level was inaccessible because of absent interval seen in 25 (8.14%) patients and non-measurable interval either due to high rising psoas muscle (19 patients, 6.19%) or abnormal laterally positioned iliac vessels (11 patients, 3.58%) [Fig. 2a, b]. Among this group, 44 MRI scans [23 male, 21 females] were <40 years age, seven [five male, two females] were between 40 and 60 years age and four [two male, two females] were >60 years age. The value was taken as zero for both absent and non-measurable bare window at L4–L5 level while doing statistical data analysis. It was largest at L2–L3 (1.39 ± 0.39 cm) level followed by L3–L4 and L4–L5 level (1.28 ± 0.38 and 0.62 ± 0.49 cm, respectively) (Table 1). The unpaired T test was used to compare differences between sexes [Table 2]. The women had statistically significant larger size bare window than men at L2–L3 and L3–L4 levels (P < 0.001). At L4–L5 level bare window was larger in men than women, but the difference was not statistically significant (P = 0.122). On analysis of bare window size differences according to different age groups at each level using the ANOVA test, the size was found to increase with age and was statistically significant for each level (P < 0.05) (Table 3). On comparing bare window differences between each level using the unpaired t test, statistically significant differences were found between all levels (P < 0.001) [Table 4].

![Fig. 2](image-url) Axial T2 MR image at mid-disc level of L4–L5 level showing non-measurable bare window because of; a High rising psoas major muscle; b Abnormal laterally positioned iliac vessels; O: approximate intervertebral disc centre

<table>
<thead>
<tr>
<th>Disc Level</th>
<th>Mean [cm]</th>
<th>SD</th>
<th>Min. [cm]</th>
<th>Max. [cm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>L2–L3 Bare window</td>
<td>1.39</td>
<td>0.39</td>
<td>0.44</td>
<td>2.89</td>
</tr>
<tr>
<td>Psoas major window</td>
<td>0.88</td>
<td>0.38</td>
<td>0.00</td>
<td>2.04</td>
</tr>
<tr>
<td>L3–L4 Bare window</td>
<td>1.28</td>
<td>0.38</td>
<td>0.38</td>
<td>2.67</td>
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<tr>
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<td>0.39</td>
<td>0.00</td>
<td>2.43</td>
</tr>
<tr>
<td>L4–L5 Bare window</td>
<td>0.62</td>
<td>0.49</td>
<td>0.00</td>
<td>2.12</td>
</tr>
<tr>
<td>Psoas major window</td>
<td>1.27</td>
<td>0.35</td>
<td>0.28</td>
<td>2.53</td>
</tr>
</tbody>
</table>

Min, minimum; Max, maximum
The psoas major window was largest at L4–L5 level (1.27 ± 0.35 cm) followed by L3–L4 and L2–L3 level (1.19 ± 0.39 and 0.88 ± 0.38 cm respectively) (Table 1). On comparison between sexes using unpaired T test, males had larger values than females at each level which were statistically significant (P < 0.001) (Table 2). Differences between each level were found to be statistically significant using unpaired t test (P < 0.001) (Table 4).

**Psoas Major Window**

The psoas major window was largest at L4–L5 level (1.27 ± 0.35 cm) followed by L3–L4 and L2–L3 level (1.19 ± 0.39 and 0.88 ± 0.38 cm respectively) (Table 1). On comparison between sexes using unpaired T test, males had larger values than females at each level which were statistically significant (P < 0.001) (Table 2). Differences between each level were found to be statistically significant using unpaired t test (P < 0.001) (Table 4).

**Discussion**

The novel OLIF technique has become increasingly popular in view of its several advantages like minimal blood loss and tissue damage with preservation of posterior tension band, allows larger size cage placement with the adequate restoration of disc height and provides indirect decompression, achieves better correction of sagittal and coronal alignment, and has minimal risk of lumbar plexus injury [13]. However, there exists a paucity of high-quality literature regarding OLIF, although promising early results have demonstrated its feasibility [6]. As this relatively new technique involves
traversing through an unfamiliar anatomy, it has its own specific approach-related complications. The most common complication is postoperative numbness in the groin or anterior thigh and hip flexion weakness because of undue retraction of the psoas muscle and its associated sensory nerves. Other reported complications include ureter injury, vascular complications involving main vessels, segmental artery or iliolumbar vein, peritoneal injury, and abdominal ileus because of overzealous retroperitoneal space manipulation [14].

For widespread acceptance of any new technique, a thorough anatomical knowledge is required to assess its feasibility and facilitate improvement in surgical skills of the surgeons resulting in minimizing complications [7]. According to Liu et al., the anatomical measurements made in vivo have credibility and reliable resemblance to the human surgical state [9]. Prior morphometric studies have highlighted significant differences among the Indian and western population with regard to various spinal parameters [15, 16]. Therefore, we decided to evaluate morphometric data regarding the OLIF operative windows in the Indian population, as no prior study has documented it in the existing literature. We evaluated the OLIF parameters from L2–L3 to L4–L5 levels. The oblique access trajectory above L2 level may be affected by ribs or by blockage because of the left kidney and its accompanying vasculature. OLIF at L5–S1 level remains a challenge because of risks involved with mobilization of iliac vessels and the presence of iliac wing [11]. In view of these reasons, L1–L2 and L5–S1 levels were not included in the present study.

The bare window represents the unobstructed oblique corridor leading to the intervertebral disc between the aortiliac vessels and left psoas major [7]. On assessing mean bare window interval size of different lumbar levels, our result patterns were similar to prior studies that showed a progressive decrease in corridor size as we proceed from upper to lower lumbar levels [7, 10–12, 17]. The differences in bare window size among different levels in our study were statistically significant, as was reported by Molinares et al. in their study [10].

On comparison of our results with those of prior published studies concerning the western population, we found that our mean bare window measurement at each lumbar level from L2–L3 to L4–L5 level was smaller on comparison to theirs, which might be because of anatomical variations based on racial differences [10–12]. Prior MRI-based morphometric studies among the Asian population concerning OLIF technique by Chen et al. and Zhang et al. have also illustrated smaller bare window size in Chinese in comparison to the western population based on racial differences [7, 17]. With regard to sex differences concerning bare window interval size, our results were similar to those reported by Chen et al. [7]. Female had statistically significant larger bare window at L2–L3 to L4–L5 levels, whereas difference at L4–L5 level was not statistically significant. On analysing bare window at each level with regard to different age groups, the results showed statistically significant larger corridor size with increasing age at each level. Our result patterns are similar to those documented by Li et al., and they proposed atrophy of psoas muscle with increasing age resulting in widening of bare window interval as the reason for it [11]. The results of a study by Chen et al. also illustrated that psoas major width decreased at each level with increasing age because of age-related muscle degeneration [7].

The safety and feasibility of the OLIF technique depend on the presence of an adequate bare window interval. As per Ng et al. an absent bare window corridor would be a contradiction for the OLIF procedure [18]. Based on methodology

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Comparison of present study results with previous published studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Molinares et al. [10] study (x ± S, cm)</td>
</tr>
<tr>
<td>BW [Disc level]</td>
<td></td>
</tr>
<tr>
<td>L2–L3</td>
<td>1.60 ± 0.58</td>
</tr>
<tr>
<td>L3–L4</td>
<td>1.42 ± 0.57</td>
</tr>
<tr>
<td>L4–L5</td>
<td>1.03 ± 0.68</td>
</tr>
<tr>
<td>PM O</td>
<td></td>
</tr>
<tr>
<td>L2–L3</td>
<td>1.04 ± 0.42</td>
</tr>
<tr>
<td>L3–L4</td>
<td>1.34 ± 0.42</td>
</tr>
<tr>
<td>L4–L5</td>
<td>1.40 ± 0.39</td>
</tr>
<tr>
<td>PM P</td>
<td></td>
</tr>
<tr>
<td>L2–L3</td>
<td>1.34 ± 0.54</td>
</tr>
<tr>
<td>L3–L4</td>
<td>2.20 ± 0.74</td>
</tr>
<tr>
<td>L4–L5</td>
<td>3.37 ± 0.69</td>
</tr>
</tbody>
</table>

All values (x ± S, cm) are mean ± SD [cm]: BW Bare window; PM O Psoas major window; PM P Psoas major width
as per prior published studies, bare window interval was present in all our patients at L2–L3 and L3–L4 levels [7, 9]. Molinares et al. reported absent bare window in one case at L2–L3 level whereas Chen et al. reported absent bare window at both L2–L3 and L3–L4 levels in a single case [7, 10]. In our study at L4–L5 level which showed an overall narrower bare window, twenty-five cases (8.14%) had an absent interval similar to results of prior studies. Molinares et al. reported absent bare window in nine cases (9%) at L4–L5 level, whereas Chen et al. reported it in twenty-nine cases (7.25%) of their study [7, 10]. In a recent MRI-based study by Ng et al. regarding bare window interval at L4–L5 level, the authors proposed that 25.2 percent or approximately one-fourth of the adult patients do not have accessible oblique corridor at this level. This group of patients in their study either had an absent bare window or high rising psoas major as the reason for inaccessible bare window interval at L4–L5 level [18]. Prior study by Louie et al. based on MRI evaluation of psoas muscle morphology at L4–L5 level raised concerns regarding the presence of tear drop morphology synonymous with high rising psoas which may increase the risk of neurovascular injury during direct and oblique lateral lumbar spine approaches, and proposed for considering alternate approach in such cases [19]. Another recent MRI-based study by Wang et al. analysed the anatomical relationship between left psoas major and the aorta or left common iliac artery concerning OLIF working corridor and proposed a classification system for their assessment. They proposed that cases in whom location of the left psoas major and left common iliac artery at L4–L5 level lie in zone AL, OLIF should be avoided in view of the high risk of vascular injury.

The zone AL corresponded to the front tangential line for left psoas major lying in zone A as per Moro classification and left tangential line to left iliac artery lying lateral to left border of intervertebral disc [20, 21]. Based on our measurement method, we were unable to measure bare window interval in thirty cases (9.77%) at L4–L5 level in our study. The reasons responsible were similar to those proposed by prior studies: disturbed psoas anatomy (high rising psoas major) seen in nineteen cases (6.19%) or an abnormal laterally positioned iliac vessels present in eleven cases (3.58%). In total 17.9% of patients belonging to our study did not have accessible bare window interval at L4–L5 level.

On the basis of their study, Ng et al. have recently proposed a new grading system (grade 0–3) for the assessment of bare window interval size concerning OLIF approach. According to them, it will provide a better objective description of bare window size and help in assessing the feasibility of the OLIF approach. They suggested that grade 1 bare window size (≤ 1 cm) is not an absolute contraindication for OLIF technique but requires surgeon expertise in mobilizing psoas muscle for adequate disc space exposure and proper cage insertion [18]. We support their thought that surgeons who are beginning to attempt this technique should consider alternative approaches in such cases.

In our study population the mean bare window size was > 1 cm at L2–L3 and L3–L4 levels irrespective of age and sex. At L4–L5 level, the mean bare window was > 1 cm in > 60 year age group only, whereas < 1 cm in both 40–60 and < 40 year age groups.

The evaluation of psoas major window and psoas major width size have a role in assessing the ease or difficulty which a surgeon can face while retracting it during the OLIF procedure. The results of our study showed significant differences in psoas major width between each level, largest at L4–L5 level followed by L3–4 and L2–L3 level. On comparing sex differences, men had significantly wider psoas than women at each level. The existing studies by Chen et al. and Liu et al. also highlighted similar results pattern regarding psoas window and psoas major width size at each lumbar level [7, 9]. Following an overall comparative assessment of our study results with prior published studies in the existing literature, we thus propose regarding the feasibility of OLIF approach at L2–L3 and L3–L4 levels in the Indian population irrespective of age and gender. At L4–L5 level this technique may be better suited for the elderly Indian population. The results of present MRI-based morphometric study can be combined with future clinical based studies in the Indian population to further verify our results, which will be our further research goal.

The present study has its own limitations. There may be some element of error in measuring the anatomic parameters concerning the OLIF technique. Although we selected an overall large sample size for the present study, subcategory analysis regarding different age groups may be underpowered because of the smaller sample size concerning certain age groups within the study population. In our study, we did not evaluate parameters like height, weight or body mass index which may have an influence on the size of operative windows concerning the OLIF technique. The present study data was mainly of patients from northern India, which may not represent full spectrum of India’s ethnic diversity.

However, despite these limitations, this is the first morphometric study concerning this novel technique in the Indian population.

Conclusion

To the best of our knowledge, this is the first known anatomical study concerning novel OLIF technique in the Indian population. The OLIF technique is well suited for lumbar interbody fusion at L2–L3 and L3–L4 level in the Indian population irrespective of age and sex. At L4–L5 level, overall 17.9 percent of the study population were unsuitable for this technique due to inaccessible bare window. In our
opinion, this level may be better suited for OLIF approach in the elderly Indian population, especially for surgeons who are beginning to attempt this technique in their surgical practice. Preoperative MRI assessment for the OLIF is important to assess its feasibility, as there exists significant age and gender differences in the Indian population for anatomic parameters concerning OLIF operative windows from L2-L3 to L4-L5 levels.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s43465-021-00393-7.

Acknowledgements We thank Dr Preethi Selvaraj, MD, for her assistance with the statistical analysis of our data.

Funding Nil.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Approval of ethical committee at our institute was obtained prior to the study [Approval number: SU/SMS&R/76-A/2020/16].

Informed consent As it was a retrospective study, it was not possible to obtain informed consent. Image data which was used for the publication was anonymized. Hence the waiver for informed consent concerning the present retrospective study was taken from our institute ethical committee.

References


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Effect of Coronal Angulation of Sacral Vestibule S2 on Morphometric Analysis of Sacral Vestibule Using Plain Computed Tomography in North-West Indian Population

Tarun Kumar · Narinder Singh

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Abstract
Background The present study was aimed to study and develop in-depth understanding of the effect of the coronal angulation of sacral vestibule S2 on morphometry of sacral vestibule in north-west Indian population presenting to our institution, which will go a long way in planning to treat the posterior pelvic injuries with percutaneous screws, thereby reducing the morbidity associated with open fixation.

Methods This study was conducted in the Department of Orthopaedics and Radiodiagnosis at Dr Rajendra Prasad Govt. Medical College, Kangra at Tanda over a period of one year. All the patients of the age > 18 years and above submitting for either abdominal, lower spinal or non-orthopedic pathology of pelvic region, presenting for computed tomography to the Department of Radiodiagnosis were included in the study.

Results The coronal angulation of S2 vestibule ranged from 1° to 10° with a mean of 5.06° ± 2.77°. There was a weak relation between coronal angulation of S2 and age-groups 18–30 years \( (r = 0.105; P = 0.186) \), 31–40 years \( (r = 0.040; P = 0.715) \), 41–50 years \( (r = -0.085; P = 0.330) \), 51–60 years \( (r = 0.119; P = 0.079) \), and > 60 years \( (r = -0.166; P = 0.605) \). There was a non-significant difference in coronal angulation of S2 \( (P = 0.913) \) between males and females. There was a weak relation between interspinus distance with coronal angulation of S2 \( (r = 0.069; P = 0.090) \). There was no relation between height with coronal angulation of S2 \( (P = 0.019; P = 0.631) \).

Conclusion The present study, the first of its kind in the north-western part of India arrived to help us anthropometric measurements of sacral vestibule, thereby, helping in development of local protocols for percutaneous fixation in sacral fracture.

Keywords Sacral vestibule · Coronal angulation of the vestibule · Interspinous distance

Introduction

The sacral bone is an inverted triangle that sits obliquely between the two innominate bones of the pelvis at the distal aspect of the spinal column. It functions mechanically to convey axial load from the lumbar spine into the lower extremities for balanced locomotion. The ventral sacral body is concave and derived from five vertebrae. The transverse processes of the sacral vertebrae coalesce to form the sacral ala, which projects laterally from the upper sacral promontory [1].

The standard treatment of unstable sacral fractures is surgical fixation due to a high incidence of residual morbidity under conservative treatment. The primary goal is anatomic reduction, followed by a rigid fracture fixation. There are several operating techniques like fixation with iliosacral screws or plates, triangular osteosynthesis, ilioiliac (plates, internal fixators, and bars) and trans-sacral screws or bars. In recent years, sacroiliac screws and spinopelvic internal fixators have become the preferred implants for fixation of posterior pelvic ring fractures. Whereas full weight bearing is allowed for most spinopelvic fixations, none or partial weight bearing is recommended for iliosacral screw fixations [2].

The present study was aimed to study and develop in-depth understanding of the morphometry of sacral vestibule in north-west Indian population presenting to our institution, which will go a long way in planning to treat the posterior...
pelvic injuries with percutaneous screws, thereby reducing
the morbidity associated with open fixation.

**Materials and Methods**

This study was conducted in the Department of Orthopaedics and Radiodiagnosis at Dr Rajendra Prasad Govt. Medical College, Kangra at Tanda over a period of one year. All the patients of the age > 18 years and above submitting for either abdominal, lower spinal or non-orthopedic pathology of pelvic region, presenting for computed tomography to the Department of Radiodiagnosis were included in the study. The patients were informed about the aims and methods of the study and once consent was given for participation; they were evaluated. The evaluation included clinical assessment for height. This helped to draw comparison while arriving at morphometry of sacral vestibule.

The following patients were excluded from the study.

1. Age < 18 years.
2. The patient with pelvic ring dysmorphism.
3. Osteolytic pelvic lesions.
4. Fractures involving the posterior elements.
5. Post-operated cases of above fracture
6. Not willing to participate in the study
7. Implants obscuring the lumbosacral junction.

Each patient and his attendants were adequately informed about the aims, methods, the anticipated benefits and potential risks of the study and the discomfort it might entail them and the remedies thereof. Every precaution was taken to respect the privacy of the patient, the confidentiality of the patient’s information and to minimize the impact of the study on his/her physical and mental integrity and personality. The patients were given the right to abstain from participation in the study or to withdraw consent to participate at any time of the study without reprisal. Due care and caution were taken at all stages of the research to ensure that the patient was put to minimum risk, suffer from no irreversible adverse effects and generally, benefit from and by the research. Written informed consent was obtained from all the patients and attendants included in the study.

The subjects included in this study followed the protocol generally used by the Department of Radiodiagnosis for the conditions mentioned above. The subjects were placed in the supine position with fully extended knee joint with patella facing the sky for CT examination. 3D volume reconstruction of surface anatomy of bony pelvis was then performed using available CT data.

All the sacra were scanned for anteroposterior tomogram. All angles were measured at the CT workstation. Measurements of the angles were performed by a junior resident (the investigator) from the Department of Orthopaedics Dr. RPGMC Tanda and were supervised by consulting orthopedician and radiologist.

Following parameters were noted in each patient according to the sex of the patient:

- Age of the patient
- Sex of the patient
- Coronal angulation of vestibule S2
- Interspinus distance
- Height of the patient

**Statistical Analyses**

Data were presented as frequency, percentages, and median (inter-quartile range; IQR). Difference between quantitative variables was compared using Mann–Whitney U test. Spearman correlation coefficient was used to find the relation between two variables. *P* value < 0.05 was considered significant. Statistical analyses were performed using SPSS v20.

**Coronal Angulation**

A coronal angulation was calculated as the angle subtended by a line drawn perpendicular to the axis of the osseous corridor and a line connecting the top of the iliac crests. The axis of coronal CT reformats was reset so that the axis was perpendicular to the superior end plate of the first sacral segment. Reformats were then made perpendicular to the second sacral osseous corridor. It was measured in degrees.

**Coronal Angulation**

<table>
<thead>
<tr>
<th></th>
<th>S2</th>
</tr>
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<tbody>
<tr>
<td>Minimum</td>
<td>1°</td>
</tr>
<tr>
<td>Maximum</td>
<td>10°</td>
</tr>
<tr>
<td>Mean</td>
<td>5.06° ± 2.77°</td>
</tr>
<tr>
<td>Median</td>
<td>5</td>
</tr>
<tr>
<td>IQR</td>
<td>3</td>
</tr>
</tbody>
</table>

The coronal angulation S2 ranged from 1° to 10° with a mean of 5.06° ± 2.77°, respectively.

**Relation with age** (Comparative analysis of coronal angulation of S2).
There was a significant difference in coronal angulation between age-groups 18–30 and 51–60 years (4.66 ± 1.89 vs. 5.38 ± 3.09; \( P = 0.010 \)), and between age-groups 18–30 and > 60 years (4.66 ± 1.89 vs. 7.17 ± 1.90; \( P = 0.000 \)), and between age-groups 31–40 and 51–60 years (5.16 ± 2.90 vs. 5.38 ± 3.09; \( P = 0.037 \)), and between age-groups 31–40 and > 60 years (5.16 ± 2.90 vs. 7.17 ± 1.90; \( P = 0.020 \)), and between age-groups 41–50 and > 60 years (5.38 ± 2.90 vs. 7.17 ± 1.90; \( P = 0.049 \)).

There was a weak relation between interspinus distance with coronal angulation of S2 (\( r = 0.069; P = 0.090 \)).

**Relation with Age**

<table>
<thead>
<tr>
<th>Age-group</th>
<th>Mean ± SD</th>
<th>Min–max</th>
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</thead>
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<tr>
<td>S2</td>
<td>4.66 ± 1.89</td>
<td>1–8</td>
<td>0.738; 0.080</td>
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<tr>
<td>31–40</td>
<td>4.56 ± 2.99</td>
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<td>41–50</td>
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</tr>
<tr>
<td>51–60</td>
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<td>1–10</td>
<td>0.020; 0.049</td>
</tr>
<tr>
<td>&gt; 60</td>
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<td>5–10</td>
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**Relation with Sex**

<table>
<thead>
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<th>Female</th>
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<tbody>
<tr>
<td>S2</td>
<td>5.08 ± 2.81</td>
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<tr>
<td>IQR</td>
<td>6.0</td>
<td>5.0</td>
<td></td>
</tr>
</tbody>
</table>

There was no significant difference in coronal angulation of S2 (\( P = 0.913 \)) between males and females.

**Relation with Interspinus Distance**

The sacral vestibule refers to the three-dimensional (3D) screw space that is available in the narrowest part of the iliosacral screw channel. The sacral vestibule concept has been proposed by Carlson et al. which is described as the three-dimensional screw space available in the narrowest part of iliosacral screw channel. It has two components S1 and S2. The S2 being smaller and associated with increased risk of spinal canal injury. Anteroposteriorly, the vestibule is dumbbell shaped, but it is elliptical on the lateral view [3]. The present study was aimed to morphometrically analyze sacral vestibule using CT at Department of Orthopaedics, Dr RPGMC Kangra at Tanda. A total of 610 patients were included in the study. The present study was aimed to study the effect of coronal angulation of the sacral vestibule S2 on morphometric analysis of sacral vestibule using plain computed tomography.

The coronal angulation of S2 vestibule ranged from 1° to 10° with a mean of 5.06° ± 2.77°. There was a weak relation between coronal angulation of S2 and age-groups 18–30 years (\( r = 0.105; P = 0.186 \)), 31–40 years (\( r = 0.040; P = 0.715 \)), 41–50 years (\( r = -0.085; P = 0.330 \)), 51–60 years (\( r = 0.119; P = 0.079 \)), and > 60 years (\( r = -0.166; P = 0.605 \)). There was non-significant difference in coronal angulation of S2 (\( P = 0.913 \)) between males and females. There was a weak relation between interspinus distance with coronal angulation of S2 (\( r = 0.069; P = 0.090 \)). There was no relation between height with coronal angulation of S2 (\( r = 0.019; P = 0.631 \)).

The proper location and length to insert iliosacral screws are parallel to the long diameter with the inclination angle of the vestibule; therefore, these both parameters are very important references for the operation. Due to smaller size in these parameters, the insertion location, direction of the
screw, and the position relationships between the screws are particularly limited for female patients [4]. Sacral variations are common in Indian population; however, these parameters are higher than Chinese populations [5].

Kaiser et al. measurements showed that coronal angulation of S2 vestibule was $5.2^\circ \pm 4.9^\circ$. Our results are in concordance with Kaiser et al. [6]. We observed that after age of 60 years, coronal angulation decreases significantly with age. The above-mentioned results were comparable to our study. Therefore, the placement of iliosacral screws should be considered carefully based on the size, gender, height and ethnicity of the patient.

**Conclusion**

The present study, the first of its kind in north-western part of India arrived to help us in anthropometric measurements of sacral vestibule S2, thereby helping in the development of local protocols for percutaneous fixation in sacral fracture.

**Compliance with Ethical Standards**

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical standard statement** This article does not contain any studies with human or animal subjects performed by the any of the authors.

**Informed consent** For this type of study informed consent is not required.

**References**


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Proposal for a New Fixation Method for Pauwels Type III Femoral Neck Fracture-Metaphyseal Stem: A Finite-Element Analysis

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Abstract
Objective To evaluate the biomechanical behavior of a metaphyseal stem specifically designed for the fixation of Pauwels type-III femoral neck fractures using finite-element analysis.

Methods Three different constructions were studied: the dynamic hip screw with a superior anti-rotation screw (DHS + ARS), multiple cannulated screws in an inverted triangle configuration (ASNIS), and the Metaphyseal Nailing System (MNS), a new implant developed by the authors. Vertical and total displacement, localized and total maximum and minimum principal, and the Von Mises peak stresses were evaluated.

Results Results are shown for the DHS + ARS, ASNIS, and MNS models, respectively. Vertical displacement (mm) was 1.49, 3.63, and 1.90; total displacement (mm) was: 5.33, 6.02, and 6.30; localized maximum principal (Mpa) was: 2.77, 4.5, and 1.7; Total maximum principal (Mpa) was: 126, 223, and 531; localized minimum principal (Mpa) was: −1.8, −3.15, and −0.39; total minimum (Mpa) was: −121, −449, and −245; and Von Mises peak stress (MPA) was: 315.5, 326.1, and 286.0.

Conclusion The present FEM study showed that the MNS device increases general stresses and reduces localized stresses, when compared to the DHS + ARS and ASNIS constructions used to fix Pauwels type-III femoral neck fracture in synthetic models. In this sense, the MNS showed a low fracture focus shift, conducive to the consolidation environment. The significant reduction in the maximum principal stress, allows to affirm that the main deforming force, the shear, in this fracture pattern, was considerably reduced and the low value of Von Mises obtained, consistent with an implant capable of making an effective load sharing.

Keywords Femoral neck fracture · Internal fixation · Intramedullary fixation · Finite-element analysis

Introduction

Femoral neck fracture in young adult is usually the result of high-energy trauma [1]. The treatment in this population aims at anatomical reduction and stable internal fixation [2]. The degree of fracture displacement and the quality of reduction are important factors for a satisfactory final outcome [3]. Pauwels type-III fractures (equal to or greater than 70 degrees of fracture line inclination) are subjected to greater shearing forces [4], resulting in enormous challenges in terms of fixation, stabilization, and consolidation [5].

Epidemiological studies show that up to 59% and between 11 and 86% of these fractures do not unite and present head necrosis, respectively [4]. An important meta-analysis showed implant failures in about 10% of cases in young patients [6]. The difficulty to reduce the fracture and to
adequately position the implants are challenging, even for most experienced surgeons [7, 8]. The repair must withstand shearing forces inherent in the vertical pattern to the greatest extent possible [7]. In this scenario, the search for effective internal fixation constructions has become the focus of scientific research over the past years.

Currently, dynamic hip screw (DHS) and multiple cannulated screws, either combined or not with a buttress plate, are the most widely used and studied [5, 8–13] techniques. However, to the best of our knowledge, there are very few studies on intramedullary implants (InI), even though InI have been shown to be biomechanically superior to extramedullary implants (EI) [9–11]. In a recent study, it was shown that intramedullary fixation with cannulated screws has advantages in treating complicated femoral neck fractures [14].

In this study, we used the Finite-Element Method (FEM) to determine the biomechanical behavior of three different constructions used to stabilize a Pauwels type-III fracture, the Dynamic Hip Screw with anti-rotation screw (DHS + ARS), multiple cannulated screws in an inverted triangle formation (ASNIS), and the Metaphyseal Nailing System (MNS), a new implant developed by the authors.

**Materials and Methods**

For conducting the analyses, tomographic images of a fourth generation, 10 PCF (Pound per Cubic Feet) medium-sized left Sawbone® synthetic femur model, 3403-106 (Sawbone USA, a Pacific Research Company, Washington, USA) were used.

The tomographic images were obtained and archived in DICOM (digital imaging and communications in medicine) format. The tomograph used was the Emotion (Siemens™, Munich, Germany) at a 512 x 512 resolution and cuts 1.0 mm apart were taken. The DICOM file was imported into the InVesalius™ program for assembling a 3D anatomical structure that, using the standard triangle language (STL) format, allowed the construction of biocads (Fig. 1).

The preparation of the three-dimensional (3D) virtual models of each system (bone, synthesis) was performed using the Rhinoceros™ software (Robert McNeel & Associates, USA) and the FEM analysis was performed in the SimLab™ software (HyperWorks, USA) using the Optistic solver, running on a computer powered by Intel Xeon CPU E-3–1240 V3 3.40 GHz, with 32 GB RAM in a 64-bit Windows 7 operating system.

After building the model (biocads), a cut (osteotomy) was made at the middle third of the femoral neck at an angle of 70° to the ground, thus establishing a femoral neck fracture characteristic of a Pauwels Type III fracture (Fig. 1).

The 135 deg dynamic hip screw (DHS) and the 7.0 mm cannulated screw models were built observing all dimension parameters for each follow-up of the structures, similar to that of the DePuy Synthes manufacturer (DePuy-Synthes–J & J Company, Paoli, USA) and the tested models were named according to the syntheses used: DHS + ARS, ASNIS, and MNS (Fig. 2).

The MNS model design consisted of a stem and five screws (three for locking the implant in the metaphyseal bone and two for fixation of the femoral neck). The stem was modeled 13.0-mm wide and 46.88-mm long in the form of a hollow cylinder (cannulated with 5.0-mm in diameter), which allowed the introduction of a 4.5-mm locking screw into the distal end of the stem through its interior, providing the distal locking of the stem in the femur. There are also two additional locking screws located in the proximal region of the stem with the same diameter. All locking screws of the model are identified by the purple color. Fixation screws are placed between the locking screws and allow the fixation of the fracture, the most cephalic one (in red) having 5.0-mm in diameter and the most caudal one, 10.0-mm in diameter (in orange) (Fig. 3). The angle between the neck shaft and the cephalic fixation screws is 90 degrees apart.

To perform the simulations, we defined the properties of the materials, Elastic Modulus, and Poisson’s ratio of each of the parts of the digital models, namely: cortical bone, trabecular bone, and alloy steel, the latter being an alloy common to all metal models of this test (Table 1). The alloy steel L16 was used.

After performing the mesh control of each part, to ensure the perfect contact between the different structures, application regions of the loads onto the Z, X, and Y axes were selected, where 6000 N were applied to the Z axis, which would correspond to a load greater than one 100 kg person in monopodal support. No loading was applied onto the X and Y axes. Subsequently, regions of movement restriction (fixations) were established, marked in all directions of X, Y, and Z axes to ensure the system’s stability. The element...
adopted for mesh formation was Tetrahedral and the models were tested positioned at 20° of inclination to the Z axis (adduction) with the loading being applied perpendicular to the ground in the upper region of the femoral head. (Fig. 4).
Data were collected regarding dislocations and stresses using FEM, namely: localized displacement (\(D_{loc}\)) (Fig. 5a) of fracture and total displacement (\(D_{tot}\)) in millimeter (mm) of the entire model. Localized (Loc) maximum (Max) and minimum (min) principal were evaluated in the region adjacent to the fracture trace, and the Max Loc was evaluated in the upper region of the femoral neck and the Min Loc in the lower region of this same region (Fig. 5b, c). Such analyses took place in these regions, respectively, since in the upper region of the neck, it is the site of action of the traction force. Otherwise, the lower region of the neck is the site of greatest compressive strength. Finally, the Max and Min total (Max tot and Min tot) were measured in Mega pascal (Mpa). The equivalent Von Mises peak stress (Mpa) was measured for the synthesis material of the models. Such data are important for: 1. assessing whether the value of displacement would provide an environment capable of providing consolidation; 2. with the analysis of the deforming forces, mainly the shear force (through the evaluation of the maximum principal), will we be able to identify the behavior of the load on the fracture; 3. assess the capacity of the implant to perform load sharing, using the result of Von Mises.

Results of displacements, principals, and Von Mises stresses were presented in absolute values and comparative percentile.

Results

Results are shown for the DHS + ARS, ASNIS, and MNS models, respectively (Table 2).

\[\begin{array}{|c|c|c|}
\hline
\text{Material} & \text{Elastic modulus (Mpa)} & \text{Poisson’s ratio (\(v\))} \\
\hline
\text{Cortical bone} & 17 & 0.26 \\
\text{Trabecular bone} & 1.7 & 0.26 \\
\text{Syntheses (steel)} & 193 & 0.33 \\
\hline
\end{array}\]

\[\text{D locs} \text{ obtained were 1.49 mm, 3.63 mm, and 1.90 mm.}\]
\[\text{D tots were 5.33 mm, 6.02 mm, and 6.30 mm.} \]
\[\text{It was demonstrated that the use of the MNS device caused an increase in D loc of 0.41 mm (27%) when compared to the DHS + ARS device and a reduction of 1.73 mm (47%) when compared to ASNIS. D tot was 0.97 mm (18%) and 0.28 mm (4%) higher than DHS + ARS and ASNIS, respectively.}\]
\[\text{Max Loc values were 2.77 Mpa, 4.5 Mpa and 1.7 Mpa.}\]
\[\text{Max Tots were 126 Mpa, 223 Mpa, and 531 Mpa for DHS + ARS, ASNIS, and MNS models, respectively.}\]
\[\text{It was possible to observe that the MNS device caused a reduction in Max Loc of 1.07 Mpa (38%) and 2.8 Mpa (62%) and an increase in Max Tot of 405 Mpa (76%) and 308 Mpa (58%), when compared to DHS + ARS and ASNIS, respectively.}\]
\[\text{Min Loc values were } -1.8 \text{ Mpa, } -3.15 \text{ Mpa, and } -0.39 \text{ Mpa, and those for Min Tots were } -121 \text{ Mpa, } -449 \text{ Mpa}\]
\[\text{and } -245 \text{ Mpa for the DHS + ARS, ASNIS, and MNS models, respectively.}\]
\[\text{Thus, a reduction of 1.41 Mpa (27%) and 2.76 Mpa (87%) in MNS Min Loc was observed when compared to DHS + ARS and ASNIS, respectively.}\]
\[\text{Regarding MNS Min tot, an increase of 124 Mpa (50%) was observed when compared to DHS + ARS and reduction of 204 Mpa (45%) when compared to ASNIS.}\]
\[\text{Maximum Von Mises peak stress values were 315.5 Mpa, 326.1 Mpa, and 286.0 Mpa for the DHS + ARS, ASNIS, and MNS models, respectively.}\]
\[\text{We thus observed a reduction of 29.5 Mpa (9%) and 40.1 Mpa (12%) of the values from MNS to DHS + ARS and ASNIS, respectively (Fig. 6).}\]

Discussion

InI allow fracture treatment by minimally invasive means, being thus considered more biological systems, preserving the vascularization of the site, besides having biomechanical advantages when compared to the EI [15].

In the treatment of traumatological pathologies of the proximal femur, the benefits of InI were confirmed as a routine indication for unstable intertrochanteric fractures over time, reducing the rate of complications and the need for re-operations [16]. Studies of the use of InI, conventionally used in proximal femoral fractures have a failure rate of 38.4%, which shows the importance of developing specific intramedullary implant designs for this pathology [17].
InI models used in proximal femoral fractures have several designs, but all of them need to be introduced into the femoral canal and have pre-determined attachment angles. These two aggregate factors may make it difficult for the surgeon to better position his fixation on the femoral head, a factor already confirmed in the literature as a determinant in the best surgical evolution of this pathology. Because it is short, the MNS does not invade the femoral diaphysis, being restricted only to the metaphyseal region of the proximal femur. For this reason, it allows prioritizing positioning and angulation, made by means of external guides, guidewires, and radioscopic control. The use of guide wires and external guides, prior to the introduction of the nail, allows it to be fixed in the medial cortex of the femur in various positions, with priority being given to the one that best allows the introduction of the cephalad screw in an optimized position. This contributes to the better positioning of the screws of the neck and the femoral head.

The literature shows an InI model that is indicated for the treatment of femoral neck fractures, as it has a compression...
However, its design differs little from conventional nails on the proximal end of the femur [18]. To optimize the results in terms of fracture stability and biomechanical aspects, the authors of the present study highlight some observations, which led them to develop the MNS. The shortest distance from the fracture line to the MNS complex (smaller moment arm) optimizes the implant’s biomechanics and generates greater fracture stability. The intramedullary stem acts in a buttress mechanism (as a tutor) avoiding proximal migration and allows angular stability of the sliding screws (cephalic screws). In addition, it allows for an adequate entry point on the lateral aspect of the greater trochanter, thus reducing the risk of inadvertent femoral canal reaming. The InI used to treat proximal fractures of the femur, when they fail, have their greatest point of weakness in the region of the entrance of the cephalic screw [19]. We can observe that, at the location of the insertion of the screws, the MNS has 1.5 mm of stem wall. This can be a critical point of the proposed innovation. The results observed did not show tensions located in the area of screw insertion towards the femoral neck (Fig. 6c). The authors believe that this behavior occurred due to the presence of two locking screws in the proximal region of the nail. This presence of two screws and their dimensions (in the proximal region of the MNS) is a factor that needs further studies. Studies that explore the values of different dimensions may demonstrate the need for smaller diameters, or a smaller number of screws, without interference in the resistance.

Observing the results obtained with the MNS model, it is possible to affirm that the increase of total stresses (Max and Min Tot), with reduction of localized stresses (Max and Min loc) and lower Von Mises value, when compared to the DHS + ARS and ASNIS constructions used to fix Pauwels type-III femoral neck fracture in synthetic models. In this sense, the MNS showed a low fracture focus shift, conducive to the consolidation environment. The significant reduction in the maximum principal stress allows to affirm that the main deforming force, the shear, in this fracture pattern, was considerably reduced and the low value of Von Mises obtained, consistent with an implant capable of making an effective load sharing.

**Conclusion**

The present FEM study showed that the MNS device increases general stresses and reduces localized stresses when compared to the DHS + ARS and ASNIS constructions used to fix Pauwels type-III femoral neck fracture in synthetic models. In this sense, the MNS showed a low fracture focus shift, conducive to the consolidation environment. The significant reduction in the maximum principal stress allows to affirm that the main deforming force, the shear, in this fracture pattern, was considerably reduced and the low value of Von Mises obtained, consistent with an implant capable of making an effective load sharing.

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**Declarations**

**Conflict of Interest** The authors declare that they have no conflict of interest.
**Ethical Standard Statement**  This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent**  For this type of study, informed consent is not required.

**References**


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Novel Design of Minimal Incision Double Oblique Device for Osteosynthesis (DODO) of Hip: Results of an In-silico Study Based on the Femur Morphometrics of the Northeast (NE) Indian population

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Abstract

**Background** Hip fractures account for a large proportion of hospitalization among the trauma cases. Low cost, simple technique, easy removal, and high rate of the bone union makes extramedullary (EM) fixation techniques a preferred choice. A close-fit bone and plate are essential for the success of such implantation. Various studies have found femur morphometry being related to regional features and social differences. Most of the available commercial implants are developed based on the data of the Caucasian population.

**Methods** In the herein study, a novel design, Double Oblique Device for Osteosynthesis of hip (DODO), is proposed while considering the regional morphometry of the Northeast (NE) population of India. This study employs finite element (FE) analysis to compare the biomechanical outcome of the new device with that of proximal femoral locking plate (PFLP) and variable angle dynamic hip screw (VA-DHS) on a femur having an Evans type-I intertrochanteric fracture.

**Results** The stress shielding was substantially high for the PFLP and VA-DHS in the distal bone fragment (lateral aspect) and for DODO in the femoral head. The difference in axial displacement between the post-implanted DODO-fixed femur and its respective intact femur was predicted to be almost the same as that of PFLP-fixed femur and its respective intact femur.

**Conclusion** The computational results found the new device to be a viable alternative to the conventional plating techniques, especially for the NE population of India, and predicted better to comparable biomechanical characteristics.

**Keywords** Extracapsular hip fracture · Finite element analysis · Osteosynthesis · Oblique screw orientation · Stress shielding

Introduction

The aging of the world population due to the rise in life expectancy has resulted in increased incidences of hip fracture, especially in the geriatric population. The continuously growing number of motor vehicle accidents in the present age of globalisation has equally contributed to the trauma cases of proximal femoral fractures in younger adults. Intertrochanteric femoral fracture, most notably, accounts for up to 50% of all such fractures [1]. These fractures are commonly associated with a significant rate of morbidity and mortality [2]. Intertrochanteric fractures involve the upper end of the femur between the greater and lesser trochanter with or without extension in the upper femoral shaft. This kind of fracture is classified as either stable or unstable intertrochanteric fracture. The primary aim of treatment usually comprises stable fixation and early weight-bearing. It may be noted that early weight-bearing helps in reducing the morbidity and mortality of the patients.

Operative intervention generally includes intramedullary (IM) (e.g., Proximal femoral nail anti-rotation (PFNA); Proximal femoral nails (PFN); Intramedullary hip screw (IMH); Gamma nail (GN); InterTan nail (TN)) or extramedullary (EM) fixation techniques (e.g. Proximal femoral locking plate (PFLP); Dynamic hip screw (DHS); Compression hip screw (CHS)). IM fixations are extensively used by clinicians all over, given their less operating time,
less blood loss, reduced hospital stay, small incisions, and better biomechanical strength [3, 4]. However, certain disadvantages associated with IM fixations include iatrogenic comminution, technical difficulties in the insertion of the nail, particularly in an obese and highly muscular patient or in femurs with an excessive bow, and difficulty in removal of the nail after fracture healing due to bone formation into the medullary canal [5, 6]. Also, there is a high rate of general complications in case of prolonged overall recovery time [7]. The overall failure rate for such fixations is reported to be around 3–16.5% [8, 9]. Moreover, IM devices are significantly costlier implants than the DHS, with almost similar outcomes [3]. Radiation exposure was also found to be higher in the case of IM fixation as compared to EM fixations [10]. In recent times, the use of EM plating techniques is being advocated owing to the advent of some new-age plating techniques [11]. The EM techniques do not intervene largely inside the structure of the femur and keep the bone anatomy intact (reserved) and support total bone healing (osteosynthesis) at the fracture location. Though complicated in implantation, plating techniques are beneficial in long-term results, especially where the bone anatomy of the patient needs to be retrieved through osteosynthesis.

Generally, it is observed, the success of such implants, by and large, relies on the ethnic, demographic and morphometric variations. Data obtained from the morphometric study of the proximal femur demonstrated that femoral morphometry had regional features and social differences [12, 13]. Proximal femoral geometry is determined by genetic and environmental factors, e.g., age, race, sex, and lifestyle [14, 15]. Tribes of Northeast (NE) India belong to the Mongoloids, characterised by short and wide face, broad nose, projecting cheek bones and relatively shorter stature [16]. In contrast, the Caucasoids are characterised by a long head, high forehead, long and narrow nose and taller stature than mongoloids. It is a longstanding belief among the Indian and Asia–Pacific arthroplasty surgeons that the currently available prosthetic components do not meet the requirements of these anthropometrically smaller ethnic groups [17]. Most of the commercially available implants in the market are developed based on the data of the Caucasian population of the western countries, and thus they may not be an ideal fit for Indian patients due to anatomic variations. Siwach et al. [18] suggested the use of modified implants according to Indian anthropometry to lessen the incidences of intraoperative complications like fractures and splintering. Few other complications owing to such geometric and morphometric mismatch include aseptic loosening, improper load distribution and discomfort leading to long-term surgical failure [19, 20]. Agarwala et al. [17] revealed in their study that there exist significant differences in anthropometric parameters of hip joints among the population of southern Assam (NE, India) when compared to that of the western population. Pushparthna et al. [21] also observed that femoral length is proportional to the average height of a race. To achieve an optimum surgical outcome, the geometry of the implant, therefore, ideally should match closely with that of the femora of the local population.

Metallic implants have considerably higher modulus and consequently bears a bulk amount of the physiological load. Stress shielding is a direct fallout of such discrepancy of load sharing between implant and bone, resulting in the bone being deprived of the essential mechanical stimulus required for its maintenance [22, 23]. Larger-sized implants, typically designed for Caucasian patients, have higher structural stiffness, which may further aggravate the adverse effect of implant-induced stress shielding, especially on smaller bones of the NE population. Therefore, it is crucial to design an implant through which adequate loads can be transferred to the bone such that the effect of stress shielding can be reduced considerably.

Although a significant number of experiments and computational studies assessing modifications of intramedullary fixations can be found in the literature [19, 24], very few have focussed on the lengths of the side plates [1, 25–27]. To the best of the author’s knowledge, there is no study that has incorporated inclined screw orientation with shorter side plates considering regional morphometry, in addition to an anti-rotation screw. The primary objective of the study is to biomechanically compare a new device for hip osteosynthesis to that of conventional commercially available implants, e.g., PFLP and DHS, using finite element (FE) analysis. The new design, to be called henceforward as Double Oblique Device for Osteosynthesis of hip (DODO), features a shorter side plate to address the anthropometric requirement of the NE population while increasing the screw pull-out strength to prevent plate lift-off. We hypothesized that the new design is biomechanically comparable, if not superior, to the commercial designs of EM fixation devices typically used to treat Evans type-I intertrochanteric femur fractures.

**Materials and Methods**

**3D Model Generation of the Implanted Femur**

Two large-sized 4th-generation Sawbones femurs (Sawbones, Europe AB, Malmo, Sweden, model# 3406), which have the characteristics of real cadaveric femur, were procured and prepared as two-part intertrochanteric fracture, clinically known as Evans type-I, and subsequently fixated with a PFLP (thickness: 6 mm, Sharma Orthopaedics, India) and a Variable Angle DHS (VA-DHS) plate (thickness: 5.8 mm, Kaushik Implants, India) by an experienced orthopaedic registrar (one of the co-authors). The 3D FE model of the PFLP and VA-DHS implanted femur was generated.
from Computed Tomography (CT) scan dataset (512 × 512 pixels with a pixel spacing of 0.64 mm) of the PFLP, and VA-DHS fixated femur specimen, using the medical image processing program, Simpleware™ (Synopsys Inc., Mountain view, USA). The FE model corresponding to DODO was generated using the manufacturer supplied CAD model of the left femur. Based on a formula that femur length is a quarter of the total height of the human body, the femur length of the CAD model was scaled down to 37 cm, taking into consideration the short height of the NE population of India [28, 29] as opposed to the 48.5 cm Sawbones model for the large femur (Fig. 1). The 3D scaling down ensured proportional scaling down of all the parameters in the entire femur model. An intertrochanteric fracture, simulated as a two-part fracture with a gap of 10 mm, was created, mimicking the fracture of the PFLP fixated femur (Fig. 2b). The DODO was modelled and virtually implanted in the CAD femur in the NURBS modelling environment of Rhinoceros v14.0 (Rhinoceros, Robert McNeel & Associates, Seattle, USA) (Fig. 2a). A total of four screws were fixed virtually: one proximal locking (cancellous screw) and three distal dynamic (cortical screws). The distal dynamic screws were assumed to be in contact with bone having a coefficient of friction set as 0.3. The distal-most screw was obliquely oriented at an angle of 50°. Additionally, one anti-rotation screw was attached proximally at the top of the locking screw for enhanced stability. Full specifications of the DODO, PFLP, and VA-DHS implants are mentioned in Table 1.

**FE Modelling of the Intact and Implanted Femur**

The 3D models (Fig. 3) were then imported into Ansys ICEM CFD v15.0 (ANSYS Inc., PA, USA) to generate a volumetric mesh comprising 4-noded unstructured tetrahedral elements. After that, the volumetric mesh was imported into Ansys Mechanical v15.0 (ANSYS Inc., PA, USA) and converted into the 10-noded tetrahedral mesh for better accuracy and further analysis (Fig. 4). The meshing parameters were carried forward from the authors’ earlier work on similar bone [30]. The total number of elements for the DODO, PFLP, and VA-DHS fixated femur were 470,183, 716,742 and 783,070, respectively. Tip Apex Distance (TAD) was kept below 25 mm while fixating and designing both the implants to prevent screw cut out [31]. A static load of 1.5 kN and 2 kN was applied vertically downward through the femoral head of the 37 cm and 48.5 cm bone, respectively (Fig. 4). A condition of zero displacement was applied at distal femoral nodes sufficiently away from the point of application of load. The reason for giving different maximum static load was that DODO femur should describe physiological loading of native NE population of India having low body weight (60 kg in avg.), whereas PFLP and VA-DHS fixated large femur are meant to describe the loading condition of Caucasian patients having higher body weight (80 kg in avg.).

**Material Properties**

The material model for bone and implant was considered as per Table 2. Linear elastic, isotropic, and homogeneous
material properties were applied to the cancellous bone, whereas orthotropic material properties were applied to the cortical bone based on the data provided by the manufacturer [32]. The materials for plate and screw were considered to be titanium (Ti) alloy (Young’s Modulus, \(E = 110 \text{ GPa}\)). Poisson’s ratio was set as 0.3 for all materials. All interfaces between bone and plate were assumed to be bonded under all conditions.

### Results

Figure 5 illustrates the von Mises stress distribution in the femur cortex for both intact and implanted cases. The average von Mises stress at the calcar region of the NE femur (37 cm long femur) for the DODO implant was found to be \(\sim 11.0 \text{ MPa}\), and that in the femoral shaft was \(\sim 18.0 \text{ MPa}\). The corresponding average stress values in the intact NE femur was found to be \(\sim 16.0 \text{ MPa}\). No significant difference was noted in von Mises stresses for identical calcar sites for PFLP and VA-DHS-implanted Caucasian femur (48.5 cm long femur), clocking average values of \(\sim 13.0 \text{ MPa}\) and \(\sim 18.6 \text{ MPa}\), respectively. For the femoral shaft, the respective average stress values were \(\sim 10.0 \text{ MPa}\) and \(\sim 14.2 \text{ MPa}\). The predicted average von Mises stress for the corresponding 48.5 cm intact femur was 15.0 MPa. In the case of DODO, maximum stress was found to be in the first point of intersection between the lateral plate and proximal locking screw (Fig. 6). Stress concentration was also predicted at the intersection area of the screws with the lateral plate in all the implants.

The implant-induced stress shielding on the femur demonstrated a similar pattern (Fig. 5). In all the three femoral constructs, i.e., DODO, PFLP, and VA-DHS-fixated femur, a significant portion of the proximal femoral head and the region adjoining to the plate was stress-shielded. The stress shielding was substantially high for the PFLP and VA-DHS in the distal bone fragment (lateral aspect) and for DODO in the femoral head. Proximally in the femoral head, stress shielding was predicted to be 46% for DODO-implanted NE femur, 37% for PFLP implanted Caucasian femur, and 24% for VA-DHS-implanted Caucasian femur. However, the corresponding values were found to be 37%, 44%, and 41%, respectively, in the distal femur (Fig. 7).

In order to assess post-implantation stability, the maximum axial displacement of the DODO femur construct was compared with that for PFLP and VA-DHS-fixated femoral
constructs (Fig. 8). Axial displacement for the DODO construct was predicted to be 3.7 mm compared to 2.5 mm for the intact NE femur. For PFLP and VA-DHS-fixated Caucasian femur, the predicted axial displacement values were 1.9 mm and 3.5 mm as opposed to 2.9 mm in the corresponding intact Caucasian femur.

The conventional implants showed high rigidity and higher degree of stress shielding in NE population femur. The intensity of stress shielding on PFLP implanted NE femur was predicted to be 48% and 45% at femoral head and femoral shaft, respectively. For VA-DHS, the values were found to be 35% and 43%, respectively. The percentage bone volume stress-shielded on NE femur due to implantation was found to be 69% for PFLP, and 60% for VA-DHS, whereas it was only 54% on DODO-implanted NE femur. On implanting DODO on Caucasian femur, femur intensity of stress shielding was found to be 43% on femoral head and 36% on femoral shaft. However, DODO implanted on Caucasian femur was found to have high axial displacement of 4.8 mm as compared to 2.9 mm in intact bone.

**Discussion**

Intertrochanteric fractures can be fixated with various implants, which can either be IM- or EM-type devices. While the outcomes of the two techniques are still debatable, there is hardly any consensus on their relative superiority. Fracture severity, osteoporosis, cost, intra- and post-operative complications, and, above all, femoral geometry and morphometry make the selection of the implant a difficult task. The present study offers a noble design of implant for stable intertrochanteric fracture considering the regional morphometry of the NE population of India. To establish the suitability and biomechanical stability of the new design, the DODO-fixated femoral construct representing regional geometry was compared with conventional PFLP and VA-DHS-fixated femur of Caucasian geometric variation. FE analysis based on *in silico* models was employed to predict the stress and displacement patterns for the biomechanical comparison.

It may be observed that, for all implanted models, the laterally fixed plate shields the cortex significantly from lateral tensile stress arising from bending (Fig. 5). Contrary to the overall uniform load distribution in the intact bone, the load flow pattern in a laterally plated bone is predominantly medio-lateral, i.e., the load flows from the bone to...
the implant in the proximal segment and from the implant to the bone in the distal segment of the fractured femur. The above-mentioned load transfer justifies the greater intensity of stresses in the proximal locking screw and distal-most dynamic screw in all models (Fig. 6). The length of DODO is kept almost 50% less compared to the other two plates. The former thus predicted almost similar stress distribution, especially at the distal femur when compared with the intact model, unlike the PFLP and VA-DHS-fixated femur. Therefore, DODO induced a lower level of stress shielding as compared to the other implants. Implanting DODO in Caucasian femur resulted in lesser stress shielding intensity albeit with a compromised mechanical stability of the bone-implant construct. This further corroborates the hypothesis that DODO is tailor made for shorter femur and hence may be unsuitable for longer, Caucasian femur. On the other hand, PFLP and VA-DHS, as much as they continue to be in use on NE femurs, impart higher axial stability albeit with a slight compromise on greater amount of stress shielding. Owing to large lengths of PFLP and VA-DHS as compared to DODO, continuous stress shielding in longer terms can lead to cortical thinning especially underneath the plate [30].

The diameter of the proximal locking screw in DODO was purposefully kept large. This was done to compensate for the reduced number of distal screws and increase the overall strength of the modified implant. Moreover, the addition of the anti-rotation screw increased the stability of the overall construct. Previous studies also found that the addition of an anti-rotation screw provides significantly greater biomechanical resistance [33] and reduced lag screw migration rate [34]. Also, a higher level of stress shielding imparted by DODO in the proximal femur may provide a

Fig. 5 The von Mises stress distribution in anterior (A) and medial (M) aspects of intact and DODO-implanted NE femur (first two); intact, PFLP and VA-DHS implanted Caucasian femur (last three)
major biomechanical advantage to reduce complications like varus collapse. However, long-term exposure to high-stress shielding in proximal femur may increase varus collapse for osteoporotic geriatric patients.

The phenomenon of screw pull-out at the distal end of the plate leading to plate lift-off from the femur shaft is a major cause of failure in the plating techniques [35, 36]. This occurs due to lack of screw pull-out strength in the distal end of the plate. To counter this, the distal screw in DODO was inserted at an inclined orientation of 50° with respect to the plate. Such inclination of the distal dynamic screw provides an advantage in the form of longer bone to screw interface, thereby enhancing the bone-implant anchorage and overall compressive strength of the construct. Screws inserted at an inclined angle were found to provide superior mechanical stability in spinal instrumentation [37]. Perren et al. [38] observed the highest pull-out forces in constructs with 40° divergent angled screws, whereas inclined screw did not improve the fixation strength when angulated up to 30°, regardless of whether in diverging or converging fashion. Stoffel et al. [39] also asserted that oblique screws at the end of the plate increase fixation strength. Furthermore, it is worth noting that the DODO has been designed considering the salient features of Ti alloys. Post-implantation CT and MRI images of Ti-alloy implants have fewer interferences as compared to “blurring” with stainless steel implants. Lightweight, high strength-to-weight ratio, lower modulus

![Fig. 6 von Mises stress distribution contours for a DODO, b PFLP and c VA-DHS implants](image)

![Fig. 7 Bar chart: percentage of stress shielding in the region of the femoral head and femoral shaft due to implantation of DODO on NE femur as compared to PFLP and VA-DHS implanted Caucasian femur](image)

![Fig. 8 Bar chart: axial displacement of various implant fixed femurs and corresponding intact bone](image)
of elasticity, and excellent resistance to corrosion make it an ideal choice as implant material [40].

It may be noted here that a few biomechanical studies have also supported the use of shorter DHS for intertrochanteric fracture fixations. Rog et al. [1], in their study, demonstrated that a DHS with a two- or four-hole side plate is biomechanically comparable with regards to the axial and torsional stiffness of the construct. McLouglin et al. [25] compared the strength and stiffness of a DHS with a two-hole and four-hole side plates and found that the two-hole side plate to be biomechanically comparable to the four-hole side plate, with paradoxically less fracture movement in the two-hole side plate. Various clinical studies have also supported the use of shorter plates for intertrochanteric hip fractures. Bolhofner et al. [26], in a clinical study involving 69 patients with intertrochanteric fractures, found the use of 135° sliding hip screw with a two-hole side plate to be producing satisfactory healing with relatively less blood loss and shorter surgical time without the loss of side plate fixations.

The proof-of-concept DODO design, however, is not without some limitations. The axial stiffness of the construct, though at par with some other conventional implants, is marginally compromised if compared with the intact bone (Fig. 5). The present analysis considered only the femur length aspect of the NE population. FE analysis of DODO, implanted on the averaged patient-specific femur of the NE population, would have been more appropriate. Also, the intra-racial variation of the femur length within the NE population is not considered. Moreover, there is ample scope to evaluate different parametric variations (e.g., angling of distal screws for traditional implants, altering plate/screw dimensions etc.) in the design. That being said, the present in silico work is primarily meant for prototyping and hence warrants in vitro assessment and ethical clearance before contemplating implantation in real bone. Stress concentration at some locations in the implant could be seen (Fig. 6), which potentially can be the region of implant failure. However, in a few locations of the implant and femur, stress singularities are encountered. A stress singularity is a location in an FE model where stress values become unbounded [41]. This typically happens near screw holes, sharp edges in screws, etc., and it requires specially curated, sufficiently fine tetra mesh to attain reasonable accuracy. Needless to mention, such meshing techniques may compromise the efficiency of the program significantly. Nevertheless, a supporting in-vitro and, if possible, in vivo validation can render further insight into the region-specific design efficacies of the novel implant.

**Conclusion**

Limitations aside, DODO was found to be a viable alternative to the conventional plating techniques, especially for the NE population of India, and predicted better to comparable biomechanical characteristics, especially for Evans type-I intertrochanteric fracture. The use of a large diameter proximal locking screw along with the anti-rotation screw predicted enhanced stability of the implanted construct under a physiologically representative static compressive load. The inclined orientation of the distal screw may help reduce the chances of the plate lift-off phenomenon. Moreover, the stress shielding in the distal femur was reduced significantly, thus providing a more uniform stress distribution. The use of a shorter plate for short-femora patients further enables less-invasive surgery as the amount of skin cut is reduced, thereby facilitating shorter surgical time.

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**Declarations**

**Conflict of interest** The authors hereby declare that there are no potential conflicts of interest regarding any financial support, research, authorship and publication of this article.

**Ethical standard statement** This study was approved by the National Healthcare Group Institutional Review Board.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**References**


of pertrochanteric femoral fractures using the dynamic hip screw. 

**Der Unfallchirurg**, 92(12), 571–576


Predictors of 1-year Mortality After Hip Fracture Surgery in Patients with Age 50 years and Above: An Indian Experience

Ravi Gupta1 · Deepam Vashist1 · Parmanand Gupta1 · Ashwani Soni1

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Abstract

Background Hip fractures are considered as a major cause of mortality worldwide. Even after being the second most populous country in the world and facing huge burden of hip fractures, there is scarcity of data from India. For the first time in Indian context, we analysed the predictors of mortality after hip fracture surgery in patients with age 50 years and above.

Materials and Methods In this prospective cohort study, patients with age ≥ 50 years and having hip fractures presented to our institute from January 2018 through October 2018 were enrolled after meeting including and excluding criteria. Patients were followed-up for minimum 1 year after surgery. Association between 1-year mortality and different affecting variables were analysed. Significant variables were further analysed using logistic regression to find independent predictors.

Results Out of 87 patients followed-up for 1 year, 25 patients died within 1 year of surgery. Age > 75 years, road traffic accident as mode of injury, delay in surgery > 48 h, > 2 co-morbidities, haemoglobin level ≤ 10 at the time of admission and osteoporosis are significantly associated with high mortality. When these significant variables were further analysed using logistic regression, age > 75 years and > 2 co-morbidities were only factors associated independently with high mortality.

Conclusion In patients with age 50 years and above, following hip fracture surgery, age > 75 years and > 2 co-morbidities are the predictors of 1-year mortality when adjusted for other variable. A better designed multi-centric study can be more helpful in understanding the things in Indian context.

Keywords Hip · Fracture · Elderly · Mortality

Introduction

Elderly patients undergoing hip fracture surgery have high mortality rates when compared with age and sex matched younger population. This higher mortality ranges from 14 to 36% in different studies [1–3]. International guidelines for hip fracture care suggest that delay in surgery leads to significantly higher mortality and other complication rates and a patient with hip fracture should undergo surgery within 24–48 h of hospital admission [4, 5]. In contrast, many studies have found that timing of surgery has no effect on mortality when adjusted for other variables [6–9]. Other studies have shown that higher mortality rate was associated with age, male sex and co-morbidities [10]. Low vitamin D levels and poor bone quality, though associated with higher risk of hip fractures, have not been studied for risk of morbidity or mortality in these patients.

It is estimated that by year 2025, in India, the incidence of hip fracture in elderly adults will be more than 400,000 annually [11]. Despite of this huge disease burden, there is scarcity of data from India regarding hip fractures. Unlike in developed countries where a multidisciplinary protocol-based approach is there for management of these fractures, in India, such guidelines and protocols are missing [12]. Lack of osteoporotic management, delayed presentation and unmanaged co-morbidities are common and further complicate the situation [12].

The purpose of our study was to analyse prospectively, the predictors of 1-year mortality after hip fracture surgery.

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in patients with age 50 years or above presented to our institution from January 2018 through October 2018. To the best of our knowledge, our study is the first from India analysing these predictors. Our study will be helpful in better understanding the problem and improving the management in Indian context.

**Materials and Methods**

Our study was a prospective cohort study. After getting ethical clearance from institutional ethical board, the patients were enrolled over the period January 2018 through October 2018. Our inclusion criteria were—all the patients admitted to our institute with hip fractures having age 50 years or above. Exclusion criteria were—other associated traumatic injury, open fractures, fracture due to malignancy and patient not willing to participate in study.

In all the patients, after getting X-rays done and diagnosis was made, surgery was planned accordingly. For patients having intra-capsular hip fracture and age 60 years or above, modular cemented hemiarthroplasty was planned. For patients with age less than 60 years having intra-capsular hip fracture, screw fixation was planned. For all the patients having extra-capsular fracture, proximal femur nailing (two proximal screws) was planned. For all the patients with age less than 60 years having intra-capsular hip fracture, screw fixation was planned. In all the patients with age less than 60 years, fixation of fracture was planned to preserve the joint. All the relevant investigations were done and consultations were taken from different specialities as per the co-morbid conditions. Surgery was planned as early as possible on routine list. After surgery patients were encouraged to mobilise as early as possible. Patients who underwent replacement surgery were mobilised full weight bearing from second day of surgery. Patients who underwent fracture fixation were allowed partial weight bearing (40% body weight) till 3 weeks followed by full weight bearing. On bed, physiotherapy was encouraged all the time after surgery. After discharge from hospital, patients were followed-up in out-patient department at 3, 6 and 12 months. All the patients were followed-up for minimum of 1 year.

We defined hip fracture as femur trochanteric region fracture (31A) or femur neck fracture (31B) according to AO/OTA classification. Continuous variables were defined as mean ± S.D. (Table 1). Diabetes, hypertension, cardiovascular disease, cerebrovascular disease and chronic respiratory disease were evaluated as co-morbidities during our study. Discrete variables were defined as frequency and percentage (Table 2). Our outcome variable was mortality within 1 year. Statistical analysis was done to determine the association between 1-year mortality and independent variables. All independent variables were first analysed for their association with mortality using odd ratio. Chi-square or Fisher’s exact test was done to calculate p value. Variables found to be significant were further analysed using logistic regression analysis. Analysis was done using enter method whereby all independent variables were inserted into the model simultaneously. For all the calculations, significant difference was defined at p < 0.05. Written consent was taken from all the patients before enrolling them for study.
Results

Total 90 patients were enrolled in our study meeting our inclusion and exclusion criteria. 3 patients were lost to follow-up before completing 1 year so excluded from analysis. Of 87 patients, 44 were male and 43 were female with mean age $71.85 \pm 10.48$ years. Descriptive data for 87 patients are shown in Tables 1 and 2. Of 87 patients, 25 patients died within 1 year of surgery. When analysed for association with mortality, age $> 75$ years, mode of injury as RTA (road traffic accident), delay in surgery for $> 48$ h, more than 2 co-morbidities, Hb (haemoglobin) level $\leq 10$ g per decilitre (at the time of admission) and T-score $<-2.5$ were found to be significantly associated (Table 3). When these significantly associated variables were further analysed using logistic regression, age $> 75$ years and $> 2$ co-morbidities were found to be independent predictors of mortality within 1 year (Table 4).

Discussion

Hip fracture in elderly is a major public health problem in terms of morbidity and mortality and costs a huge financial burden [13]. After hip fracture surgery in elderly patients

<table>
<thead>
<tr>
<th>Table 3 Predictors of mortality</th>
<th>Mortality</th>
<th>Lived</th>
<th>Odd ratio (C.I.)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
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<tr>
<td>$&gt; 75$</td>
<td>17</td>
<td>16</td>
<td>6.10 (2.21–16.85)</td>
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<tr>
<td>$\leq 75$</td>
<td>08</td>
<td>46</td>
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<tr>
<td>Sex</td>
<td></td>
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<tr>
<td>Male</td>
<td>12</td>
<td>32</td>
<td>0.86 0.34–2.19</td>
<td>0.76</td>
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<tr>
<td>Female</td>
<td>13</td>
<td>30</td>
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<tr>
<td>Mode of injury</td>
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<tr>
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<td>23</td>
<td>41</td>
<td>5.89 1.26–27.41</td>
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<tr>
<td>Low energy fall</td>
<td>02</td>
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<td>49</td>
<td>1.061 (0.33–3.36)</td>
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<td>51</td>
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<tr>
<td>$\leq 48$ h</td>
<td>01</td>
<td>17</td>
<td>0.11 (0.01–0.88)</td>
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<tr>
<td>$\leq 5$ days</td>
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<td>30</td>
<td>0.50 (0.18–1.33)</td>
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<tr>
<td>$&gt; 5$ days</td>
<td>17</td>
<td>32</td>
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<tr>
<td>Delay in surgery</td>
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<tr>
<td>$\leq 7$ days</td>
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<td>38</td>
<td>0.68 (0.26–1.74)</td>
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<td>$&gt; 7$ days</td>
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<tr>
<td>$\leq 2$</td>
<td>08</td>
<td>49</td>
<td>0.12 (0.04–0.35)</td>
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<tr>
<td>$&gt; 2$</td>
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<td>13</td>
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<tr>
<td>$\leq 10$</td>
<td>12</td>
<td>09</td>
<td>5.43 (1.89–15.62)</td>
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<tr>
<td>$&gt; 10$</td>
<td>13</td>
<td>53</td>
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<tr>
<td>T-score</td>
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<tr>
<td>$\leq (-2.5)$ (osteoporosis)</td>
<td>15</td>
<td>17</td>
<td>3.97 (1.49–10.53)</td>
<td>0.04</td>
</tr>
<tr>
<td>$&gt; (-2.5)$ (osteopenia/normal)</td>
<td>10</td>
<td>45</td>
<td></td>
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<tr>
<td>Body mass index</td>
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<tr>
<td>$\geq 25$ (overweight/obese)</td>
<td>11</td>
<td>23</td>
<td>1.33 (0.51–3.42)</td>
<td>0.55</td>
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<tr>
<td>$&lt; 25$ (normal)</td>
<td>14</td>
<td>39</td>
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Various factors have been reported to be associated with this high mortality rate. Timing of surgery is widely accepted to be the most important and current guidelines from developed world suggest surgery within 48 h of injury [4, 5]. However, in India, it is not mostly possible to operate these patients within 48 h mainly due to lack of protocol based multidisciplinary approach and deficiency of resources [12]. Protocol-based approach if present anywhere is only on experimental basis [12, 14–16]. In our study, only 18 of 87 patients were operated within 48 h. 6 patients had delay more than 21 days. All these six patients were managed with massages by local quacks before presenting to us. This faith in alternate medicine is another major reason for late presentation and delayed surgery in India. Late presentation to hospital is described by other Indian authors also [12, 15].

Though it is believed widely that timing of surgery affects mortality, many studies concluded that early surgery is not associated with lesser mortality [17–20]. Smektala et al. analysed patients with age more than 65 years with isolated femoral neck or pertrochanteric femoral fractures [17]. According to time period from fracture to surgery, authors divided the patients in three groups—short (≤ 12 h), medium (12 to ≤ 36 h) and long (> 36 h). The authors concluded that there was no association between 1-year mortality and time to surgery. Moran et al. in their prospective study of elderly patients who underwent surgical treatment of hip fractures concluded that surgical delay up to 4 days was not associated with increased 30 days mortality when patients did not have associated co-morbidities [18]. When surgery was delayed, patients having co-morbidities had mortality rate 2.5 times as compared to patients without co-morbidities. Orosz et al. also in a prospective cohort study of 1206 hip fracture patients having age > 50 years compared the mortality rates when surgery was done within or after 24 h. The authors concluded that early surgery was not associated with improved mortality [19]. Similarly, Al-ani et al. in their prospective study of 850 consecutive patients concluded that mortality rate was not affected by timing of surgery when patients were divided according to surgery done with 24 h, 36 h and 48 h of admission [20].

Moreover, other authors concluded that factors other than timing of surgery were associated with mortality. Siegmeth et al. in their prospective review found that mortality rate was not affected by timing of surgery when adjusted for ASA (American Society of Anaesthesiologist) score, mental score and pre-fracture mobility score [9]. Khan et al. in their systematic review of 52 studies found that mortality was more associated with surgery delay in studies where confounding variables were not adjusted [7]. The authors concluded that studies with more careful methodology were less likely to have a beneficial effect of early surgery on mortality. Vidan et al. concluded in a prospective cohort study of elderly hip fracture patients that high mortality due to delay in surgery was explained by the medical reasons of delay rather than by delay itself [8]. The authors argued that young and fit patients undergo early surgery and so the effect of time on mortality, as described by other authors, was actually a selection bias. Similarly, Franzo et al. in their study found that co-morbidity, male sex, advancing age and multiple surgeries were predictors of mortality. Furthermore, the authors concluded that mortality in elderly patients who underwent hip fracture surgery was not associated with delay in surgery after adjusting for patient risk factors and volume of hospital surgical activity [6]. The authors defined surgical delay as ‘2 or more days’ after hospital admission.

In our study, we divided patients in three groups according to delay in surgery—≤ 48 h vs >48 h, ≤ 5 days vs > 5 days and ≤ 7 days vs > 7 days. We in our study found that age > 75 years, RTA as mode of injury, delay in surgery > 48 h, > 2 co-morbidities, ≤ 10 Hb and osteoporosis are significantly associated with high mortality rate. However, when these significant variables were analysed using logistic regression we found that age > 75 years and > 2 co-morbidities were only factors associated independently with high mortality.

Our finding regarding co-morbidity as predictor of mortality was in consistence with previous studies [21–23]. Roche et al. concluded that 3 or more co-morbidities increased mortality in elderly patients with hip fractures [21]. Cher et al. compared Charlson Comorbiditi Index (CCI) and delay in surgery as a predictor of mortality at 30 days, 90 days and 2 years after hip fracture [22]. The authors found CCI as a dominant predictor of both short- and long-term mortality as compared to delay in surgery. Similarly, Kenzora et al. found pre-operative medical conditions

<table>
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<th>Table 4 Logistic regression analysis of significant predictors</th>
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<tr>
<td>Age</td>
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<tr>
<td>Mode of injury</td>
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<td>Delay in surgery (≤ 48 h or &gt;48 h)</td>
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<td>Co-morbidities</td>
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<td>Pre-operative haemoglobin</td>
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<td>T-score</td>
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</table>
highly significant factor effecting mortality after hip fracture surgery [23]. Systematic reviews and meta-analysis also by different authors concluded co-morbidities as predictors of mortality. [24–26]. Xu et al. in their systematic review found that multiple co-morbidities were predictor of mortality after hip fractures in 14 of 15 studies [26]. Chand et al. also in their meta-analysis found that co-morbidities were associated with mortality after hip fracture surgery [25]. Similarly, Hu et al. in their meta-analysis found that multiple co-morbidities were predictor of mortality after hip fracture surgery in elderly patients.

As in our study, age was found by other authors also in their systematic reviews to be significantly associated with mortality after hip fracture surgery in elderly patients. [24, 26, 27]. While Smith et al. described age > 85 year, Xu et al. and Hu et al. simply described advanced age being associated with high mortality. We found age > 75 years to be associated with high mortality in our study. Xu et al. in their systematic review reported that males had high mortality as compared to females [24]. Similarly, Hu et al. and Smith et al. in their meta-analysis found male gender as a mortality predictor [26, 27]. In our study, we did not find any significant association between mortality and gender.

Regarding type of fracture there are conflicting results. Xu et al. in their systematic review found that extra-capsular fractures were associated with high mortality rate, while Smith et al. found that intra-capsular fractures had 77% higher mortality rate compared with extra-capsular fractures [24, 27]. Hu et al. in their meta-analysis found moderate evidence that intertrochanteric femur fractures had high mortality rates than neck femur fractures in elderly patients [26]. Our study did not find any significant association between mortality and type of fracture.

Hb level is considered to be a potentially modifiable predictor and its measurement is easy to do with relatively little expenses. In recent studies, low level of Hb at the time of admission was found to be significantly associated with high mortality rates in elderly patients with hip fracture [28, 29]. Similarly, Hu et al. in their meta-analysis found moderate evidence in favour of association between low Hb and excess mortality in elderly hip fracture patients [26]. In our study, though Hb level ≤10 was found to be associated with high mortality on univariate analysis, after adjusting for other factors on multivariate analysis, there was no significant association between Hb level and mortality.

Vitamin D level and bone quality, though, have been extensively studied as factors for hip fracture occurrence, we are not aware of any study evaluating Vitamin D level and bone quality as a predictor of mortality in elderly patients after having hip fracture surgery. In our study, though we did not find any significant association between vitamin D level and mortality, osteoporosis was found to be associated with high mortality rates. However, after multivariate analysis, osteoporosis also was found not to be associated significantly with high mortality rates. Similarly, RTA as mode on injury was found to be a predictor of mortality as compared to low-energy fall but when analysed on multivariate analysis model, there was no association between mortality and mode of injury.

Even though we have a lot of literature available, it is difficult to make any consensus on predictors of mortality after hip fracture surgery as previous studies found variable results. Moreover most of the available literature is from developed countries. Lack of protocol-based multidisciplinary approach, limited resources, delayed presentation and unmanaged co-morbidities make our Indian patients different than those analysed in studies from developed world. Our study is the first study from India analysing the predictors of mortality after hip fracture surgery, though we acknowledge the limitations of our study. First, our study had a small sample size. Too many variables analysed from a relatively small sample may cause overfitting of regression model. Second, there may be other variables affecting mortality which were not analysed in current study like intra-operative hypotension/hypoxia due to cementation [30], electrolyte imbalance, blood transfusion requirement, post-operative activity level, fracture stability and others [26].

In conclusion, our study shows that in patients with age 50 years and above, following hip fracture surgery, age > 75 years and > 2 co-morbidities are the predictors of 1-year mortality when adjusted for other variable. A better designed multi-centric study can be more helpful in understanding the things in Indian context.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent For this type of study informed consent is not required.

References


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Can ACL Tears be Restricted to Sports Injuries Alone? A Retrospective Analysis

Shuaib Ahmed · Munis Ashraf · Santosh Sahanand · David V. Rajan

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Abstract
Background The number of people injured following a road traffic accident (RTA) are as high as 2–5 crores around the world every year. The literature from western population suggests that ACL injuries are encountered mostly following high velocity sports injuries in clinical practise. But, in India there are a large group of individuals presenting with ACL injuries following RTAs.
Methods We performed a retrospective analysis of all patients with ACL injuries presenting to our hospital following RTAs. All the information pertaining to the ligaments injured, vehicular factors, time of the day and environmental factors were recorded. The data was then analysed statistically.
Results Most injuries occurred in the 31–40 year age group and velocity in the same range. Injuries due to bike skid predominated in our study amounting to 55.9%. Interestingly, very low velocities accidents due to stray dogs accounted to 43.8% and they occur mostly at night.
Conclusion The number of patients presenting with RTA related ACL injuries in our country are numerous. Hence, we have made an attempt to show that ACL injuries can occur even at low velocity following motor vehicle accidents in contrast to the western population, where sports related injuries are the most common etiology for such mishaps.

Keywords Anterior cruciate ligament · Road traffic accident · India

Introduction

Motor vehicle accident injures 2–5 crore people around the world, and at the same time kills nearly 13 lakh individuals each year. World Health Organization (WHO) has stated that for people in the age group of 15–29 years, it is the leading cause of fatality. It is envisioned that vehicular crashes will climb as the top five prominent causes of death by the year 2030 [1].

Meanwhile, India has emerged as a top nation in the number of deaths following road accident deaths among the 199 Countries. This was reported in the World Road Statistics, 2018. In the year 2018, a mammoth total of 4,67,044 road traffic accidents have been reported by States and Union Territories (UTs) which claimed 1,51,417 lives and caused injuries to 4,69,418 individuals. Among these two-wheeler accidents were 1,64,313 which amounted to 35.2% share, among accidents caused by other vehicles [2].

There is meager data regarding analysis of two wheeler accidents occurring specially in the Indian subcontinent. Each month on an average nearly 38,920 individuals meet with an accident out of which 12,618 people die every month [2].

Anterior cruciate ligament (ACL) is one of the most common ligaments injured world-wide with an annual incidence of under quarter million cases. A predicted number of about 70% of ACL injuries are sustained through noncontact mechanisms, while the remaining 30% result from direct contacts [3].
It is quite evident that ACL injuries in the western population are mostly due to sports activities or domestic falls [4]. But in the Indian population vehicular accidents depict a distinct number of ACL injuries which have been rising over the past few years [2].

The attempt to curb road traffic accidents as well as implement road safety measures is the need of the hour. Hence, since there is little or no statistics pertaining to road traffic accidents leading to knee ligament injuries, we have enlisted numerous parameters to record the data of these patients at our Institute. The prime focus was involvement of ACL apart from the other ligamentous and bony structure injuries around the knee.

Here, we present results of the analysis of incidence of ACL and related knee injuries following two-wheeler accidents in India and the circumstances which lead to the accident. Hence, we have made an attempt to propose a few preventive measures which can be imposed so as to avert the chances of knee injuries and hence curtail morbidity and mortality rates and in-turn reduce loss of work hours and reduced quality of life.

Materials and Methods

A retrospective observational study of all patients who had reported to our Hospital between January 2014 and January 2019 was done. The patients taken into our study were ACL and related injuries following motor-cycle related accidents (group 1). The remaining set of individuals affected by non-RTA related ACL injuries due to sports related and domestic fall were classified as group 2. The diagnosis was confirmed radiologically using 1.5 T MRI scan. A written informed consent was obtained from each patient. Inclusion criteria were cases with ACL injuries solely or associated with other ligaments following RTA were included. Exclusion criteria were poly trauma cases, open fractures in the ACL injured limb, head injury patients and pediatric age groups.

The patient’s data sheet was recorded with respect to the ligaments injured (ACL, PCL, PLC, MCL, LCL and ALL) and anatomical sites of chondral defects (femur, tibia and patella). Additionally, other parameters such as type of vehicle (geared or non-geared), speed (in km/h) preceding the collision. If the patient was the driver or pillion rider, accidents due to direct collision (two-wheeler vs two-wheeler, two-wheeler vs four-wheeler and stray animals such as dogs, cats or cows and crash against a wall or sign boards were classified under contact injuries, while those accidents due to skidding from two-wheeler, pot holes, slippery roads and loss of balance were included in non-contact injuries. Furthermore, the injuries occurring during the day and night were recorded. Day was considered as cases from dawn to dusk (on an average 6.30 AM to 6.30 PM) and night was during the remaining hours.

The data were entered in an excel sheet and was analysed using the SPSS software. The basic demographic variables were expressed as percentages and the association between various factors contributing to the cause (ACL tear) was analysed using Chi-square test. Finally, if the p value was < 0.05, it was considered as statistically significant.

Results

A total of 2138 cases pertaining to ACL injuries presented at a single Centre were retrieved, of which 745 cases (34.8%) alone were categorized in group 1 and the rest 1393 cases (65.1%) were in group 2. A total of 508 cases which had complete data were included in the study and the remaining 237 cases were excluded as they either did not fulfill the criteria or there was insufficient data. All the patients met with accidents within the State of Tamil Nadu, India (Fig. 1).

Gender

Male dominated with 406 patients and female cases were 102.

Fig. 1 Pie-chart showing distribution of various cases in our study pool
Side Dominance

Maximum cases of right sided injuries were noted \(n = 289\), 56.8%), while the number of left sided knee trauma cases were 219 (43.1%).

Age

The age distribution was done. Those below 20 years and above 60 years of age, and with a confidence interval of 10, the intermediate age groups were classified. Most of the cases were in 31–40 years \(n = 177\), 34.8%) and the least belonged to the elderly population above 60 years \(n = 8\), 1.5%). A little more than a dozen individuals were noted below 20 years of age \(n = 15\), 2.9%).

Velocity

The speed of vehicles was classified with differences of 10 km/h confidence intervals from 30 to 60 and beyond 60 km/h. This was further sub-classified into very low velocity \(<30\) km/h), low velocity \((31–40\) km/h) and high velocity \((>40\) km/h). Maximum number of cases were noted in the 31–40 km/h group amounting to 288 cases (56.7%) (Fig. 2).

Fig. 2  Bar chart illustrating distribution of cases according to velocity (km/h)

Table 1  Mode of injury vs velocity (km/h)

<table>
<thead>
<tr>
<th>Mode of injury vs velocity (km/h)</th>
<th>Velocity (km/h)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-wheeler vs two-wheeler</td>
<td>6</td>
<td>119</td>
</tr>
<tr>
<td>Skid</td>
<td>21</td>
<td>284</td>
</tr>
<tr>
<td>Stray dog</td>
<td>21</td>
<td>77</td>
</tr>
<tr>
<td>Two-wheeler vs four-wheeler</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>508</td>
</tr>
</tbody>
</table>

Mode of Injury

There were four main modes viz. two-wheeler vs two-wheeler, skidding and falling, stray animal related accidents and two-wheeler vs four-wheeler. Injuries due to skidding were on top of the list, 284 cases (55.9%) and these occurred mostly at 31–40 km/h velocity \(n = 189\), 37.2%). At higher velocities, i.e., >40 km/h injury occurred mainly due to either two-wheeler vs two-wheeler or two-wheeler vs four-wheeler collisions \((n = 90)\). It is interesting to note that at very low velocity, accidents due to stray animals showed a significant percentage of 43.8\% \((n = 21)\). However, we did not come across any injuries due to pedestrians (Table 1).

Diurnal Variation

An enormous number of 346 cases (68.1%) were documented to have met with road traffic accident during the daylight (Table 2). Most of these cases were in the range 31–40 km/h \(n = 201\), 39.5%). However, at very low speeds \((n = 48)\), 60.4% cases \((n = 29)\) were seen during the night (Table 3). During the day (Table 4), injuries due to skidding were most prevalent \((n = 201\), 39.5%) and most of them clocked at 31–40 km/h \((n = 141\), 27.7%). A vital point to note is that injuries due to stray dogs still remained maximum \((n = 10)\) even during the day at very low velocity (Table 4). The data during night showed a similar trend as day with ACL tear due to skid \((n = 83\), 16.3%) followed by trauma due to stray dogs \((n = 44\), 8.6%); total cases at night were 162 (Table 2). A clear attention can be drawn towards stray dog related trauma which happened mostly in the night \((n = 44\), total = 77) (Table 2).

Table 2  Diurnal variation vs mode of injury

<table>
<thead>
<tr>
<th>Time of day</th>
<th>Mode of injury vs two-wheeler</th>
<th>Skid</th>
<th>Stray dog</th>
<th>Two-wheeler vs four-wheeler</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>88</td>
<td>201</td>
<td>33</td>
<td>24</td>
<td>346</td>
</tr>
<tr>
<td>Night</td>
<td>31</td>
<td>83</td>
<td>44</td>
<td>4</td>
<td>162</td>
</tr>
<tr>
<td>Total</td>
<td>119</td>
<td>284</td>
<td>77</td>
<td>28</td>
<td>508</td>
</tr>
</tbody>
</table>

Table 3  Mode of injury

<table>
<thead>
<tr>
<th>Mode of injury vs two-wheeler</th>
<th>Velocity (km/h)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-wheeler vs two-wheeler</td>
<td>6</td>
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</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>508</td>
</tr>
</tbody>
</table>
Periarticular Structures

The other ligaments around the knee which were injured were grouped under “other ligaments” category, so as to help in statistical evaluation, 117 cases with various ligaments were injured. These patients were dominant in the category of 31–40 km/h which was 46.2% (n = 54). A striking information to note was at very low velocity, a significant number (n = 25, P < 0.05) of patients were having concomitant multi-ligament injuries.

Contact/Non-contact Injuries

Contact accidents (n = 255, 50.1%) were almost similar to non-contact (n = 253, 49.8%) and most of them were in the high velocity category (n = 122). The non-contact injuries were maximum in 31–40 km/h range (n = 244) and were due to skidding.

Driver/Pillion

Drivers who ended up with injuries were maximum (n = 446, 87.7%) and they occurred mostly due to skidding and falling (n = 236). Pillion riders were meager in count (n = 62, 12.2%) and they too were injured because of two-wheeler skidding and falling.

Road Construction

Tar road were on top of the list with 374 (73.6%) cases causing knee injuries. This was followed by muddy roads with 133 patients. Finally, one case met with an accident on road made of gravel. The injuries occurring on tar roads were mainly due to skidding and falling (n = 202). However, stray dog related injuries were almost comparable on tar roads (n = 41, 8%) and muddy roads (n = 36, 7%).

Model of the Vehicle

Geared motorcycles had maximum injuries amounting to 388 (76.3%) followed by non-geared vehicles which were 120 cases. Moreover, at high velocities geared vehicles had maximum accidents (n = 131, 25.7%).

Discussion

Over the course of many decades several studies have been done on the incidence and mode of injury to the ACL. Most of them have proved that damage to the ACL is caused mainly due to Sports [5]. On the contrary, in our study we have learned that in the Indian context, vehicular collisions contribute significantly towards injury to ACL and other knee structures. The after effects of ACL injury include not only temporary but in some cases, even permanent disability which incurs a significant cost to patients [6][7]. Hence, there is a growing need to take effective measures to avert the sizable number of RTA related ACL tears.

In 2018, the WHO issued a Global Report on Road Safety, stating that, India accounts for nearly 11% of the accident related casualties in the world [2]. The transportation of freight and passengers in India is preferred by road. The rapidly bursting population, remarkable growth in the use of motor vehicles coupled with rising urbanization has made people vulnerable to incessant RTAs resulting in mortalities and morbidities [8][9].

The highest number of RTAs in India were recorded in the State of Tamil Nadu (63,920) which amounts to 13.7%
of share 2018 [2]. Our study consisted of patients from this region with utmost attention given to ACL injuries along with other parameters as mentioned previously. The total number of cases were 508, in which all the victims were travelling on a two-wheeler. According to the Indian statistics published in 2018 [2], two-wheeler accidents ranked as the largest share with respect to RTAs (35.2%), total number of individuals killed (31.4%) and persons wounded (32.7%). One among the ample factors may be a considerable increase in the vehicle density (number of vehicles per km of road) which was recorded to be 42.95 as compared to the data in 2010 which was nearly half (27.88) [2]. Besides, in terms of vehicular composition on road, two-wheelers contribute to about 70% and hence there is an absolute need to focus on safety related to this segment of vehicles.

The 2018 data in India showed maximum RTAs among youngsters (20–45 years) [2] and a similar trend was seen in our study, where ACL injury following RTA was highest in 20–40 years (n = 349). They belong to the economically active age group and hence are predisposed to injuries [1]. Gender distribution was dominated by men (86%) and this corroborated with our results of masculine population (79.9%). World-wide the incidence of men being victims of RTAs has been maximum [10].

There are various modes of injuries among which mishaps due to skidding and falling were maximum in our study (n = 284, 55.9%) followed by vehicle to vehicle collision (n = 119, 23.4%). Conversely, Indian statistics [2] showed that direct collisions constituted to 52.02% injuries. Vehicular collisions are the result of interplay between plentiful factors, which can be broadly categorized as, human errors, environmental conditions, road construction and vehicular condition. Human factors which constitute to almost 75% [2], outnumber all other causes. In our study, there were 147 cases (28.9%) of injuries due to direct collision (two-wheeler vs two/four-wheeler). Inclusion of skidding and falling under the same category falls in the grey zone, as such, mishaps can occur due to multiple reasons as mentioned earlier. But, reckless and drunken driving do result in RTAs [2]11 and according to the statistics in 2018, accidents due to the former were responsible for majority cases. We found that 73 cases (14.3%) that met with an accident due to skidding and falling were in the high velocity range.

In our study we have found that most of the cases (56.7%) were in the range of 31–40 km/h (low velocity). A similar presentation in 39th Orthop aedic World Congress SICOT, Montreal 2018 was done by Kerketta et al. [12]. They performed a study with a smaller sample size and their main aim was to study the incidence of ACL injuries in low velocity two wheeler RTAs. They concluded that most of the injuries were in the same velocity range as our study and the individuals predominated in the 20–40 year age group. In addition, they also mentioned a limitation of lesser sample size (n = 50) in their study.

Next, road environment plays a pivotal role in causing RTAs in our Country. One of the main reasons for this being weather conditions that mainly influence the condition of roads leading to their early wear and tear. The other causes include, tapering roads, faulty configuration of crossroads, ineffective lighting and poor design. Many of the contractors in India are either inexperienced or are focused on personal gain which subsequently results in establishment of unsafe roads having several ditches and pot holes [11]. The research conducted by us constituted more than half of our sample size (n = 284, 55.9%) due to skidding and falling. This category included crashes occurring due to pot-holes in addition to other causes enlisted. With regards to composition of road, we had 26.2% cases (n = 133) which took place on muddy roads. This indicates that bad roads form hurdles to smooth travel and consequently lead to ACL injuries.

Climatic conditions predispose to RTAs and are unpredictable factors. The pendulum of increased rate of accidents is swayed in an ascending direction due to slick roads combined with poor visibility making driving unpropitious to travelers [1]. However, a record of weather conditions was not noted in our dataset and this is one of the limitations of our study.

Daylight improves visibility and can help ameliorate chances RTAs. But at the same time the confidence to rev up a motorcycle equally surges and hence, piles up the already mammoth cases of RTAs. The census in 2018, revealed that 6 PM to 9 PM accounted to 18.6 of RTAs followed by 3 PM to 6 PM and this pattern has been persistent in the preceding 5 years [2]. Our analysis showed that cases in the day peaked to 346 (68.1%). Most of these cases were in the low velocity range (n = 201). A striking information at very low velocity cases in the night rose to 60.4% (n = 29) and this may indicate that due to lesser visibility the drivers may be more cautious. Moreover, stray animal accidents were highest at night (n = 44) which all the more proves that these creatures create a nuisance to people travelling on the road.

Maintenance of vehicles in good condition also plays a crucial role in the occurrence of RTAs. A well-oiled automobile can help avert an ACL injury at the primordial level [1]. In addition, geared vehicles assist in revving a two-wheeler to higher speeds and we had 76.4% cases (n = 388) in our study. But, this cannot be concluded that non-gear vehicles have fewer chances of meeting with mishaps.

Therefore, keeping in mind the ACL injuries occurring at an enormous rate, it is incumbent to act upon mitigating their rates. The government plays a humongous role to scale down the incidence of RTAs and hence shrink the number of ACL injuries. We have framed several preventive strategies that can be imposed so as to lower the rising cases of RTAs.
Preventive Measures

The foremost factor which needs emphasis is to decrease the exposure to risk. Empiric data signifies that on an average rise in speed of 1 km/h is linked with a 3% higher risk of a RTA resulting in an injury [13]. Risk occurs due to a person’s need to travel which can be for official reasons or entertainment purposes. Thus, there is a need to bring down the number of people commuting long distances especially for monetary gains and this can only be achieved by advocating necessary actions to boost local economy and create surplus job opportunities. Besides, abundant establishments relating to leisure can be erected which will in-turn shrink the risk of RTAs.

There is an inexhaustible list of precautionary measures but we have enlisted a few points with regards to our study.

- Improvement of infrastructure such as adequate road lighting, use of neon paints to demarcate the road lanes and use of neon lights, fixing of road fencing to prevent animal crossing and planting speed limit sign boards.
- Enforcing stringent laws so as to limit vehicular speed on highways and accomplishing this by surveillance using road-side cameras.
- Regular set-up of traffic police check posts so as to assist in strict implementation of traffic laws.
- Using state-of-art devices such as drones for effective surveillance of hilly areas.
- Involvement of animal activists and stray dog detection teams.
- The mixed composition of vehicles on roads has caused a nuisance leading to RTAs. To put it differently, the same road is used by various motorized and non-motorized vehicles, and at varied speeds. The exposure to risk can only be reduced by enforcing rules and regulations and separating vehicles according to their velocities.
- Ministry of road transport and highways has passed the Motor Vehicle Amendment Act 2019. The essence of this act is on road safety which includes several measures such as, heavy fines for traffic violations, high-tech use of vehicle fitness and driving tests etc. [2].

Limitations of the Study

- The history pertaining to consumption of alcohol, intake of drugs, while driving and possession of valid driver’s license was not recorded.
- An important information regarding the position of the limb and knee joint at the time of injury could not be documented as the patients were unable to recollect this subtle but vital information.
- The patients could not recall the exact speed of the vehicle at the time of the accident and hence, an arbitrary value was taken based on the vague information provided by them.
- A record of the road categories such as, National, State and other Highways was not listed in our study.
- We did not pay significant focus on the weather conditions at the time of trauma, since this was a retrospective study data pertaining to this was not recorded.

However, one deduction can be that in Tamil Nadu (India), where the accidents occur almost March–July consists of summer, while the remaining months the climate is unpredictable with phases of moderate rainfall.

A far larger sample size especially at a national level is needed to study the variation of knee ligament injuries and hence implement necessary measures.

Conclusion

The morbidity associated with ACL injuries is disabling and when these mishaps occur due to road traffic accidents, it can be disastrous. Though some of the factors leading to these mishaps are preventable, the effective implementation needs tremendous amount of efforts from individual level to the government authorities. In this manuscript, we have combined the orthopedic and preventive medicine point of view in averting the chances of ACL injuries. This is particularly important as the State of Tamil Nadu ranks highest among RTA related injuries and ACL injury is one among them. The effective implementation of preventive measures as listed can contribute to a large extent towards a decline in RTA related knee ligament injuries.

Compliance with Ethical Standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.
Ethical standard statement  This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent  For this type of study informed consent is not required.

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Analyze the Differential Rates of Anterior Cruciate Ligament Injuries Between Men and Women by Biomechanical Study of Single-Leg Landing in Badminton

Hsiang-Jui Tseng¹,² · Hon-Lok Lo² · Yu-Chuan Lin² · Wen-Chih Liu¹ · Sung-Yen Lin²,³ · Pei-Hsi Chou²,³ · Cheng-Chang Lu¹,³

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Abstract
Background In female badminton players, certain landings are associated with injury to the anterior cruciate ligament (ACL). However, the kinematic and kinetic changes of the landing leg and the effects of risky posture on ACL injuries among female vs male badminton players are still unknown. We hypothesized that female players land with a significantly higher knee valgus angle and moment compared to male players during single-leg landings in badminton.

Methods Ten male and ten female badminton players were enrolled in this study. In the laboratory, these subjects performed back-stepping to the backhand side with a concurrent overhead stroke, a single-leg landing on the force plate, and a return to the starting position. The kinematic data in the stance phase were normalized ranging from 0% as initial contact to 100% as toe-off; and 0% as initial contact to 100% as maximum knee flexion in the impact phase.

Results The knee valgus angle in female players was significantly higher in initial contact (5.06° ± 6.83° vs −5.10° ± 4.30, \( p = .001 \)) and maximal knee valgus angle (7.58° ± 9.54° vs −3.93° ± 4.22°, \( p = .004 \)) compared to male players. The knee valgus moment was significantly higher in male players than female players (−0.09 ± 0.12 vs 0.03 ± 0.10 N·m/kg, \( p = .032 \)) in initial contact during the impact phase. During landings, female badminton players had lower hip flexion angles, greater knee valgus angles, and greater ankle dorsiflexion angles.

Conclusion Female badminton players presented higher knee valgus angles but smaller knee valgus moments compared with male players during backward single-leg landings. The concomitant kinematic and kinetic changes of the hip, knee, and ankle joints also can play an important role in the higher incidence of ACL injury in female athletes.

Keywords Anterior cruciate ligament · Female athlete · Motion analysis · Badminton

Introduction
Anterior cruciate ligament (ACL) injury usually occurs in sports that require repeated jumping, landing, and changing positions, such as basketball, soccer, and volleyball with noncontact injury. The incidence of ACL injuries among female athletes is higher than that among males, with three to six times risk [1–3]. Most investigators have proposed multiple factors including hormone and menstrual cycle effects, as well as anatomic, genetic, and neuromuscular differences between female and male athletes [4–8]. Hewett et al. [5] and Numata et al. [9] found that significantly larger knee valgus angles and moments in the female athletes who subsequently sustained an ACL injury compared to the uninjured athletes. Following injury video analysis, Olsen [10] and Koga [11] also concluded that increased knee valgus angle and moment during the impact phase of landing are key predictors that are reliably associated with increasing ACL injuries in female athletes.

Badminton movements require jumping and landing frequently and quickly returning to the original starting
position. In addition, badminton athletes are required to hold the racket and laterally bend the trunk during overhead strokes, increasing the imbalance and load in the landing leg [12–14]. In 2010, Kimura et al. [14] found that the ACL injuries most commonly occur in the leg opposite the racket-holding side during single-leg landing in the back-hand side court after overhead stroke. They subsequently conducted a 3-D motion-analysis study and that female badminton players presented significantly larger knee valgus angles at maximum knee flexion and maximum knee valgus moment on single-legged landing following stepping to the backhand side [13]. The authors concluded that single-leg landing following backward stepping to the backhand-side court with an overhead stroke is a high-risk posture associated with ACL injuries in female badminton players with increased knee valgus angle and moment.

However, the various kinematic and kinetic changes that occur in the landing leg and the influence of these factors on knee injuries in female vs male badminton players are still unknown. To prevent knee injury and improve the landing technique in female badminton players, physicians and coaches must clarify the kinematic and kinetic differences in risky landing postures and associated ACL injuries in female vs male players. Accordingly, this study investigated the kinematic and kinetic differences in the landing leg and the elevated risk of high ACL injury during the badminton movements of female vs male players. Of particular interest was the posture as players stepped backward to the backhand-side rear court with a single-leg landing following an overhead stroke. We proposed two hypotheses in this study: First, female badminton players presented with significantly higher knee valgus angles and moments compared with male players during a single-leg landing. Second, we hypothesized that the differential kinematic and kinetic changes in the hip, knee, and ankle joints during single-leg landings also contributed to an elevated risk of ACL injury in female vs male players.

Materials and Methods

Participants

Ten male and ten female badminton players were enrolled in this study. They all participated in the University school badminton team and practiced at least three times per week. The inclusion criteria included no prior surgery and no history of injury in the trunk, spine, or four extremities and no limitations in any joint’s range of motion or muscle weakness. All subjects were right-hand dominant and held the racket in the right hand. Before participating in this study, all subjects read and signed the approval consent. Ethical approval was granted by the Medicine Institutional Review Board and adhered to the Declaration of Helsinki.

Laboratory Set-Up

Six camera motion-analysis system (Qualisys Motion Capture Systems, Qualisys AB, Sweden) was used to collect the trial data at a sampling frequency of 100 Hz. The ground reaction force was collected by the force plate (Kistler Instrument, Inc, Winterthur, Switzerland) embedded in the floor a sampling frequency of 400 Hz. Before testing, the motion analysis system and force plate were set up synchronously and were calibrated with Qualisys Track Manager software (version 1.9.254; Qualisys). Every subject was fitted with 19 retroreflective markers on the anatomical landmarks as Helen Hayes model. The motions of the hips, knees, and ankles in the sagittal, frontal, and transverse planes were captured using the Qualisys Motion Capture Camera Systems. The captured trajectories of the retroreflective markers were recorded with Qualisys Track Manager software (version 1.9.254; Qualisys).

Testing Procedure

The testing procedure and purposes were explained to each subject before testing. The sex, age, body weight, body height, and experience with badminton (i.e., number of years playing the game) were recorded.

Based on previous research, the stepping backward to the backhand-side rear court with a single-leg landing after an overhead stroke is associated with high-risk postures for ACL injury as described by Kimura [13] and shown in Fig. 1. To minimize the bias of individual differences in footsteps and overhead strokes, an experienced coach who was blinded to the topic of this study from the university’s badminton team modeled the appropriate actions to ensure that subjects’ uniform movements desired during the recording. A 45-degree-line on the floor was marked and the participants can perform backward single-leg landing on the force plate directly and then back to starting point (Fig. 1). All subjects were permitted to practice the task several times and then performed and recorded eight to ten successful trials. To prevent injury and familiarize the experiment environment, all participants were asked to perform 15 minutes warming up (running, static stretch, and several badminton overhead strokes) without markers before the test and a 30-s rest between each trial to minimize the influence of fatigue. Moreover, all participants used the same rackets provided by the laboratory to reduce the errors in the experiment.
Data Analysis

All data regarding marker trajectories were recorded and digitized by QTM software. The kinematic and kinetic data from the sagittal, frontal, and transverse planes of the left hip, knee, and ankle joints were analyzed by the Visual 3D software program and are presented as means (standard deviation; SD) for all trials. First, we identified and subtracted value of the stance phase which was determined the timings of the initial contact (IC) to the toe off (TO) of the left leg landing on the force plate with threshold values set at 10 N. Further, we analyzed the impact phase of the landing because most noncontact ACL injuries occur during the early phase of the landing \[13, 15\]. The impact phase of landing was defined as IC to the maximum knee flexion (MKF) during landing. The kinematic data were normalized in the range from 0% at IC to 100% at TO in the stance phase and from 0% at IC to 100% at MKF in the impact phase. The joint force and moment in the kinetic data were normalized by body weight. The kinematic and kinetic data of the left knee joint during the stance and impact phases were recorded. Statistical comparisons of the kinematic and kinetic data between female and male badminton players were made by independent \(t\)-test using SPSS version 14 software (SPSS, Chicago, IL, USA). A \(p\) value < 0.05 was considered to be statistically significant.

Results

Ten female and ten male badminton players participated in the study. There were no significant differences in average age and badminton-playing experience. The average height of female players was significantly shorter than that of male players, and the body weight was significantly lower in female compared to male players. The results of subject profiles are shown in the Table 1. The significant differences in body height and weight between female and male players is typical of the normal distributions of height and weight.
among athletes in south Asia [16]. The body heights and weights were normalized for calculation of the kinetic data.

Table 1  The subject profiles of female and male badminton players

<table>
<thead>
<tr>
<th></th>
<th>Female (n = 10)</th>
<th>Male (n = 10)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>23.44 ± 4.17</td>
<td>21.76 ± 2.34</td>
<td>.301</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>161.70 ± 5.78</td>
<td>175.22 ± 3.86</td>
<td>.000</td>
</tr>
<tr>
<td>Body weight (Kg)</td>
<td>54.60 ± 4.22</td>
<td>67.67 ± 9.57</td>
<td>.001</td>
</tr>
<tr>
<td>Experiences (years)</td>
<td>3.65 ± 3.49</td>
<td>4.78 ± 3.24</td>
<td>.477</td>
</tr>
</tbody>
</table>

The average duration of the impact phase in the female badminton players was significantly shorter than that of male players (p = 0.006). No significant difference was found in the maximal knee flexion (MKF) angle during the stance phase between female and male players (p = 0.421) (Fig. 2a, d, Symbol ▲). Significant greater in knee valgus angle in the female players compared with the male players were present in the IC (p = 0.001), MKF (p = 0.009), and maximal knee valgus angle (p = 0.004) (Fig. 2e). The kinematic changes in the knee joint during the stance phase are summarized in Table 2.

![Fig. 2 The kinematic changes between sexes in stance phase A–C and impact phase D–F of the landing knee. Symbol * presents significant difference p < .05; ** presents highly significant difference p < .01. Symbol ▲ presents maximal knee flexion time point](image-url)
During the impact phase, the maximal knee extension moment ($p=0.042$) (Fig. 3a) and knee’s external rotation moment in IC ($p=0.017$) (Fig. 3c) was significantly larger in the female players compared with that in male players. The knee valgus moment in male players showed a trend toward being larger than that in female players during the impact phase, the significance appeared during the IC ($p=0.032$) (Fig. 3b). The knee joint moment changes during the impact phase are summarized in Table 3.

The change of knee lateral/medial force in female players initialized with knee lateral force opposite in male players with knee medial force in the IC with significant difference ($p=0.001$) (Fig. 3d). The maximal knee compression force was significantly larger in female players compared with male players ($p=0.030$) (Fig. 3f). The knee joint force changes during the impact phase are summarized in Table 4.

During the impact phase of landing, the female players had a significantly smaller hip flexion angle than did male players ($p=0.017$) in the MKF (Figs. 4a). The hip abduction angle was significantly smaller in female players compared with male players ($p=0.009$) in the IC during the impact phase (Figs. 4b). In the MKF of the impact phase, the female players presented significant greater hip external rotation angles compared with male players ($p=0.009$) with hip internal rotation angles (Figs. 4c). The female players presented obviously larger ankle dorsiflexion angles ($p=0.012$) (Fig. 4d) and inversion angles ($p=0.005$) (Fig. 4f) compared to that of male players in MKF during the impact phase. These data of kinematic changes of hip and ankle joints are summarized in supplementary data.

### Discussion

In this study, we investigated the task of stepping backward to the backhand-side rear court with a single-leg landing after an overhead stroke to investigate the kinematic and kinetic differences in the landing leg between female and male badminton players. This study demonstrated significant kinematic and kinetic differences in the hip, knee, and ankle joints of female vs male badminton players during landing in an ACL injury risky posture in badminton. The female players showed a shorter stance phase, a larger hip external rotation angle, a larger knee valgus angle, greater knee extension and external rotation moment, less knee valgus moment, greater knee compression force, and greater ankle dorsiflexion and inversion angle during landing. Conversely, the male badminton players showed a longer stance phase, more hip flexion and abduction and a greater internal rotation angle, a larger knee varus angle, greater knee valgus moment, and less knee compression force during landing.

Previous studies have found that increased knee valgus angles and moments during landing are associated with a greater risk of ACL injuries in female athletes [5, 10, 11, 17]. Therefore, we hypothesized that the knee valgus angle and moment would be higher in female athletes compared to male athletes during badminton movements associated with increased risk of ACL injury. However, in the study results disproved the hypothesis by showing a significantly higher knee valgus angle in female players but a higher valgus moment in male badminton players during badminton landing. In the coronal plane of knee motion during the impact phase, we found that female badminton players maintained the knee in the valgus position; conversely, male players kept the knee in the varus position with significant differences. During the impact phase, the knee valgus moment in female players was smaller than that in male players and showed a significant difference in IC phase. Possible reasons for these findings against the hypothesis may be the male badminton player presented with significant knee varus angle (Fig. 2e) with larger medial knee force (Fig. 3d) in IC during the impact phase, resulting in increased knee valgus moment compensatorily (Fig. 3b). Conversely, the female players landed initially with knee valgus angle and significant higher

| **Table 2** Knee joint kinematics (Means (SD Standard Deviations; degrees) at initial contact (IC) and maximal knee flexion (MKF) during the impact phase of landing |
|------------------|------------------|-----------------|--------|
| **Extension**    | **Flexion**      | **Valgus**      | **Varus** |
| **Internal rotation** | **External rotation** | **IC**         | **MKF**  | **IC** | **MKF** | **p value** |
| **IC**           | **MKF**          | **IC**          | **MKF**  |        |        |          |
| Female ($n=10$)  | Male ($n=10$)    |                |          |        |        |          |
| Extension +      | IC               | −29.09° (7.83°) | −24.28° (7.19°) | .183  |
| Flexion −        | MKF              | −58.10° (7.63°) | −61.78° (11.58°) | .421  |
| MCF time (s) (% of stance phase) | 31.52 (11.62 %) | 52.00 (16.56 %) | .006** |
| Valgus +         | IC               | 5.06° (6.83°)  | −5.10° (4.30°)  | .001** |
| Varus −          | MKF              | 4.33° (11.99°) | −9.26° (6.97°)  | .009** |
| Max valgus angle | IC               | 7.58° (9.54°)  | −3.92° (4.22°)  | .004** |
| External rotation + | IC              | −1.63° (1.55°) | −2.32° (0.98°)  | .267   |
| Internal rotation − | MKF             | −3.36° (4.38°) | −2.66° (4.51°)  | .738   |

IC initial contact; MKF maximum knee flexion

*Presents a significant difference ($p<.05$); **presents a highly significant difference ($p<.01$)
lateral force which induced a knee varus moment to balance the risky landing posture and avoid excessive lateral collapse. According to the data, the increased knee valgus angle and moment during landing may predict the higher risk of ACL injury risk between injured and noninjured female athletes, but they cannot explain the different incidence of ACL injury between females and males.

Kinematic changes in the sagittal plane during landing in female and male athletes has been discussed in some previous studies [10, 17–20]. Salci et al. [19] performed a landing-motion analysis in female and male volleyball athletes; the results showed that female athletes had significantly lower knee and hip flexion angles than did male athletes. Decker [20] found that female athletes presented greater knee extension and ankle plantar flexion with a similar maximum knee flexion angle compared to male athletes. In our study, the female players presented significantly smaller hip flexion angles and larger ankle dorsiflexion angles than
did male players; however, we found no difference in the maximal knee flexion angle in badminton players of either sex. We also found that the total duration of the impact phase was 21% shorter in female athletes than in male athletes. Our study indicated that female badminton players landed with more ankle dorsiflexion to compensate for less hip flexion and more erect posture with a shorter energy-absorbing time; male badminton players landed with more hip flexion with stronger thigh muscle control and a longer impact phase to absorb the impact force.

Few articles have examined hip and ankle joint biomechanical changes in the coronal and transverse planes during the landing phase in female vs male athletes [21]. Our study revealed that female players presented a greater ankle inversion angle in MKF and that male players performed more hip abduction in IC during the landing impact phase. In the knee valgus landing position, female athletes used the strategy of increasing ankle inversion instead of the hip joint in the coronal plane to compensate for the valgus knee posture during risky landing postures in badminton movements.

The force applied to the knee during landing may affect the risk of ACL injuries [22, 23]. In our study, the female badminton players presented a knee valgus angle with significantly larger knee lateral force in IC and more compression force during the impact phase in risky landing postures, which may correlate with the increasing risk of knee injury during badminton movements.

We acknowledge that the present study has a number of limitations. This study was limited with small sample size and the nonrandom acquisition of subjects in both groups. Moreover, we had limited data from the participants’ muscle power, girth, maximal jumping height, calcium and Vitamin D profile in this study. Furthermore, we limited in laboratory construction and equipment with room height, camera numbers and sampling rate which might affect landing force and data sampling. In this study, the measurement errors of Helen Hayes model which include the knee marker misplacement, the errors from skin movement artifacts, the definition of joint center location, and leg length difference might influence the kinematic result (24–26). Participants’ different badminton skill levels

### Table 3
Knee joint kinetic moment (Means (SD Standard Deviations; N∙m/kg) at initial contact (IC) and maximal knee flexion (MKF) during the impact phase of landing

<table>
<thead>
<tr>
<th></th>
<th>Female(n = 10)</th>
<th>Male(n = 10)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension +</td>
<td>IC</td>
<td>−0.06 (0.22)</td>
<td>−0.14 (0.23)</td>
</tr>
<tr>
<td>Flexion −</td>
<td>MKF</td>
<td>0.46 (0.44)</td>
<td>0.27 (0.42)</td>
</tr>
<tr>
<td>Max extension moment</td>
<td>IC</td>
<td>1.03 (0.47)</td>
<td>0.60 (0.37)</td>
</tr>
<tr>
<td>Valgus +</td>
<td>IC</td>
<td>−0.09 (0.12)</td>
<td>0.03 (0.10)</td>
</tr>
<tr>
<td>Varus −</td>
<td>MKF</td>
<td>−0.01 (0.23)</td>
<td>0.14 (0.16)</td>
</tr>
<tr>
<td>Max valgus moment</td>
<td>IC</td>
<td>0.11 (0.17)</td>
<td>0.18 (0.13)</td>
</tr>
<tr>
<td>External rotation +</td>
<td>IC</td>
<td>0.06 (0.06)</td>
<td>−0.02 (0.06)</td>
</tr>
<tr>
<td>Internal rotation −</td>
<td>MKF</td>
<td>0.05 (0.07)</td>
<td>−0.02 (0.10)</td>
</tr>
<tr>
<td>Max external rotation moment</td>
<td>IC</td>
<td>0.11 (0.07)</td>
<td>0.14 (0.14)</td>
</tr>
</tbody>
</table>

*IC initial contact, MKF maximum knee flexion
*presents a significant difference (p < .05); **presents a highly significant difference (p < .01)

### Table 4
Knee joint force (Means (SD Standard Deviations; Body Weight) at initial contact (IC) and maximal knee flexion (MKF) during the impact phase of landing

<table>
<thead>
<tr>
<th></th>
<th>Female(n = 10)</th>
<th>Male(n = 10)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral +</td>
<td>IC</td>
<td>0.42 (0.48)</td>
<td>−0.38 (0.43)</td>
</tr>
<tr>
<td>Medial −</td>
<td>MKF</td>
<td>−0.33 (0.35)</td>
<td>−0.11 (0.29)</td>
</tr>
<tr>
<td>Posterior +</td>
<td>IC</td>
<td>0.33 (0.85)</td>
<td>0.22 (0.71)</td>
</tr>
<tr>
<td>Anterior −</td>
<td>MKF</td>
<td>−0.98 (0.88)</td>
<td>−0.72 (1.04)</td>
</tr>
<tr>
<td>Maximum posterior force</td>
<td>IC</td>
<td>0.58 (0.72)</td>
<td>0.96 (0.38)</td>
</tr>
<tr>
<td>Tension +</td>
<td>IC</td>
<td>0.61 (0.44)</td>
<td>1.15 (0.57)</td>
</tr>
<tr>
<td>Compression −</td>
<td>MKF</td>
<td>−2.18 (1.98)</td>
<td>−1.25 (2.02)</td>
</tr>
<tr>
<td>Maximum compression force</td>
<td>IC</td>
<td>−5.70 (2.68)</td>
<td>−2.78 (2.49)</td>
</tr>
</tbody>
</table>

*IC initial contact, MKF maximum knee flexion
*presents a significant difference (p < .05); **presents a highly significant difference (p < .01)
might be an important factor that affected the performance of badminton maneuvers in this study. The relationship between these biomechanical differences and real ACL injuries is still in question.

In conclusion, we found higher knee valgus angles in female players during risky landing postures in badminton movements associated with ACL damage. However, the increased valgus moment of the landing knee is not the predicting factor for ACL injury in female and male badminton players. The concomitant kinematic and kinetic changes of the hip, knee, and ankle joints also play an important part in the differential incidence of ACL injury between female and male athletics.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s43465-021-00421-6.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent For this type of study, informed consent is not required.

References

Effects of Local Administration of Tranexamic Acid on Reducing Postoperative Blood Loss in Surgeries for Closed, Sanders III–IV Calcaneal Fractures: A Randomized Controlled Study

Lang Zhong¹ · Yu Liu¹ · Yongcai Wang¹ · Hongchuan Wang¹

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Abstract
Purpose To investigate whether local administration of tranexamic acid (TXA) is effective in postoperative blood loss reduction in surgeries for Sanders III–IV calcaneal fractures.

Methods Calcaneal fracture patients who were hospitalized in our hospital from August 2014 to April 2018 and underwent open reduction internal fixation (ORIF) via lateral approach with an L-shaped incision were included in the present study. 53 Patients were randomly divided into three groups, groups A (17), B (17) and C (19). Twenty milliliters of 10 mg/ml and 20 mg/ml TXA solution were perfused into the incision of patients in group A and group B, respectively. Twenty milliliters of saline were perfused into the incision of patients in group C as control. The volume of postoperative drainage, postoperative blood test, coagulation test, and wound complications were analyzed to evaluate the effectiveness of local administration of TXA on blood loss reduction.

Results The amount of drainage at 24 and 48 h after the procedure was 110 ± 170, 30 ± 10 ml and 130 ± 160, 20 ± 17 ml for patients in group A and group B, respectively. The corresponding numbers for patients in group C were 360 ± 320, 20 ± 10 ml. The difference between group A and group C was statistically significant, so was the difference between group B and group C. No statistically significant difference was found between group A and group B. Postoperative blood test results revealed that the levels of hemoglobin and hematocrit were significantly higher in group A and group B when each compared to that of group C. In contrast, no difference was found between group A and group B. No significant difference was found between each experimental group and the control group in terms of platelet counts, prothrombin time (P.T.), activated partial prothrombin time (APTT), and wound complications.

Conclusion Local administration of TXA is effective in the reduction of postoperative blood loss in surgeries for Sanders III–IV types of calcaneal fractures without notably associated side effects.

Keywords Calcaneal fracture · Tranexamic acid · Postoperative blood loss · Complication

Introduction
Calcaneal fractures account for approximately 2% of all bone fractures and represent 60% of fractures of tarsal bones [1]. For closed, Sanders III–IV calcaneal fractures, open reduction internal fixation (ORIF) is the standard treatment. However, a large amount of perioperative blood loss is usually associated with the surgeries to repair calcaneal fractures as calcaneus is a cancellous bone with abundant blood supply, which increases the chance of blood transfusion and the associated risks to patients with calcaneal fractures [2]. The usage of tourniquet in calcaneal fracture repairing surgeries significantly reduced the blood loss during the procedure, but the amount of postoperative blood loss remains large. Moreover, the large amount of postoperative blood loss around the affected calcaneus will also increase the risk of wound complications [3]. Therefore, new approaches to reduce postoperative blood loss in calcaneal fracture repairing surgeries remain to be developed [4].

Tranexamic acid (TXA) is a synthetic analog of lysine that functions as an antifibrinolytic agent through the competitive binding to the lysine sites on plasminogen,
plasmin, and plasminogen activator [5], by which it inhibits fibrinolysis and thrombolysis to reduce the blood loss due to the surgeries effectively. TXA is widely used in cardiovascular surgeries, hip and knee surgeries, and spine surgeries [6–8]. Recently, more and more clinicians are interested in the local administration of TXA in surgeries due to the risk of deep venous thrombosis induced by intravenous usage of TXA [9]. Kim and the colleagues reported that TXA was more effective when used intraarticularly than intravenously with respect to the reduction of perioperative blood loss and lowering the blood transfusion rate [10]. In the present study, we investigated the effects of local administration of TXA in the incision on blood loss reduction in the ORIF procedure for calcaneal fractures. Postoperative drainage volume wound complications, postoperative coagulation index, and other factors were analyzed to evaluate the effects of local administration of TXA on the reduction of postoperative blood loss in surgeries for closed, Sander III–IV calcaneal fractures.

Patients and Methods

Ethics Approval and Consent to Participate

This study was approved by the local institutional review board of Leshan People’s Hospital. Written informed consent (including patients’ details, images, or videos) was obtained from all participants. All experiments were performed in accordance with relevant guidelines and regulations. This study was conducted in accordance with the Declaration of Helsinki.

Patients hospitalized in Leshan People’s Hospital from August 2014 to April 2018 for ORIF to repair calcaneal fractures were included in the present study, including 42 males and 11 females. Patients were randomly divided into three groups, with a random number table method. There were 17, 17, and 19 patients in experimental group A, experimental group B, and control group C, respectively.

Inclusion Criteria

The inclusion criteria were as the following: (1) patients who underwent ORIF with conventional plates and pins via extended lateral approach with L-shaped incision for closed, Sanders III–IV calcaneal fractures; (2) patients’ age ranged from 18 to 70 years; and (3) patients were fully informed about the surgeries and the trial, and the consent form was signed by each participated patient. The trial was approved by the ethics committee of the hospital.

Exclusion Criteria

Patients were excluded from the present study if met one or more of the following criteria: patients who had coagulation problem before the procedure (preoperative platelet count < 1.5 × 10^5/mm^3, international normalized ratio (INR) > 1.4, or activated partial thromboplastin time (APTT) > 1.4-folds of normal range); patients with impaired liver function or kidney function; patients who had peripheral vascular diseases, history of vascular thrombosis, or history of long-term usage of anticoagulation medications.

TXA Solution Preparation

TXA solution was prepared in a syringe under sterile condition. 5 ml TXA stock solution (100 mg/ml) (Tranexamic Acid Injection®, TIANXIN CO.LTD, Guangzhou, China) was first drawn into a 60 ml sterile syringe, then 45 ml of physiological saline was drawn into the same syringe to dilute the TXA to 10 mg/ml. The solution was mixed well by gently shaking. The 20 mg/ml TXA solution was prepared in similar way except diluting the 5 ml TXA stock solution with 20 ml physiological saline. The syringe and the procedure are shown in Fig. 1 with representative photos.

Surgical Procedures

Surgical procedures were performed when the affected foot showed no signs of swelling and/or blisters (dermatoglyphic pattern positive). All the surgeries were performed by the same surgeon. Patients laid down on the healthy side, and tourniquets were used on the affected limb. The pressure for the tourniquet was set as 100 mmHg higher than the patient’s arterial pressure. An L-shaped incision was made dorsolateral to the fractured calcaneus to achieve a sharp, subperiosteal dissection for a full-thickness flap. The L-shaped incision was made up to the subtalar joint level vertically and stopped at the calcaneocuboid joint horizontally. Once the incision was made, the full-thickness flap was held in place with three 2.0 mm Kirschner wires by screwing one Kirschner wire into each of fibula, talus and cuboid tightly close to, and underneath the full-thickness flap. Then the incision was opened by static traction to expose the calcaneocuboid joint and subtalar joint. Bohler angle and Gissane angle were restored by prying. The length, height, and width of the calcaneus were restored using c-arm pliers. Allograft bone was used to fill the large defect that remained after the reduction. Once the reduction was satisfactorily performed, fixation was performed with the calcaneal plate. Before removing the tourniquet, the drainage tube (external 6 mm, internal
3 mm) was placed into the incision, and the incision was closed. 20 ml TXA solution or saline were perfused into the incision through the drainage tube. Then the drainage tube was clamped and connected to a 200 ml negative pressure drainage bottle. A representative picture of the drainage tube connected to a negative pressure drainage bottle is shown in Fig. 2. In addition, a representative figure demonstrating the position of drainage tube placement in the closed wound was shown in Fig. 3.

**TXA Treatment and Postoperative Management**

20 ml TXA solution was perfused into the incision of patients. The concentration of TXA in the solution was 10 mg/ml and 20 mg/ml for group A and group B, respectively. Plain saline without TXA was used as a control to be
perfused in the control group. The incision was bandaged with compression for patients in all groups. The drainage tube was re-opened 2 h after the clamping of the drainage tube, and it was removed 48 h after the surgery. Routine management of patients included the application of antibiotics for 24 h. The affected foot was intermittently iced and raised for 3 to 4 days. Patients started extension and flexion training for the affected ankle joint 2 weeks after the surgery and started weight training for the ankle 3 months after the surgery.

**Outcome Measurement**

Baseline clinical characteristics were monitored to assess the homogeneity among the groups. Collected data included age, gender, BMI index (Body mass index), preoperative blood test, anesthesia method, types of fracture, and the surgery duration.

The primary outcome measurements included the volume of drainage 24 h and 48 h after the procedure. The volume of postoperative drainage was calculated by subtracting 20 ml (the amount of perfused solution) from the total volume of drainage at the indicated time. Other primary outcomes monitored included postoperative routine blood test and coagulation test, as well as wound complications, including dehiscence, peri-wound necrosis, infection, and hematoma.

**Statistical Analysis**

SPSS 17.0 software was used to analyze the data. Data were presented as mean ± SD. One-way ANOVA was used to analyze categorical data between two groups, and $p < 0.05$ was considered significant. Two-sided Chi-squared test was used to analyze numerical data, and $\alpha$ value was set to 0.05.

### Results

Overall, 53 patients with Sanders III–IV calcaneal fractures participated in the present study, including 42 males and 11 females. They were randomly divided into three groups, group A, group B and group C. 20 ml of 10 mg/ml and 20 mg/ml TXA solution was perfused into the closed incision via drainage tube for patients in group A and group B, respectively. Moreover, 20 ml of physiological saline was perfused in the closed incision for patients in group C as control. The preoperative baseline data and the postoperative outcomes were analyzed to evaluate the effects of TXA local administration in surgeries for calcaneal fractures.

**Preoperative Baseline Data**

As illustrated in Table 1, No significant difference was found among the three groups in terms of preoperative baseline data, including gender, age, BMI index, preexisting conditions (such as diabetes, hypertension, hypothyroid etc.), waiting time until the operation, and the preoperative routine blood test results.

**Primary Outcomes**

The most important primary outcome we would like to analyze in the present study was the postoperative blood loss. As shown in Table 2, the average amount of postoperative drainage amount at 24 and 48 h were 110 ± 170, 130 ± 160 ml for patients in group A, and 130 ± 160, 20 ± 17 ml for patients in group B, respectively. Those numbers mentioned above were significantly less compared to the corresponding numbers of patients in group

Table 1  Baseline data of participated patients

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (M/F)</td>
<td>13/4</td>
<td>14/3</td>
<td>15/4</td>
<td>1.000</td>
</tr>
<tr>
<td>Age (years)</td>
<td>43.1 ± 8.5</td>
<td>40.4 ± 9.0</td>
<td>40.4 ± 8.9</td>
<td>0.573</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>23.8 ± 2.6</td>
<td>23.8 ± 2.6</td>
<td>24.0 ± 2.5</td>
<td>0.965</td>
</tr>
<tr>
<td>Pre-existing conditions (Yes/No)</td>
<td>3/14</td>
<td>3/14</td>
<td>4/15</td>
<td>1.000</td>
</tr>
<tr>
<td>Waiting period before surgery</td>
<td>11.5 ± 2.3</td>
<td>11.8 ± 2.7</td>
<td>11.8 ± 2.7</td>
<td>0.931</td>
</tr>
<tr>
<td>Preoperative blood test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (g/dl)</td>
<td>12.2 ± 0.85</td>
<td>12.3 ± 1.47</td>
<td>12.2 ± 1.24</td>
<td>0.960</td>
</tr>
<tr>
<td>Platelet count (10⁹/l)</td>
<td>255.0 ± 38.0</td>
<td>257.5 ± 40.6</td>
<td>256.4 ± 28.8</td>
<td>0.979</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>38.8 ± 3.6</td>
<td>38.7 ± 4.3</td>
<td>39.2 ± 3.3</td>
<td>0.309</td>
</tr>
<tr>
<td>PT (S)</td>
<td>12.5 ± 1.3</td>
<td>13.1 ± 0.9</td>
<td>12.7 ± 1.4</td>
<td>0.788</td>
</tr>
<tr>
<td>APTT (S)</td>
<td>38.1 ± 4.6</td>
<td>38.6 ± 3.9</td>
<td>38.3 ± 3.7</td>
<td>0.595</td>
</tr>
</tbody>
</table>

BMI: Body mass index; APTT: activated partial thromboplastin time, P.T.: prothrombin time; Numbers were presented as mean ± SD
Table 2 Postoperative blood test result

<table>
<thead>
<tr>
<th>Types of test</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative drainage (ml)</td>
<td>24 h</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (g/dl)</td>
<td>12.3 ± 0.9</td>
<td>12.2 ± 1.1</td>
<td>10.8 ± 1.6</td>
<td>0.008*</td>
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<tr>
<td>Platelet count (10^9/l)</td>
<td>245.0 ± 56.2</td>
<td>245.0 ± 56.2</td>
<td>245.0 ± 56.2</td>
<td>0.869</td>
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<tr>
<td>Hematocrit (%)</td>
<td>38.1 ± 3.5</td>
<td>37.8 ± 3.2</td>
<td>32.2 ± 3.6</td>
<td>0.000*</td>
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<tr>
<td>PT (S)</td>
<td>12.7 ± 1.4</td>
<td>13.1 ± 1.3</td>
<td>12.3 ± 1.1</td>
<td>0.178</td>
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<tr>
<td>APTT (S)</td>
<td>37.6 ± 4.4</td>
<td>38.2 ± 3.8</td>
<td>38.5 ± 3.6</td>
<td>0.595</td>
</tr>
</tbody>
</table>

APTT: activated partial thromboplastin time; PT: prothrombin time, numbers were presented as mean ± SD. *p < 0.05.

Table 3 Postoperative wound complications

<table>
<thead>
<tr>
<th>Types of complication</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dehiscence</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.000</td>
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<tr>
<td>Peri-wound necrosis</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0.503</td>
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<tr>
<td>Hematoma</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1.000</td>
</tr>
<tr>
<td>Superficial infection</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1.000</td>
</tr>
<tr>
<td>Deep infection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>0.955</td>
</tr>
</tbody>
</table>

C (control group), which were 360 ± 320, 20 ± 10 ml, respectively (p < 0.01; p < 0.05, respectively). No statistically significant difference was found between group A and group B with respect to the drainage volume, indicating that the concentration of 10 mg/ml of TXA is high enough to effectively reduce the postoperative blood loss (p = 0.664; p = 0.844, respectively). Consistently, a postoperative routine blood test revealed that the average levels of hemoglobin and hematocrit were significantly higher in group A and group B compared to those in group C (p = 0.008, p = 0.000, respectively). However, no difference was found between group A and group C, nor between group B and group C in terms of platelet count, prothrombin time (P.T.), and activated partial thromboplastin time (APTT), suggesting that the systematic coagulation was not affected by the local administration of TXA.

We also investigated the effect of TXA administration on the occurrence of common wound complications, including dehiscence, peri-wound necrosis, infection, and hematoma. No significant difference was found between the experimental groups and the control group. The detailed result is listed in Table 3. No systemic complication such as deep vein thrombosis was found in the study. Patients who had wound complications in all groups received corresponding treatments according to their specific complications. For those patients who had peri-wound necrosis and/or superficial infection, a prophylactic empirical course of oral antibiotics and wound care with damp-to-dry dressing changes were applied until the wound healed. Figure 4 shows a representative process of wound healing under the treatments in a patient in group C.

Discussion

Although tourniquets can be used to reduce the intraoperative blood loss in surgeries to repair the calcaneal fracture, the amount of postoperative blood loss is still relatively large. A large amount of postoperative blood loss will result in the deterioration of patients’ overall health status and will increase the chance of transfusion for patients, especially for those who have a compound injury or those who have severe, chronic underlying conditions [9]. Moreover, using tourniquets for a long time will not only lead to ischemia and hypoxia but also cause ischemia–reperfusion damages to the affected limb after removing the tourniquet, which will result in the activation of tissue plasminogen and ultimately the increase of postoperative blood loss. This is particularly true within 6 h after the tourniquet removal [10].

TXA, a synthetic analog of lysine, can be used to inhibit the activities of core enzymes in fibrinolysis, such as plasminogen and plasmin. It is reported that TXA could reduce perioperative blood loss by inhibiting fibrinolysis [11]. TXA has been widely used in various types of surgeries, and the dosage and using conditions have been discussed. Xie et al. reported in a randomized controlled trial that intravenous injection of 15 mg/ml TXA solution before making the incision significantly reduced the drainage volume in surgeries for Sanders II–III types of calcaneal fractures [12, 13].

However, one of the risks of systematic administration of TXA is to increase the chance of deep vein thrombosis after hyperfibrinolysis caused by TXA, which is also the case for TXA administration in surgeries [14]. Therefore, researchers investigated the possibility of local administration of TXA in surgeries. Ma et al. described the local administration of TXA in the procedure of total knee arthroplasty by perfusing TXA solution into the closed incision via drainage tube and clamping the tube for a certain amount of time to maintain the local treatment of the affected tissue with TXA [15]. It turned out that the local administration of TXA significantly reduced postoperative blood loss without increasing the occurrence of complications. Based on these findings, we tested the effects of local administration of TXA in surgeries for the
Calcaneal fracture to see if it can reduce the blood loss without inducing other complications. The results presented in our study demonstrated perfusion of TXA into the incision effectively reduced the postoperative drainage amount at day one and day two after the surgery without increasing the risk of coagulation, and the postoperative hemoglobin level was higher in TXA treated patients than that of saline-treated patients, suggesting that local administration of TXA is a promising approach to avoid large amount postoperative blood loss in surgeries for calcaneal fractures. Notably, we did not find the higher concentration of TXA (20 mg/ml) was better than the lower concentration of TXA (10 mg/ml) in terms of reducing blood loss, suggesting that the concentration of 10 mg/ml of TXA is enough.

Further investigations are required to optimize the dosage of TXA and the duration of treatment to get better results. Xie and his colleagues reported a similar effect of TXA on the blood loss reduction in calcaneal fracture surgeries [13]. In their study, they found less blood loss after surgery and no significant increase of thromboembolic events or adverse drug reaction in TXA treatment group compared to that of control group. Compared to their study, we treated the wound locally, resulting in a hugely reduced amount of TXA application. Based on the dramatically reduced amount of TXA usage, we speculated that TXA treatment in our study may reduce the chance for systematic complications caused by TXA, such as thrombosis, even more. Furthermore, local administration, instead of intravenous injection of TXA may also make the risks of systematic complications induced by TXA lower. More studies are required to confirm the speculation.

In addition to the blood loss, we also investigated whether local treatment by TXA has an effect on the occurrence of postoperative complications. Although the result demonstrated no difference between TXA treated groups and the control group, the greatly reduced postoperative blood loss may reduce the risk of complications. Moreover, as an anti-fibrinolysis agent, TXA inhibits the activity of plasmin, leading to the inhibition of pro-inflammatory factors, such as monocytes, neutrophils, platelet, endothelial cells, complement system and cytokines, which may reduce the risk of complications.
wound complications such as infection [12, 13]. More cases need to be studied to reach a conclusion.

To our knowledge, this is the first report about the local administration of TXA in calcaneal fracture repairing surgeries. The participated patients in each group showed no difference in terms of baseline data, including age, gender, waiting time before surgery, underlying medical conditions, and preoperative coagulation. Furthermore, all the surgeries were performed by the same experienced surgeon with the same approach, making the data from each group comparable to the biggest extent. However, the size of the trial in our study is relatively small; secondly, the present study excluded patients having underlying conditions such as abnormal coagulation or history of thrombosis, in whom local administration of TXA might have greater benefits on the reduction of blood loss and postoperative complications. A larger sized trial, including those patients having various preexisting conditions, is required to comprehensively evaluate the benefits of local administration of TXA, especially surgery-associated complications.

Conclusions

In the present study, we validated that local administration of TXA effectively reduced the postoperative blood loss in surgeries for Sanders III–IV types of calcaneal fractures without increasing the incidence of wound complications, suggesting the potential benefits of local administration of TXA in treatment for calcaneal fractures.

Acknowledgements Not applicable.

Authors Contributions We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. L.Z., Y.W., and Y.L. carried out the study. L.Z. Wrote the manuscript with support from H.W., L.Z., Y.W. H.W. and Y.L. fabricated the analysis. H.W. helped supervise the project.

Declarations

Conflict of interest The authors declare that there is no conflict of interest regarding the publication of this article, and all the authors and the institution are consented to publish. The data that support the findings of this study included in this manuscript and the original files are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate This study was approved by the local institutional review board of Leshan People’s Hospital. Written informed consent (including patients’ details, images, or videos) was obtained from all participants. All experiments were performed in accordance with relevant guidelines and regulations. This study was conducted in accordance with the Declaration of Helsinki.

Patients hospitalized in Leshan People’s Hospital from August 2014 to April 2018 for ORIF to repair calcaneal fractures were included in the present study, including 42 males and 11 females. Patients were randomly divided into three groups, with a random number table method. There were 17, 17, and 19 patients in experimental group A, experimental group B, and control group C, respectively.

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References


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Posterolateral Plating of Distal Tibia Fractures: Extending the Use of a Familiar Approach

Rishi Malhotra1 • Aaron Qi Yang Goh2 • Antony W. Gardner1

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Abstract
Background Distal tibia fractures present challenges in surgical management and when nailing is not an option, plate osteosynthesis is performed. This is usually done with a minimally invasive approach to reduce the risk of wound complications in an already fragile soft-tissue envelope. We propose that a posterolateral open approach can lead to stable fixation construct and comes with advantages of approaching fibula fractures via same approach and has a thicker soft tissue envelope over the fixation. We report a series of distal tibia fractures with posterolateral plate fixation and present the outcomes.

Methods This is a retrospective review conducted at a single institution, where 13 patients underwent posterolateral approach for distal tibia fracture fixation. Where required, medial plating and fibular fixation was additionally performed. Patients were followed-up with primary endpoint of successful clinical and radiological union or complications required re-intervention. Operative and long-term clinical outcomes were recorded.

Results Long term follow-up was available for 12 patients. There was 1 non-union requiring revision (8.3%). For the other patients, clinical union occurred by 14.5 weeks and radiological union by 20 weeks on average. There was no malunion and 2 patients (16.6%) underwent removal of implants for symptoms of hardware irritation.

Conclusion We found that outcomes in our cohort demonstrate posterolateral plating is safe as a primary or adjunctive method of fixation, and does not compromise other outcomes when compared with traditional fixation methods.

Keywords Distal tibia fracture • Open reduction internal fixation • Posterolateral approach • Plating

Introduction
The tibia is a commonly fractured long bone in adults, and fractures of the distal third of the tibia make up a third of all tibia fractures [1]. However, the treatment of distal tibia fractures remains a challenge. Several authors have alluded to increased surgical complications in distal tibia fractures in view of the limited soft tissue envelope and reduced vascularity [2–6]. Tibial nailing may not be feasible in very distal fractures. While plating of distal tibial fractures is commonly done, it has inherent problems in terms of soft tissue damage from surgery and hardware irritation, in view of a thin soft tissue envelope [7].

Popular approaches to distal tibial plating include medial and anterolateral approaches, but other options include posteromedial and posterolateral plating. Of particular interest is the posterolateral approach to the tibia, which was first published in 1945 [8]. Its advantages include the ability to fix fibula fractures in the same incision, and there is muscle coverage (flexor hallucis longus) over the plate which may protect the hardware from skin breakdown or infection, hence reducing the need for free flap coverage thereafter [9]. However, existing comparative literature on the posterolateral approach is limited in the setting of distal tibia fractures, while it is a popular approach in the treatment of posterior malleolar injuries.

This study, therefore, analyzed a series of patients that have undergone open reduction and plating of distal tibia fractures using a posterolateral approach. We believe that the posterolateral approach, which is seldom reported, has equivalent outcomes to standard fixation methods and is a
reliable technique with low morbidity that should be practiced by orthopaedic trauma surgeons.

**Materials and Methods**

Our institution’s electronic surgical records were searched by 2 authors independently for distal tibia fracture fixations between 2015 and 2018 inclusive. Screening through, we selected fixations which involved plating from a posterolateral approach. Pilon fractures were excluded; however, we included distal tibia fractures with simple intraarticular extension. Open fractures were also included if it did not involve a need for soft tissue reconstruction. Pathological fractures and patients with polytrauma were excluded. Data extraction was performed by 2 authors to ensure consistency in the variables.

**Admission and Preoperative Management**

As this is a retrospective study, there was no set protocol for treating these patients. Upon diagnosis of distal tibia fracture, patients were usually placed in a Plaster of Paris backslab with or without manipulation and reduction. Early external fixation was considered in instances of inadequate reduction or significant soft tissue swelling. Computed Tomography (CT) scans were obtained when intra-articular involvement was suspected. Surgery was scheduled on a trauma list (run by senior consultants) once soft tissues were suitable.

**Surgical Procedure**

Patients were suitably placed under anaesthesia and preoperative antibiotics were administered for all patients. Patients were positioned in a lateral or semi-lateral position to allow good posterolateral access but also enable the medial tibia to be approached by externally rotating the hip (Fig. 1).

In most cases, a ring fixator was applied to distract and maintain reduction of the fracture, while not interfering with surgical exposure (Fig. 2). Where an external fixator was already present, this was maintained during the cleaning and draping process.

The posterolateral approach was carried out as previously described in the AO manual by developing a plane between the peroneals and flexor hallucis longus to reveal the fracture site (Fig. 3).

The main tibia fracture was plated through a posterolateral incision. The same incision was used for fibula plating if deemed necessary. If further stability was required, a medial tibia plate was also used. Finally, syndesmotic fixation was done if needed.

The posterolateral plates were either a metaphyseal Locking Compression Plate (LCP) or proximal posteromedial tibia LCP, as there are no plates available specifically for the posterolateral distal tibia. These plates were contoured as required. Two case examples are provided in Fig. 4a, b.

**Postoperative Management**

The general regime was a backslab for 1–2 weeks and toe-touch weight bearing till wound healed. Partial weight
Fig. 2  Frame application

Fig. 3  Posterolateral approach wound exposure
bearing 5–10 kg in a walker boot was commenced with intermittent ankle motion exercises. At the 6-week mark after X-rays, patients were allowed to progressively weight bear as tolerated and gradually wean off the boot and crutches over the next 6 weeks. The exact rehabilitation plans were individualised to patient and injury profile.

Periodic follow-up was conducted to determine clinical and radiological union. A satisfactory outcome meant patients could weight bear without pain with preserved ankle motion; no formal functional scoring or quality-of-life surveys were performed. Conversely, an unsatisfactory outcome was one, where there was gait disturbance due to malunion, shortening, pain, or significant ankle stiffness.

The outcomes assessed in our study included: time taken to perform surgery, early operative complication rate, clinical union time, and radiological union time. Patient charts were also reviewed for post-operative complications, which included symptomatic hardware rate, reoperation rate, malunion (> 5°), delayed/non-union, and infection.

We obtained approval from our Institutional Review Board to access patient records for research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 [5]. Informed consent was obtained from all required patients as per regulations stipulated by our Institutional Review Board.

As this is a non-comparative, descriptive outcome case series, no statistical analysis was performed and no sample size power calculation was necessary.

**Results**

A total of 14 patients underwent posterolateral plating surgery for a distal tibia fracture from 2015 to 2018. One patient declined for their medical records to be accessed for the study leaving us with 13 patients. All patients had adequate
follow-up (till union or complication/reoperation) except for 1 patient that never returned for follow-up after discharge. Therefore, this patient’s data was only used toward the short-term outcome assessment and a total of 12 patients could be analysed for long term outcomes.

Of the 13 patients, 7 were female, and 6 were male. The mean age was 52.6 (range 22–78).

Four patients were victims of injury sustained while using motorbike or electric scooter, while 9 occurred from low energy falls. Four patients had intra-articular extension of their fracture and 1 patient had an open fracture (Gustilo grade 1). No patients were polytraumatised, but 1 patient had an ipsilateral non-displaced radial styloid fracture and another suffered an ipsilateral Lisfranc foot injury.

External fixation was employed on admission for 2 patients before definitive fixation at a later date, as there was significant soft tissue swelling and satisfactory reduction could not be achieved in a plaster back slab in the emergency department. Definitive fixation was undertaken when soft tissue swelling had reduced to safe limits for the planned procedure. The mean time from admission to definitive fixation was 5 days (range 1–9).

Reduction was aided with a frame application (9 patients) or use of the original external fixator (2 patients). The distal tibia was spanned with a single posterolateral approach plate alone in 7 patients. Additional medial plate was done in 6 patients. The fibula was fractured in all patients, and all were fixed apart from 3 which were near the proximal neck.

Outcomes

Surgical Time

The mean operative time was 2 h 44 min (range 1 h 31 min–3 h 34 min).

Operative Complications

No significant intra-operative complications occurred in any patients. All patients’ post-operative X-rays were acceptable and no early revisions were performed.

Union Time

This is the primary outcome. Clinical union was defined as the ability of patients to walk full weight bearing without symptoms of pain or apprehension. Radiological union was defined as the presence of callus bridging across the fracture site in at least 3 cortices based on anterior–posterior and lateral views.

One patient did not follow-up after initial treatment. Another patient had non-union and implant failure complications that needed ankle fusion and will be discussed later. We present the union times for the other 11 patients that had successful union from intended surgery.

The clinical union was 102 days or 14.5 weeks on average (range 51–225 days). In 5 patients the radiological union was established at the same clinic visit. However, in most cases the radiological union was assessed to occur later. The average radiological union time was 140 days or 20 weeks, (range 75–295 days).

For 11 of these patients the union was uncomplicated, while 1 patient had delayed union with complication from infection around the medial tibia plate.

If this patient was removed from the analysis, the clinical union time becomes 90 days or 12.8 weeks (range 51–146 days) and the radiological union time becomes 124 days or 17.7 weeks (range 75–189 days).

Complications

One patient had a removal of prominent titanium elastic nail in the fibula at 10 months from surgery. Another patient had a prominent medial tibial plate, but underwent removal of both tibia plates, and fibula plates during the surgery.

Apart from implant removal, 2 other required re-operation. One for non-union, and the other for infection and delayed union.

The first was a 56-year-old male and a chronic smoker of 30 pack year history. He sustained a distal third tibia fracture with intra-articular extension after falling off an electric scooter. His tibia was fixed with 2 plates along with his fibula fracture. However, it did not unite and implant failure was noted at follow-up with the plates backing out and the fracture moving into 10 degree of varus. He underwent staged ankle arthrodesis and healed with a 2 cm shorted limb and unsatisfactory outcome due to poor walking tolerance.

The other patient to suffer a delayed union was a chronic alcoholic who suffered from an infection around the medial implant. The implant was removed at 6 months from definitive surgery. After appropriate antibiotic therapy there were no further complications and the patient healed clinically by 225 days (32 weeks) and radiologically by 295 days (42 weeks).

Summary of Results

The union time for the 11 patients that united without construct change was 14.5 weeks for clinical union and 20 weeks for radiological union.

Overall results from 12 patients who completed follow-up showed 1 had delayed union and 1 had non-union (8.3% each). For 1 of these patients there was associated implant failure (8.3%), and the other patient had the only infection in the cohort (8.3%). Malunion did not occur and while 2
patients (16.6%) underwent implant removal, these were driven by other implants. With regard to the posterolateral plate specifically, there were no symptomatic implants, wound complications or infections. No intra-operative complications were noted, and mean surgical time was 2 h and 44 min. A satisfactory end outcome was obtained for 11 out of 12 patients on follow-up in terms of ankle motion/gait/function.

**Discussion**

We present the results of utilizing a posterolateral plating technique for distal tibia fracture fixation in Table 1, and compare these results against recent publications in last decade (2010–2019) that similarly used various methods of plating for distal tibia fractures. The majority are MIPO medial plating with some studies using open plating methods. At the time of writing, we could only find a few recent series that used posterolateral plating (excluding pilon fractures). Sheerin et al. [10] reported 15 cases (13 open fractures) using a blade plate. Average union time was 20 weeks. Yamamoto et al. [11] used a minimally invasive posterolateral plating technique in 5 patients and union time ranged from 20 to 54 weeks. He et al. [12] also used a MIPO posterolateral plating in 10 patients with Gustilo 3A or 3B fractures with mean union in 25.8 months. Sasikumar et al. [13] used open posterolateral plating for 7 closed and 6 Gustilo 1 open fractures (all extra-articular). They showed mean union at 20 weeks, no malunions and no non-union. This study number is similar to ours. One key difference was their operative time of 75 min. However, they did not use frame application to aid reduction, and none had additional medial plating. However, they did not initiate any weight bearing until at least 6 weeks, and full weight bearing after at least 10 weeks. Our approach to use adjunctive fixation as required, enabled early weightbearing and this did not result in any implant failures.

The results of other plating methods in recent literature show consistent findings. Union times tend to occur between 3 and 6 months, non-union rates are less than 10%, malunion rates were variable but usually less than 10%, and infection/wound complications tending to be a bit more common between 10 to 20% usually. Our union times are comparable to the majority of larger studies and complication rate has been generally lower or comparable to most studies. Malunion was not observed in our series, possibly due to the frequent use of frame distraction which enabled easier maintenance of reduction. Furthermore, the posterolateral approach allows for good visualisation at the fracture site which also assists in reduction. Hence initial fixations were generally anatomical. The concern would then be whether an open approach results in wound complications.

The infection rate of 8.3% in our series was due to a delayed, deep infection that involved the medial plate on the subcutaneous border of the tibia. There were no complications of the posterolateral wound. This contrasts to the majority of studies described in Table 1 which used only MIPO medial plating fixation, yet reported frequent complications of wound infection or breakdown. The posterolateral approach, therefore, appears to be safe, although we are unable to examine whether the amount of delay of surgical management plays an important role here.

The tissues around the mid-Achilles tendon are supplied by the posterior tibial and peroneal angiosomes. Incisions placed around the Achilles are safe [14], and the posterolateral approach respects this concept.

Symptoms of hardware irritation were not observed with posterolateral plate implants due to good soft tissue coverage.

Distal tibia fractures typically start distally at the anteromedial aspect and extend proximally to the posterolateral tibia. The hypothesis supporting the use of a posterolateral plate from a biomechanical point of view is that this fracture pattern gets ‘buttressed’ by the plate itself. Therefore, a posterolateral plate alone should provide a more stable fixation than a single medial plate, which may place more strain on the distal screws. Thicker, stronger plates can potentially be applied on the posterolateral tibia as there is more soft tissue coverage. The anteromedial subcutaneous border of the tibia is less tolerant to implants, and therefore, plates should be as low profile as possible. We applied low profile medial plates only if additional stabilisation was deemed beneficial. The strong fixation allowed us to begin early weight-bearing for patients, which is desirable, and is usually only achieved with tibial nailing.

Thus, the role of open posterolateral plating in distal tibia fractures may have the following advantages: good fracture reduction, biomechanically strong fixation, early progression to weightbearing, low wound complication rate, low malunion and low rate of implant removal. Further studies from both biomechanical and clinical standpoints are needed, and we recommend larger patient numbers to validate these benefits.

**Limitations**

With a small series we cannot make strong conclusions. Ideally with larger numbers we could assess differences in outcomes related to presence of open fracture, intra-articular involvement, use of frame during reduction, use of dual versus single plate, or patient profile. Other case series on the posterolateral approach have also been limited in numbers and are often specific to pilon fractures. Because this
Table 1  Recent literature on plating distal tibia fractures (> 10 patients)

<table>
<thead>
<tr>
<th>Study</th>
<th>Study info</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parameters</td>
<td>Union time (weeks)</td>
</tr>
<tr>
<td>This study</td>
<td>13 patients Intra and Extra-articular Gustilo 1 open/closed fractures Open posterolateral plating with or without medial MIPO</td>
<td>14.5 (clinical) 20 (X-ray)</td>
</tr>
<tr>
<td>He et al. [12]</td>
<td>10 patients Intra and Extra-articular Open 3A and 3B Posterolateral MIPO plating</td>
<td>25.8</td>
</tr>
<tr>
<td>Beytemur et al. [16]</td>
<td>36 patients Intra-articular Open/closed fractures Medial MIPO</td>
<td>15.2</td>
</tr>
<tr>
<td>Li et al. [17]</td>
<td>Meta-analysis 233 patients Open/Closed fractures Medial MIPO</td>
<td>15–21.8</td>
</tr>
<tr>
<td>Costa et al. [3]</td>
<td>141 patients Extra-articular Closed fractures Medial MIPO</td>
<td></td>
</tr>
<tr>
<td>Viberg et al. [6]</td>
<td>71 patients Intra and Extra-articular Open/closed fractures Medial MIPO/Open plating</td>
<td>7</td>
</tr>
<tr>
<td>Sasikumar et al. [13]</td>
<td>13 patients Extra-articular Open/closed fractures Posterolateral open plating</td>
<td>20</td>
</tr>
</tbody>
</table>
is uncommonly described in the literature, our series is still relevant and provides an avenue for further research.

Nearly half our patients underwent additional medial plating and results are not specific to the posterolateral plate alone. We would rather add that in daily practice, one should have a wide armamentarium and obtain a stable, biologically friendly construct to enable early rehabilitation.

Comparisons between studies are made challenging by differing criteria definition of union. Bastias et al. [19] defined union as pain free weightbearing with 1 cortex radiologically healed, whereas Beytemur et al. [16] and Kawalkar and Martand [15] required clinical union with 3 cortices healed on X-rays. Vallier et al. [22] did not take clinical features into account as long as 3 cortices were healed. We separately assessed clinical union as absence of fracture site tenderness and pain-free weight-bearing. Radiological union occurred when 3 out of 4 cortices are bridged as per criteria described for distal tibia fracture healing by Im and Tae [24].

The timing of patient follow-up can affect the reported union data. Frequent serial radiographs and examination may be more useful but is rarely convenient in modern clinical practice, and again a particular drawback of a retrospective study design.

### Table 1 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Study info</th>
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<td>Union time (weeks)</td>
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<td>Yu et al. [18]</td>
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<td>Xue et al. [20]</td>
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<td>Iqbal and Pidikiti [21]</td>
<td>Systematic review 134 patients Extra-articular Open/closed fractures Plating type unspecified</td>
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<td>Vallier et al. [22]</td>
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<td>Ronga et al. [5]</td>
<td>21 patients Intra and Extra-articular Closed fractures Medial MIPO</td>
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</table>
Conclusion

Distal tibia fractures are at risk of complications and we propose that a posterolateral plating approach, whether used alone or in combination with other stabilization methods, is a safe and stable form of fixation. In these fractures, the surgical aim is to provide a biomechanically stable construct to allow early rehabilitation. We suggest the following approach towards distal tibia fractures which are unsuitable for nailing: frame application can be considered to optimise reduction. Subsequent posterolateral plating of the tibia provides a buttress fixation which is mechanically favourable in weaker metaphyseal or osteoporotic bone. Fibula fixation can be performed through the same approach. Depending on amount of screw purchase distally and quality of bone, additional medial plating can strengthen the fixation. Patients can then be started on early weightbearing in a Walker boot.

In line with our hypothesis, we demonstrated that the posterolateral approach did not compromise union or alignment and indeed had less wound complication or hardware irritation than generally reported for other common methods of plating.

Author Contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by RM, AQYG and AWG. The first draft of the manuscript was written by RM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of Interest Rishi Malhotra, Aaron Goh Qi Yang, and Antony Gartner declare that they have no conflict of interest.

Ethical Standard Statement This study was approved by the National Healthcare Group Institutional Review Board.

Informed Consent Informed consent was obtained from all individual participants included in the study.

References

non-locking plates for treating distal tibial fractures? *Foot and Ankle Surgery, 20*(2), 115–119


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Hallux valgus with and without metatarsalgia in women: a matched-cohort study of plantar pressure measurements

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Abstract

Background Few previous studies focused on plantar loading patterns in HV patients with metatarsalgia. Are there any differences in plantar pressure measurements in women with HV with and without metatarsalgia?

Methods A prospective matched-cohort study was designed to analyze plantar pressure measurements in women with HV with and without metatarsalgia from January 2017 to December 2019. The inclusion criteria were age over 18 years old, women, diagnosis of HV with metatarsalgia. Control group had the same inclusion criteria, except metatarsalgia. Patient-reported outcomes scores included American Orthopedic Foot and Ankle Society Score (AOFAS), and Visual Analog Scale (VAS). Radiographic data were obtained according to the guidelines of the AOFAS Committee on Angular Measurements. Plantar pressure measurements were performed using a platform.

Results Forty-seven patients met the inclusion criteria. An age-, BMI-, and hallux valgus angle-matched cohort of 47 patients were also selected. There were no statistically significant differences in demographic data and radiographic assessment. HV with metatarsalgia group showed greater values in peak and mean force, peak and mean pressure, and pressure–time integral under toes and metatarsal heads. These differences reached statistically significant in mean force ($p = 0.009$) and peak force ($p = 0.003$) under T1; mean pressure ($p = 0.01$) and peak pressure ($p = 0.04$) under T1; and mean force ($p = 0.003$) under MH1.

The binary logistic regression analysis showed mean force under T1 as the most associated plantar pressure measurement with the presence of metatarsalgia. C-statistic was 0.66. Mean force > 35 N had a 70% of sensitivity and a 57% of specificity as a cut-off value for the presence of metatarsalgia.

Conclusion HV patients with metatarsalgia had greater values in plantar pressure measurements. Mean force under T1 could be used as a plantar pressure measurement to predict metatarsalgia.

Keywords Hallux valgus · Women · Metatarsalgia · Plantar pressure

Introduction

Metatarsalgia is a general term that refers to pain in the region of the metatarsal heads. Hallux valgus (HV) is one of the most common causes of primary metatarsalgia owing to first ray insufficiency. Another cause tested in the literature is the increase relative length of the second metatarsal [1, 2].

Previous studies reported plantar pressure measurements at the forefoot of HV patients [3–8]. However, few of them focused on plantar loading patterns in HV patients with metatarsalgia [9, 10]. Waldecker et al. reported the results of a pedographic analysis in HV patients with metatarsalgia compared with asymptomatic HV [9]. And Geng et al. analyzed differences in plantar pressures of postoperative HV patients with and without transfer metatarsalgia [10]. To our knowledge, matched-cohort studies have not been published before.

The purpose of our study was to assess differences in plantar pressure measurements in women with HV with and without metatarsalgia. We hypothesized that there would be significant differences between these groups. If there could be differences in the whole preoperative plantar pressure measurements or in some of them, plantar pressure technology might be a tool to use in orthopedic practice for a

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better understanding of the HV deformity associated with metatarsalgia.

Material and methods

Subjects

A prospective study was performed from January 2017 to December 2019 in the foot and ankle unit of a single hospital. Patients were chosen for the study according to the following inclusion criteria: age over 18 years old, women, diagnosis of HV with metatarsalgia. Patients reported pain in the region of metatarsal heads during the stance phase of gait. Criteria for exclusion were other forefoot deformities, gastrocnemius tightness, deformities of the hindfoot, arthrois, systemic diseases, neurologic disorders, history of previous surgery of the foot and lower extremity, history of trauma or infection, and patients that were incapable of stepping correctly on the pressure platform during measurement.

Control group had the same inclusion and exclusion criteria, except metatarsalgia.

The match control group was selected on a 1:1 ratio to patients without metatarsalgia, based on age within 5 years, BMI within 2 kg/m², and hallux valgus angle within 5°.

This study was performed in accordance with the ethical standards in the 1964 Declaration of Helsinki. The study was approved by our Institutional Review Board and informed written consent was obtained from all participants.

Functional assessment

The American Orthopaedic Foot and Ankle Society (AOFAS) hallux metatarsophalangeal interphalangeal score [11] and visual analogue scale (VAS) [12] were used for clinical evaluation. The orthopaedic surgeon, who did not know the plantar pressure data collection and the radiographic assessment, implemented these forms at one visit.

Radiographic assessments

Anteroposterior and lateral weight bearing radiographs were used by 2 orthopaedic surgeons, who did not know the plantar pressure data collection and functional assessment of the patients [13, 14].

On AP radiograph hallux valgus angle (HVA) [15], first–second intermetatarsal angle (IMA) [15], distal metatarsal articular angle (DMMAA) [15], first and second metatarsal length [16], and first metatarsal protrusion distance [17] were measured. On the lateral radiograph, metatarsus primus elevatus (MPE) [18], and first metatarsal declination angle (MDA) [19] were assessed.

HVA was considered normal if value was 15 degrees or less, mild if it was less than 20 degrees, moderate if it was 20 to 40 degrees, and severe if it was 40° or more [15]. A normal value was defined as 9 degrees or less for IMA and 6 degrees or less for DMMA [15]. First metatarsal protrusion distance was evaluated with Hardy and Clapham’s arc method [17]. Values were measured and recorded in millimeters (mm); measurements within the range of +1 to –1 mm were considered to be equal length. Metatarsal index was classified as plus, plus minus, and minus index, whether the first metatarsal was longer, equal, or shorter than the second metatarsal, respectively [20]. MPE were measured and recorded in mm with a normal value of 8 mm or less [18]. A value between 19° and 25° was defined as normal for MDA [19].

Plantar pressure data collection

All patients underwent plantar pressure measurements by RunTime® (Diagnostic Support España S.L., Bormujos, Spain) platform with 9600 sensors (2 sensors/cm² operating at 200 Hz). The total area was 130×45 cm, enclosing a 120×40 cm sensor area. The platform allowed a walking speed between 0.8 and 20 km per hour, and a maximum load of 130 kg. Patients were asked to walk in a relaxed way at a self-selected speed and did not look towards their feet [21]. Data collected started after feeling comfortable on the platform for a period of 15 s.

On the FreeStep® Software (Diagnostic Support España S.L., Bormujos, Spain) foot regions included (Fig. 1): great toe (T1), second to fifth toes (T2 to T5), first metatarsal head (MH1), second metatarsal head (MH2), third metatarsal head (MH3), fourth metatarsal head (MH4), fifth metatarsal head (MH5), medial midfoot (MMF), lateral midfoot (LMF), medial rearfoot (MRF), lateral rearfoot (LRF). For each region, peak pressure (Kpa), mean pressure (Kpa), maximum force (N), mean force (N), and pressure–time integral (N/cm²'s) were generated by the software. Three footprints were selected, the one in the middle of the trial, the anterior, and the posterior. The mean of these three footprints for plantar pressure measurements was calculated for further analysis. Previous research has supported this method to provide plantar pressure measurements [22, 23]. The podiatrist who conducted the analysis did not know the clinical and radiographic evaluation. Plantar pressure measurements were divided by the patient’s body weight to be normalized.

Statistical analysis

Statistical analysis was conducted with IBM SPSS 18.0 software (IBM SPSS, Armonk, NY). Statistical significance was set at $p < 0.05$. All data were explored for normality prior to inferential analysis. Descriptive statistics were used to
calculate the mean, standard deviation, and range for each estimate. Qualitative variables were showed with numbers and frequencies. Parametric comparisons of continuous data were performed using the 2-tailed Student t test. The chi-square test was used for categorical data. Associations between continuous variables were determined using Pearson’s r correlation coefficient. Binary logistic analysis was used to determine the extent of these associations. The predictive accuracy of the plantar pressure data was assessed using the c-statistics, which is equivalent to the area under the receiver operating characteristic (ROC) curve. As a rule, c-statistics between 0.70 and 0.79 are considerable acceptable, and between 0.80 and 0.89 are considered excellent [24].

Results

During the period of study, 47 women with HV and metatarsalgia were chosen for the study. And they were matched with 47 women with HV without metatarsalgia based on age, BMI, and HVA.

There were no significant differences in mean age between groups: 53.5 years (SD 6.4; range 21–67) in HV with metatarsalgia group, and 56.4 years (SD 5.3; range 36–74) in HV without metatarsalgia group (p = 0.14); and mean BMI: 25.1 kg/m² (SD 4.1; range 16.1–36.5), and 25.9 kg/m² (SD 4.1; range 17.3–36), respectively. Lesser toe deformities were present in 32 patients (68.1%) in HV with metatarsalgia group, and 13 patients (27.7%) in HV without metatarsalgia group (p < 0.001). They included 30 hammer toes and 2 claw toes in HV with metatarsalgia group, and 12 hammer toes and 1 claw toe in HV without metatarsalgia group (p = 0.86).

Functional assessment

Mean AOFAS score was statistically significantly lower in HV without metatarsalgia group 42.4 (SD 11.4; range 12–68) versus 55.0 (SD 12.7; range 27–72) in HV with metatarsalgia group (p < 0.001). Mean VAS pain was statistically significantly higher in HV without metatarsalgia group 7.8 (SD 1.3; range 5–10) versus 6.9 (SD 1.8; range 4–10) in HV with metatarsalgia group (p = 0.008).

Radiographic assessment

Radiographic assessments showed no statistically significant differences between groups (Table 1).

HVA had a positive significant correlation with IMA (r=0.334, p=0.001) and DMAA (r=0.442, p<0.001), and a negative significant correlation with MPE (r=−0.235, p=0.02). IMA has a negative significant correlation with first metatarsal length (r=−0.364, p<0.001), and second metatarsal length (r=−0.339, p=0.001). First metatarsal length had a positive significant correlation with second metatarsal length (r=0.739, p<0.001).
force found a positive correlation between VAS pain and peak AOFAS scores did not correlate with any plantar pressure measurements and AOFAS score or VAS pain.

**Plantar pressure analysis**

AOFAS scores did not correlate with any plantar pressure measurements. In patients with HV and metatarsalgia, we found a positive correlation between VAS pain and peak force ($r = 0.293, p = 0.04$), mean force ($r = 0.329, p = 0.02$), and mean pressure ($r = 0.370, p = 0.01$) under T1; and mean pressure ($r = 0.296, p = 0.04$) under T2 to T5. Conversely, in HV patients without metatarsalgia, VAS pain correlated positively with peak force ($r = 0.439, p = 0.02$), mean force ($r = 0.311, p = 0.03$), and pressure–time integral ($r = 0.373, p = 0.10$) under MH3.

Some significant correlations were found out between plantar pressures and radiographic variables. HVA showed a positive correlation with peak pressure under MMF, and a negative correlation with peak force and mean force under T1. DMAA presented a positive correlation with peak pressure and mean pressure under MH1, MH2, MH3 and MMF; peak force under MH2 and MMF, and mean force under MH2, MH3, and MMF. MDA displayed a positive correlation with peak pressure and mean pressure under T1, T2 to T5, MH1, MH2, MH3, MH4, and LRF; peak force under MH3, and MRF; and mean force under T1, MH3, MH4, and LRF. Length of the first and second metatarsal did not correlate with any plantar pressures data under the corresponding metatarsal head: peak pressure for M1 ($r = 0.002, p = 0.98$) and M2 ($r = 0.009, p = 0.93$), mean pressure for M1 ($r = 0.07, p = 0.46$) and M2 ($r = 0.05, p = 0.60$), peak force for M1 ($r = 0.08, p = 0.42$) and M2 ($r = 0.19, p = 0.06$), mean force for M1 ($r = 0.10, p = 0.32$) and M2 ($r = 0.18, p = 0.07$), and pressure–time integral for M1 ($r = 0.42, p = 0.08$) and M2 ($r = 0.09, p = 0.36$). Pearson’s correlations coefficients (r) for HVA, DMAA, and MDA, ranged from 0.217 to 0.439.

In both groups, mean pressure and peak pressure values were highest under MH3 followed by MH2. For mean force and peak force, MRF had the highest value. Pressure–time integral arrived at its highest value under MH3. HV with metatarsalgia group showed greater values in peak and mean force, peak and mean pressure, and pressure–time integral under toes and metatarsal heads. These differences reached statistically significant in mean force ($p = 0.009$) and peak force ($p = 0.003$) under T1; mean pressure ($p = 0.01$) and peak pressure ($p = 0.04$) under T1; and mean force ($p = 0.003$) under MH1. With the numbers available, there were no significant differences in pressure–time integral between groups (Table 2).

Patients with lesser toe deformities had greater plantar pressures than patients without lesser toe deformities in both groups. However, these differences were not statistically significant.

The binary logistic regression analysis showed mean force under T1 as the most associated plantar pressure measurement with the presence of metatarsalgia (Table 3). The c-statistic was 0.66 (95% CI 0.55 to 0.77) (Fig. 2). Mean force under T1 higher than 35 N had a 70% of sensitivity and a 57% of specificity as a cut-off value for the presence of metatarsalgia, positive predictive value was 62% and

### Table 1

<table>
<thead>
<tr>
<th>Hallux Valgus Categories</th>
<th>HV with metatarsalgia ($n = 47$)</th>
<th>HV without metatarsalgia ($n = 47$)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>HVA (°)</td>
<td>29.2 ± 7.2 (20–43)</td>
<td>31.2 ± 7.3 (16–44)</td>
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<td>DMAA (°)</td>
<td>13.0 ± 3.0 (7.6–22)</td>
<td>12.4 ± 2.4 (8–19.7)</td>
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<tr>
<td>MPE (mm)</td>
<td>4.6 ± 1.9 (1.3–8.9)</td>
<td>4.7 ± 2.1 (1.3–10.6)</td>
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<td>Plus/Plus minus</td>
<td>43 (91.5)</td>
<td>47 (100)</td>
<td>0.05</td>
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<tr>
<td>MDA (°)</td>
<td>21.6 ± 3.2 (14.4–27.8)</td>
<td>21.7 ± 3.4 (14.2–30)</td>
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</table>

Values are presented as mean ± standard deviation (range), n (%)

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<th>Hallux Valgus Angle</th>
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<th>HV without metatarsalgia ($n = 47$)</th>
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<tr>
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<td>2.2 ± 2.2 (--6.9 to 3.0)</td>
<td>3.0 ± 1.7 (− 7.7 to 0)</td>
<td>0.06</td>
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<tr>
<td>M1-M2 (mm)</td>
<td>7.6 ± 0.7 (6.4–9.6)</td>
<td>7.8 ± 0.6 (6.1–9.0)</td>
<td>0.32</td>
</tr>
<tr>
<td>M1 (mm)</td>
<td>6.5 ± 0.5 (5.8–7.8)</td>
<td>6.4 ± 0.4 (5.5–7.6)</td>
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<td>M2 (mm)</td>
<td>7.6 ± 0.7 (6.4–9.6)</td>
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<td>M1-M2 (mm)</td>
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<td>3.0 ± 1.7 (− 7.7 to 0)</td>
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Table 2  Plantar pressure measurements in both groups

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<td>Mean</td>
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<td>234.8</td>
<td>911.9</td>
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<tr>
<td>MH3</td>
<td>992.4</td>
<td>247.9</td>
<td>930.0</td>
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<tr>
<td>MH4</td>
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<td>685.2</td>
<td>310.7</td>
<td>619.6</td>
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<tr>
<td>MMF</td>
<td>732.2</td>
<td>155.3</td>
<td>754.3</td>
</tr>
<tr>
<td>LMF</td>
<td>821.4</td>
<td>217.2</td>
<td>811.4</td>
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<tr>
<td>MRF</td>
<td>799.2</td>
<td>230.6</td>
<td>762.0</td>
</tr>
<tr>
<td>LRF</td>
<td>817.0</td>
<td>203.1</td>
<td>797.4</td>
</tr>
<tr>
<td>Mean pressure (KPa)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>328.4</td>
<td>91.1</td>
<td>296.0</td>
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<td>111.6</td>
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<tr>
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<tr>
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<td>394.5</td>
<td>80.6</td>
<td>386.3</td>
</tr>
<tr>
<td>LRF</td>
<td>415.9</td>
<td>123.5</td>
<td>388.9</td>
</tr>
</tbody>
</table>
negative predictive value was 66%; positive likelihood ratio was 1.63 and negative likelihood ratio was 0.53 (Table 4).

**Power study**

Power analysis compared mean force under T1 in both groups. For a sample size of 47 in each group, an alpha error of $= 0.05$ and a difference of 9.2 between groups, a $Z_{\alpha}$ value of 2.32 was computed. The power of this study was 98%.

**Discussion**

The main finding of this investigation was that HV with metatarsalgia patients showed a significantly higher value of mean pressure and peak pressure under T1, a significantly higher value of mean force and peak force under T1, and a significantly higher value of mean force under MH1. Mean force under T1 was the most associated variable with the presence of metatarsalgia.

Higher loading under central metatarsals had been reported previously in HV patients. Koller et al. referred in 55 HV patients that peak pressure and maximum force were greater under MH2 and MH3 [25]. Weng et al. compared plantar pressure measurements in 229 patients with self-reported pain in the forefoot and other 35 controls. They found increased loading under MH2 and MH3, and reduced force under T1 [4]. Martinez Nova et al. found that the highest mean pressure was under MH2 in 79 female patients with mild HV [3]. In our study, mean pressures and peak pressures were also higher under MH2 and MH3.

Few studies analyzed plantar loading patterns in HV patients with metatarsalgia. Waldecker et al. reported significantly higher loading patterns of the lateral forefoot (MH2 to MH5), and significant decrease of pressure variabilities under T1, in 50 patients with HV and metatarsalgia symptomatology compared with 50 asymptomatic HV. A peak pressure $> 70$ N/cm$^2$ and a pressure–time integral $> 28$ N/cm$^2$s at lateral forefoot was established in symptomatic HV feet as a critical threshold associated with symptomatology [9]. Geng et al. focused to determine specific differences in the loading patterns between 30 reconstructive HV feet with postoperative transfer metatarsalgia and 30 postoperative feet without pain. They did not find significant differences in peak force and force–time integral of MH2 and MH3 between groups.
However, significantly higher cumulative load percentage and instant load percentage were higher in patients with transfer metatarsalgia [10]. As the magnitude of the HV increases, first ray malalignment and insufficiency arise, leading to a mechanical overloading of central metatarsals [26]. In our study, the positive correlation found between MDA and peak pressure and mean pressure under MH1, MH2, and MH3, showed this increase in pressure. Differences in plantar pressures under metatarsal heads between HV patients with and without metatarsalgia were small. Only pressure and force under T1, and maximum force under MH1 reached statistical significance. This increase loading related to the T1 region may be attributed to less pain and longer pressure–time integral. The hallux would load for a longer time, and more force would be applied. A mean force under T1 higher than 35 N as a critical threshold for the presence of metatarsalgia a 70% of sensitivity and a 57% of specificity.

Previous research about toe deformities in diabetic patients referred that toe deformities increase metatarsal pressures. Mueller et al. published higher metatarsophalangeal joint angle in diabetic patients than non-diabetic patients. They referred that hammertoe deformity was the primary structural factor that predicted forefoot peak plantar pressure during walking in people with diabetes under great toe, MH2, MH3, MH4, and MH5. However, in non-diabetic patients hammertoe deformity only predicted forefoot peak plantar pressure under MH3 [27]. Yu et al. found higher in-shoe peak plantar pressures under MH1 to MH5 for diabetic patients with claw toes compared to controls [28]. In our study, the analysis of patients with toe deformities did not find statistically significant differences in plantar pressures under metatarsal heads. Our patients with toe deformities were more prone to have metatarsal pain, as Slullitel et al. reported before [29].
The effect of functional assessment on the foot pressure is less known. Martinez Nova et al. reported a negative correlation between AOFAS clinical score with mean pressure under T1 [3, 30]. In our study, AOFAS score did not correlate with any plantar pressure measurements. VAS pain had a different plantar pressure pattern behaviour between groups. HV patients with metatarsalgia showed a positive correlation with pressure variabilities under T1. Nevertheless, HV patients without metatarsalgia showed these positive correlations with pressure variabilities under MH3. Although these correlations were weak, they suggested that patients with greater pressure in these zones had more pain.

Maestro et al. referred a long second metatarsal as the most common cause of primary metatarsalgia [31]. However, other studies contradict this theory. Kaipel et al. studied peak pressure and maximal force in 51 feet with metatarsalgia and 51 feet without metatarsalgia. They did not find a correlation between the relative length of the first and third metatarsals and maximal peak pressure and maximal force. Maximal force under MH1 was significantly lower in the metatarsalgia group. The authors concluded that metatarsal length did not influence plantar loading [32]. Slullitel et al. referred an inverse relationship between metatarsal index and metatarsalgia, thereby patients with index minus were less likely to have metatarsal pain [29]. In our study, radiographic assessments showed no statistically significant differences between groups. We only measured first MDA, with no statistically significant differences between groups. However, second to five metatarsal declination angles were not taken into account, and maybe play a role in the development of metatarsal pain.

The study has limitations that ought to be addressed. First, we did not include a control group. The purpose of our study was to assess differences in dynamic plantar pressure measurements in women patients with HV with and without metatarsalgia. Maybe, it was not justifiable to expose healthy people to radiation exposure. Second, we did not assess first tarsometatarsal instability as a cause of HV. Third, a relatively small sample size in both groups, even though we were able to identify some statistically significant differences. Fourth, we did not address walking speed, and patients walked across the platform at a self-comfortable speed. However, this study had also several strengths. First, this was a prospective study with well-established criteria and aims. Second, all radiographs were taken according to a strict protocol, which does eliminate the possibility of technical failure. Third, radiographs, functional assessment and plantar pressure analysis were blinded. Four, to our knowledge, this is the first marched cohort study focused on plantar pressure analysis in HV feet with metatarsalgia.

This study provides information about plantar pressure measurements in patients with HV and metatarsalgia. Mean force under T1 could be used as a plantar pressure measurement to predict metatarsalgia. Plantar pressure technology might be a tool to use for early screening in HV patients to predict metatarsalgia.

Funding No funding to declare.

Declarations

Conflict of interest All authors were fully involved in the study and preparation of the manuscript and declare that there is no conflict of interest.

Ethical approval All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from the patient included in the case report.

References

for the ankle-hindfoot, midfoot, hallux and lesser toes. Foot Ankle Int, 15, 349–353.


Inter-rater and Intra-rater Reliability in the Radiographic Diagnosis of Growth Arrest in Paediatric Physeal Fractures

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Abstract

Background Fractures through the physis account for 18–30% of paediatric fractures and can lead to growth arrest in 5–10% of these cases. Long-term radiographic follow-up is usually necessary to monitor for signs of growth arrest at the affected physis. Given plain radiographs of a physeal fracture obtained throughout patient follow-up, different surgeons may hold different opinions about whether or not early growth arrest has occurred despite using identical radiographs to guide decision-making. This study aims to assess the inter-rater and intra-rater reliability of early growth arrest diagnosis among orthopaedic surgeons given a set of identical plain radiographs.

Methods A retrospective chart review was conducted on patients aged 2–18 years previously treated for a physeal fracture at a paediatric tertiary care hospital between 2011 and 2018. De-identified anteroposterior (AP) and lateral radiographs of 39 patients from the date of injury and minimum one-year post-injury were administered in a survey to international paediatric orthopaedic surgeons. Each surgeon was asked whether they would diagnose the patient with growth arrest based on the radiographs provided. Surgeons were asked to complete this process again two weeks after the initial review, but using identical shuffled radiographs. Inter-rater and intra-rater reliability was calculated using appropriate kappa statistics.

Results A total of 11 paediatric orthopaedic surgeons completed the first round of the survey, and 9 of these 11 completed the second round. The inter-rater reliability for the first round was 0.22 [95% CI (0.06, 0.35)] and 0.21 [95% CI (0.02, 0.32)] for the second round. The average kappa for intra-rater reliability was −0.05 [95% CI (−0.31, 0.21)]. Comparison by injury side showed no significant variation in diagnosis \( p = 0.509, \text{ OR} = 0.90, [95\% \text{ CI} (0.67, 1.22)] \), while comparison by location of injury varied significantly \( p = 0.003 \).

Conclusions Radiographic diagnosis of growth arrest among paediatric orthopaedic surgeons demonstrated ‘fair’ inter-rater agreement and no intra-rater agreement, suggesting critical differences in identifying growth arrest on plain radiographs. Further research is necessary to develop an improved diagnostic approach for growth arrest among orthopaedic surgeons.

Level of Evidence Diagnostic level III.

Keywords Reliability · Diagnosis · Radiography · Physeal fractures · Growth arrest

Introduction

The region of the bone known as the physis, or growth plate, contributes to the length and shape of mature long bones. Fractures through the physis account for 18–30% of paediatric fractures and can lead to growth arrest and resulting deformity in 5–10% of these cases [1, 2]. Following a physeal fracture, long-term imaging assessments are often used to monitor for signs of growth arrest at the affected physis. Plain radiographs are readily accessible and provide the initial imaging approach for the evaluation of physeal injuries [3]. Partial or total growth arrest may be identified on plain radiograph by the appearance of bony bridge formation across the physis or through any persistent displacement or angulation for long term [3]. The diagnosis of growth arrest on plain radiographs, combined with further advanced imaging, may be used to guide potential surgical management in
patients with a growth disturbance. Therefore, it is clinically important to have a high level of agreement among surgeons when assessing patients with a physeal injury in order to ensure equitable treatment.

Although plain radiographs are widely used by orthopaedic surgeons to assess for initial signs of growth arrest clinically, current studies focus on the assessment of growth arrest using advanced imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT), which provide greater ability for detailed identification of bony bridging [4–6]. However, these studies often fail to report inter-rater or intra-rater reliability for the diagnosis of growth arrest using these specific imaging modalities. Additionally, it is difficult to evaluate the clinical relevance of MRI and CT as they are infrequently used in the initial assessment of growth arrest in comparison with plain radiography.

To date, there has been no known study carried out among paediatric orthopaedic surgeons to assess the reliability of growth arrest diagnosis using plain radiographs. The purpose of this study was to examine the inter-rater and intra-rater reliability of growth arrest diagnosis among orthopaedic surgeons given a set of identical plain radiographs.

**Methods**

With institutional research ethics board approval, a retrospective radiographic and chart review was conducted on patients, aged 2–18 years, previously treated for a physeal fracture at a paediatric tertiary care hospital between 2011 and 2018. All patients were obtained from a list of participants who were part of a pre-existing, ongoing prospective growth arrest prediction model study at the institution.

A total of 39 patient cases were selected for inclusion. Patients were included if they previously sustained a physeal fracture and had adequate anteroposterior (AP) and lateral radiographs from their date of injury and at a minimum one year post-injury. Patient cases were primarily chosen based on the availability of long-term follow-up (one or two year) radiographs of the injured and contralateral side, which were collected based on the protocol of the institution’s growth arrest prediction model study. Radiographs of the contralateral side were purposely included to provide raters with a greater basis for comparison during diagnosis. Eighteen patient cases had two-year follow-up radiographs in addition to their one-year follow-up radiographs that were used for the study. A variety of growth arrest patients were included in the study, such as patient cases previously diagnosed as having potential growth arrest (11 cases) alongside patient cases without a previously recorded diagnosis of growth arrest (28 cases). Although this may have resulted in a different number of patients diagnosed with growth arrest than may have actually occurred, the agreement regarding the radiographic diagnosis of growth arrest would not have been affected, which was the primary objective of the study.

This study was conducted in two parts. First, email invitations to participate in the study were distributed to six fellowship-trained orthopaedic surgeons at a single paediatric tertiary care hospital with extensive experience in managing paediatric physeal fractures. A sample of 39 radiographs of physeal fractures were evaluated by each participating surgeon. De-identified radiograph sets were randomized and distributed to each rater in separate Microsoft PowerPoint presentations (Fig. 1). Each slide in the presentation contained a set of AP and lateral radiographs along with appropriate patient demographic information (patient age, side of injury, length of time since injury). Injured and contralateral limb radiographs from the patient’s long-term follow-up visit(s) were compiled side by side for direct comparison. To investigate the subjective nature of diagnosis, surgeons were intentionally not provided with a defined criteria for diagnosis of growth arrest on the radiographs provided. Each surgeon was asked to rate whether or not they would diagnose the patient with growth arrest by answering ‘yes’ or ‘no’ on a standardized physical data collection form. Additional interpretation of the radiographs was not required as this was beyond the study’s primary objective of assessing diagnostic variability for the presence of growth arrest. To assess for intra-rater reliability, surgeons were provided with identical re-shuffled radiographs after a two-week time interval and were asked to rate whether they would diagnose the patient with growth arrest a second time.

Second, invitations to participate in the study were extended to six paediatric orthopaedic surgeons from international centres who primarily treat paediatric trauma patients. The same set of radiographs were administered in the form of a survey through Research Electronic Data Capture (REDCap) software [7] and followed the format of the PowerPoint presentations. The surveys were administered in two rounds following the same procedures described above. For both rounds, surgeons were asked to select whether or not they would diagnose the patient with growth arrest by answering ‘yes’ or ‘no’ on the REDCap survey.

Inter-rater and intra-rater reliability of growth arrest diagnosis was calculated using appropriate kappa statistics, and 95% confidence intervals (CI) were computed based on 1000 bootstrap resamples. Specifically, Fleiss’ kappa was calculated for each of the two rounds in order to assess the inter-rater reliability among surgeons [8]. Cohen’s kappa statistic was determined for each individual surgeon comparing scores between the first and second rounds for intra-rater reliability [9]. Interpretation of the kappa values was based on the criteria according to Cohen [10]: values 0.81–1.00 indicate ‘almost perfect’ agreement, 0.61–0.80 ‘substantial’, 0.41–0.60 ‘moderate’, 0.21–0.40 ‘fair’, 0.01–0.20 ‘none to
slight’, and values less than or equal to zero as ‘no agreement’. Growth arrest diagnosis was compared both by injury side and by injury type via mixed-effects logistic regression with a random intercept for ‘surgeon’ [11]. Statistical significance of injury side and type of injury was based on the likelihood ratio test. All analyses were carried out using R 3.5.3 [12].

Results

Demographics

A total of six paediatric orthopaedic surgeons from the primary institution and six paediatric orthopaedic surgeons from various international centres, known by the senior
author (KM), were invited to participate in the study in February 2019. All participating raters were fellowship-trained, board-certified paediatric orthopaedic surgeons in active practice. Of those invited, one surgeon partially completed the first survey round and 11 surgeons (7 from Canada, 2 USA, 1 Australia, 1 New Zealand, and 1 India) fully completed the first survey round. All responses from the first round of surveys were registered in late February 2019. Nine of the 11 original respondents completed the second round, with all responses registered in March 2019.

A sample of 39 radiographs of physeal fractures were evaluated by each participating surgeon. The types of physeal fractures included: distal humerus (6), distal radius (14), proximal radius (1), distal femur (1), distal tibia (15), and distal fibula (2). There were 20 left-sided injuries and 19 right-sided injuries.

**Total Growth Arrest Diagnoses**

Comparison by injury side showed no significant variation in diagnosis \( p=0.5087, \text{[OR}=0.90, 95\% \text{ CI}(0.67, 1.22)] \). In both rounds of the study, left-sided injuries were diagnosed with growth arrest a total of 152 times (36%) in comparison with a diagnosis of no growth arrest 267 times (64%). Similarly, right-sided injuries were diagnosed a total of 132 times (34%) with growth arrest and 258 times (66%) without growth arrest.

Comparison by injury type, however, showed significant variation in growth arrest diagnosis \( p=0.003 \) and predicted the surgeons’ responses (Table 1). Injuries of the right distal humerus were the most common injury type diagnosed with growth arrest (49%), while injuries of the right proximal radius were the least commonly diagnosed injury type (14%).

**Inter-rater Reliability**

The inter-rater reliability for growth arrest diagnosis showed significant variability among surgeons (Table 2). For the first round, the Fleiss’ kappa across 11 responding surgeons was 0.22 [95% CI (0.06, 0.35)], indicating fair agreement. The second round indicated fair agreement among the nine responding surgeons with a similar Fleiss’ kappa of 0.21 [95% CI (0.02, 0.32)].

**Intra-rater Reliability**

Intra-rater reliability of growth arrest diagnosis between rounds 1 and 2, which contained the same 39 patient cases arranged in a different order, showed significant variability (Table 3). In the second round, some surgeons had missing responses and were therefore excluded. The average weighted kappa for the first and second rounds was −0.05 [95% CI −0.31, 0.21], indicating no agreement.

**Discussion**

The results of this study demonstrate ‘fair’ inter-rater agreement and no intra-rater agreement with regard to growth arrest diagnosis among paediatric orthopaedic surgeons. These findings suggest critical differences in diagnosis, illustrating the difficulty in identifying growth arrest on plain radiographs. This lack of consistency is clinically relevant,

<table>
<thead>
<tr>
<th>Description of injury</th>
<th>Number of patient cases</th>
<th>Number diagnosed with no growth arrest</th>
<th>Number diagnosed with growth arrest</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p value</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left distal femur</td>
<td>1</td>
<td>14 (67%)</td>
<td>7 (33%)</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Left distal humerus</td>
<td>3</td>
<td>41 (65%)</td>
<td>22 (35%)</td>
<td>1.07</td>
<td>(0.36, 3.14)</td>
<td>&lt;0.001</td>
<td>Fair</td>
</tr>
<tr>
<td>Left distal radius</td>
<td>8</td>
<td>118 (63%)</td>
<td>70 (37%)</td>
<td>1.2</td>
<td>(0.45, 3.2)</td>
<td>0.72</td>
<td></td>
</tr>
<tr>
<td>Left distal tibia</td>
<td>7</td>
<td>94 (64%)</td>
<td>53 (36%)</td>
<td>1.13</td>
<td>(0.42, 3.06)</td>
<td>0.81</td>
<td></td>
</tr>
<tr>
<td>Right distal fibula</td>
<td>2</td>
<td>32 (78%)</td>
<td>9 (22%)</td>
<td>0.55</td>
<td>(0.16, 1.82)</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>Right distal humerus</td>
<td>3</td>
<td>31 (51%)</td>
<td>30 (49%)</td>
<td>2.06</td>
<td>(0.71, 6.02)</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Right distal radius</td>
<td>4</td>
<td>73 (71%)</td>
<td>30 (29%)</td>
<td>0.82</td>
<td>(0.29, 2.29)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Right distal tibia</td>
<td>8</td>
<td>104 (63%)</td>
<td>60 (37%)</td>
<td>1.17</td>
<td>(0.44, 3.17)</td>
<td>0.75</td>
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<tr>
<td>Right proximal radius</td>
<td>1</td>
<td>18 (86%)</td>
<td>3 (14%)</td>
<td>0.32</td>
<td>(0.07, 1.49)</td>
<td>0.15</td>
<td></td>
</tr>
</tbody>
</table>

The number of cases diagnosed with or without growth arrest is based on the responses of 12 surgeons over both rounds of the survey. One surgeon partially completed the first survey round, and 11 surgeons fully completed the first survey round, while nine of the 11 original respondents fully completed the second survey round.
given that a diagnosis of growth arrest is used to guide treatment decisions and to prevent deformity and limb length discrepancy in children with physeal fractures. Failure to have consistent diagnoses between patients may result in differing outcomes between patients presenting with similar conditions.

A limited number of studies have measured the reliability of radiographic assessment for physeal injuries. Tzavellas et al. recently conducted a reliability study of Salter–Harris classification using radiographs of physeal injuries and found moderate agreement between raters with regard to injury classification [13]. However, it was beyond the purpose of Tzavellas’ study to look at the diagnosis of growth arrest using long-term radiographs, which was the objective of our study. Studies that have assessed the interpretation of growth arrest often discuss MRI and CT imaging, which provide greater detail on the size, location, and shape of the bone bridge compared to conventional radiography, which has yet to be addressed in the current literature [4–6]. Due to the routine use and accessibility of plain radiography, our study focused on the radiographic diagnosis of growth arrest; however, future work should also consider the reliability of growth arrest diagnosis on advanced imaging. At present, there are no formal studies that report inter-rater or intra-rater reliability for the diagnosis of growth arrest using any of these imaging modalities.

There are several limitations to this study. First, no standard definition of growth arrest was given to participating surgeons before they were asked to identify the presence of growth arrest from the radiographs provided. A concrete diagnostic definition for growth arrest, typically specified by the appearance of a bony bridge across the physis, was intentionally not provided in order to investigate the subjective nature of diagnosis for physeal injuries; this could have led to some surgeons reporting a diagnosis of growth arrest due to factors other than the presence of a bone bridge on the radiograph, such as whether they believed the outcome of the injury would be clinically significant. This may indicate the need for a standardized definition and method of diagnosis for future studies involving the radiographic diagnosis of growth arrest. The inclusion of physeal fractures regardless of the site of injury could also be a weakness as the selected cases may not be an accurate representation of possible fracture types. Due to the fact that the selection of patient cases was based on the availability of contralateral-side radiographs from a minimum of a one-year follow-up for comparison, it was difficult to include a uniform distribution of fractures based on the anatomic site of injury. This study included only one patient case with a physeal fracture at the proximal end of the long bone; the rest of the patient cases represented fractures at the distal end of the long bones. Distal radius and distal tibia fractures also outnumbered other fracture types, which may have influenced the study results for the number of growth arrest diagnoses. This study would have been strengthened by greater inclusion of injuries from other anatomic sites, including those that have historically resulted in frequent growth disturbances such as the distal femur [14]. One possible way to achieve this would be to include patient cases containing radiographs from the date of injury and long-term follow-up, but without the contralateral-side image, in order to obtain a greater distribution of fracture types. Further work is required using an equal number of injury types to examine differences in diagnosis within stratified subgroups. Finally, this study could have benefitted from a larger sample of participating surgeons. There is some bias with regard to selection of the raters, all of whom were chosen by the senior author. It is possible that other surgeons who did not participate in this study may demonstrate a different level of inter-rater and intra-rater reliability than was found in this study.

This study lays the groundwork for a variety of future studies. Building on Tzavellas’ work [13], testing the inter-rater and intra-rater reliability of the Salter–Harris classification (the most widely followed classification for physeal fractures) on a large number of radiographs and raters would be useful to explore potential variabilities in fracture classification. While this study asked surgeons to diagnose the presence of growth arrest on radiographs, it would also be beneficial to assess the subjective criteria that each surgeon used to determine the diagnosis of growth arrest. Modification of future reliability studies could include the collection of data pertaining to individual assessment of bony bridging or subjective indications for diagnosis. In addition, future studies could examine the diagnostic accuracy of plain radiography and advanced imaging modalities like MRI and CT (i.e., which radiographically diagnosed growth arrests result in real growth arrests requiring treatment). It is also well known

### Table 3 Intra-rater kappa statistics and overall average

<table>
<thead>
<tr>
<th>Rater</th>
<th>Kappa</th>
<th>95% CI</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.04</td>
<td>(−0.27, 0.35)</td>
<td>Poor</td>
</tr>
<tr>
<td>2</td>
<td>−0.04</td>
<td>(−0.35, 0.27)</td>
<td>Poor</td>
</tr>
<tr>
<td>3</td>
<td>−0.22</td>
<td>(−0.52, 0.07)</td>
<td>Poor</td>
</tr>
<tr>
<td>4</td>
<td>−0.18</td>
<td>(−0.47, 0.12)</td>
<td>Poor</td>
</tr>
<tr>
<td>5</td>
<td>NA</td>
<td>(NA, NA)</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>NA</td>
<td>(NA, NA)</td>
<td>NA</td>
</tr>
<tr>
<td>7</td>
<td>0.18</td>
<td>(−0.14, 0.49)</td>
<td>Poor</td>
</tr>
<tr>
<td>8</td>
<td>−0.16</td>
<td>(−0.41, 0.10)</td>
<td>Poor</td>
</tr>
<tr>
<td>9</td>
<td>−0.1</td>
<td>(−0.39, 0.19)</td>
<td>Poor</td>
</tr>
<tr>
<td>10</td>
<td>0.07</td>
<td>(−0.25, 0.38)</td>
<td>Poor</td>
</tr>
<tr>
<td>11</td>
<td>N/A</td>
<td>(NA, NA)</td>
<td>NA</td>
</tr>
<tr>
<td>12</td>
<td>−0.07</td>
<td>(−0.15, 0.00)</td>
<td>Poor</td>
</tr>
<tr>
<td>Average</td>
<td>−0.05</td>
<td>(−0.31, 0.21)</td>
<td>Poor</td>
</tr>
</tbody>
</table>
that growth disturbances can occur after good anatomic reduction in Salter–Harris Type III, IV, and V physeal fractures where the growth plate has likely been damaged at the moment of impact [15]. A retrospective study to evaluate the timing of reduction and its role in the development of growth arrest after injury may be of worthwhile investigation.

The current study illustrates variability among surgeons when diagnosing growth arrest on plain radiographs. These discrepancies, though interesting, are not necessarily expected to change clinical practice since further advanced imaging is compulsory when there are queries related to diagnosis of physeal injuries. However, these findings may serve as an initial step towards highlighting disagreement among surgeons with regard to radiographic diagnosis of growth arrest. A more robust study that includes a greater number of patient cases and comparisons to advanced imaging may further investigate this disagreement in diagnosis. At the very least, this study demonstrates the need for a standardized definition of growth arrest and a greater need for improved methods of identifying growth arrest on plain radiographs.

Conclusion

This study provides evidence for a low level of both inter-rater and intra-rater reliabilities among paediatric orthopaedic surgeons in the radiographic diagnosis of growth arrest following a physeal injury. These findings suggest differences with regard to the interpretation of growth arrest on plain radiographs at the patient’s one-or two-year follow-up visit. Potential future studies can look at the reliability of growth arrest diagnosis in plain radiographs with regard to Salter–Harris classification, levels of clinical experience between raters, as well as reliability of advanced imaging methods, such as MRI and CT. Further understanding of the levels of agreement in growth arrest diagnosis may help identify potentially critical variation during diagnosis, and as such, encourage development of an improved diagnostic approach in order to optimize clinical and functional outcomes in patients with physeal fractures.

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Compliance with Ethical Standards

Conflicts of Interest KM has received research support from Allergan, Pega Medical and Depuy Synthes (Johnson & Johnson). None are directly relevant to the research in this paper. For the remaining authors, none were declared.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent All participants provided informed consent prior to their participation.

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Corrective Procedure for Flexion Contracture of the Elbow in Neonatal Palsy Sequelae: Long-term Follow-up

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Abstract
Background  Aim of this paper is to validate a procedure for correcting elbow flexion contracture in patients suffering from brachial plexus neonatal palsy sequelae during their teens. Elbow flexion contracture represents an unsolved problem in the natural history of obstetric brachial plexus palsy (OBPP) because of the consistent deformity recurrence. Following a previous paper, in which an original technique was proposed in a small sample of patients, the authors show the possible correction of the deformity in a larger group of patients.

Methods  The procedure includes a combination of a posterior approach to the elbow with olecranon tip section and an anterior one with capsulotomy and soft tissue release to improve elbow range of motion. A series of 26 patients, who underwent the procedure, were checked out in medium and long term. Collected data were age, type of brachial plexus palsy, length of hospitalization, duration of surgery, preoperative and postoperative elbow range of motion, preoperative and postoperative DASH scores and satisfaction scores. Explaining further details about the procedure, the Authors report their results, including a statistical analysis.

Results  At the final follow-up, the mean increase of elbow extension was about 22°. Functional outcomes were successful as well, with a mean increase of 10 points of DASH score. Over 75% of patients were fully satisfied with their outcome.

Conclusions  The outcome has confirmed the good efficacy of the procedure in increasing elbow extension but also in improving cosmetic appearance in adolescents suffering from flexed elbow in OBPP sequelae.

Keywords  Neonatal brachial plexus palsy · Elbow joint · Olecranon process · Flexion contracture · Anterior capsular release

Introduction
The incidence of obstetric brachial plexus palsy (OBPP) has demonstrated a progressive decline in the last 2 decades [1]. Recent studies have calculated a current rate of 1.2–1.3 per 1000 births in the United States [1, 2]. According to many different studies, most patients suffering from neonatal brachial plexus injury completely recover, while only a percentage between 10 and 20% of children show persisting neurological symptoms [3–6]. In spite of the decrease of frequency, among young population OBPP sequelae are still representing a significant functional and cosmetic disability of the upper limb. When a brachial plexus injury does not totally recover, shoulder and elbow joints usually present with deformities, without forgetting possible severe defects of the forearm and hand in extensive palsy, in which elbow contracture is generally neglected. Commonly, attention has been drawn to shoulder involvement; however, elbow deformities should not be overlooked. It has been estimated that about 48% of children with OBPP develop an elbow flexion contracture [7], which can impair functional capability and cosmetic appearance of the upper limb. Effectively, loss of more than 30° of elbow extension causes a limitation of common daily activities such as hygiene, eating...
and opening a door [8]. Since standard treatment for elbow flexion contracture has not been defined yet, many different strategies, both surgical and conservative, have been proposed in the medical publishing. In 2017, we published significant results obtained with a new technique, consisting in olecranon resection and anterior capsular release, in a case series of 11 patients treated between 2007 and 2011 [9]. On this basis, we hypothesized that limitation of elbow extension during growth would be due to soft tissue retraction in combination with a progressive humero-ulnar joint deformation. In authors’ opinion, anterior capsular release along with targeted bone resection of the olecranon tip should improve elbow postoperative extension and ease correction maintenance. The aim of this paper is to prove long-term efficacy of the procedure, both functional and cosmetic, in a larger sample of patients.

Methods

Between January 2007 and September 2017, a total number of 29 cases of elbow flexion contracture following OBPP were corrected by means of olecranon resection and anterior capsular release. All recruited patients had a flexion contracture of 30° or more and an elbow flexion strength of 4 or higher, according to the Medical Research Council Score. Only 26 were included in the present study because 3 patients were lost to follow-up. There were 6 females and 20 males. The mean age at surgery was 16.7 years, ranging from 13 to 24 years. As for the type of brachial plexus injury, patients could be grouped as follows: 11 with a C5–C6 lesion, 11 with a C5–C6–C7 lesion and 4 with a total lesion. Elbow range of motion was recorded with a goniometer before surgery, 6 months after and at final follow-up. Measurements were made with the forearm fully supinated and considering 0° as complete extension and 150° as complete flexion. Anteroposterior and lateral radiograms of the elbow were obtained before surgery. Some patients underwent CT scan for better assessment of skeletal structures, particularly in more severe conditions of contracture. DASH test was administered before and after surgery and at final follow-up. Moreover, to evaluate subjective satisfaction at final follow-up, patients had to answer a 5-point Likert test: (1) Very satisfied, (2) Satisfied, (3) Neither satisfied nor dissatisfied, (4) Dissatisfied and (5) Very dissatisfied. The project was approved by Institutional Review Board.

Surgical Procedure

Before surgery, an informed consent was signed by the patient or, if minor, by his parents.

The same surgeon (level of expertise V according to Tang classification [10]) performed all the interventions under general anaesthesia using a tourniquet. All the patients underwent olecranon resection and anterior elbow arthrolysis following the same procedure which consists in a double step, anterior and posterior, to the elbow. The posterior approach starts with a skin longitudinal incision along the posterior aspect of the elbow, centered on the olecranon process. Proceeding through the subcutaneous fat, distal triceps tendon insertion is exposed, and a V–Y incision performed on the fibrillar tendon structure without utterly detaching the muscles tendinous complex. Elevating the sectioned ends of the triceps tendon, the posterior part of the olecranon and posterior cuff are seen. After incision of posterior cuff, the olecranon tip is identified and resected using an oscillating saw. The correct amount of resection is assessed both clinically and radiographically by pinning olecranon tip with a Kirschner wire (Fig. 1). Approximately 1 cm of the tip of the olecranon bone is severed, which corresponds to the olecranon upper fourth part shown on X-ray (Fig. 2). Actually, the section appears to be wider, considering the cartilaginous cap, invisible under fluoroscopy.
Resected margins are refined with an osteotome and a rasp to achieve a smooth surface. Olecranon stump reshaping is often needed because of the joint incongruence due to its asymmetrical growth. The incised tricipital tendinous insertion was thoroughly sutured. The anterior approach reckons on an incision that runs on anteromedial part of the elbow to detect the lacertus fibrosus and the distal part of the biceps muscle with its insertional tendon, which is often tight and retracted. Incidentally, we prefer not to perform biceps tendon lengthening to avoid loss of active flexion of the elbow.

After elevation of median nerve and vascular bundle, along with biceps muscle belly, aponeurosis of the brachialis muscle is exposed. This thick structure is cut taking care to preserve underlying muscle tissue. After identification of the coronoid process through brachialis muscle fibers, capsular joint resection is realized using a scalpel and completed with scissors (Fig. 3).

A passive elbow extension confirms the complete cut of the anterior part of the joint cuff.

The surgical procedure is followed by immobilization in an elbow plaster for 7 days. Afterwards, a dedicated dynamic orthosis is maintained full time for 6 weeks. In this way, wearing the orthosis, patients are able to start a physiotherapeutic program of passive and active motion of the elbow (Fig. 4). After this period, patients have to maintain the orthosis at night for 6 months (ranging from 8 to 12 h a day), intensifying the rehabilitation program (three times a week with a physiotherapist and daily exercises at home).

### Statistical Analysis

The Wilcoxon test was adopted to compare results before and after treatment, as the range of motion values was not normally distributed. A P value inferior to 0.05 was considered statistically significant. To describe the sample, categorical data were expressed as frequencies, while quantitative values were expressed as means, DS, and ranges.
Results

The mean follow-up period was 7 years and 3 months, ranging from 3 to 11 years. All the patients experienced an improvement of elbow extension in the postoperative, without demonstrating significative loss of active flexion. The mean preoperative extension lag was 61.5 ± 16.7°. A mean raise of 23.77 ± 7.25° (range 10–40°) of extension was obtained 6 months after surgery, compared to the initial range of motion ($P < 0.05$). Such result was maintained in the long term, with a minimal loss of the achieved extension. Compared to the result at 6 months, the patients demonstrated a mean decrease of only 1.54 ± 5.05° (range $-15°/+10°$) of extension at final follow-up. The final follow-up mean increase was 22.12 ± 7.24° (range 5–40°) compared to preoperative extension ($P < 0.05$). The mean postoperative extension lag was 39.4 ± 15.5° at final follow-up. DASH scores demonstrated a good functional outcome with a mean improvement of 10.54 ± 5.36 (range 5–25) at 6 months and 10.15 ± 5.56 (range 2–24) at final follow-up, compared to the preoperative score ($P < 0.05$). As for active flexion, the patients experienced a statistically non-significant loss of 2.88 ± 5.86° (range $-5°/+20°$) at final follow-up compared to preoperative condition (Fig. 5). The average duration of surgery was 81.92 ± 21.26 min (range 45–150). The average length of stay in hospital was 5.85 ± 1.62 days (range 3–9).

The results of the Likert test showed that 8 patients (30.77%) were very satisfied, 12 (46.15%) were satisfied, 3 (11.54%) were neither satisfied nor dissatisfied, two were dissatisfied (7.69%) and one were very dissatisfied (3.85%).
ness of both extension and flexion motion; however, the severe elbow involvement, primarily expressed as a weakness during growth, patients suffering from OBPP can develop consequences of neonatal brachial palsy on the elbow joint. The most typical anomaly is limitation of elbow extension due to combined factors acting on elbow joint during growth, i.e. forced position of the upper extremity and joint contractures.

**Discussion**

Acquired deformities of the shoulder have always been the main interest in the field of OBPP sequelae. Glenoid retroversion, changes in humeral head shape, rotator cuff atrophy, internal and external rotator muscles imbalance have been thoroughly investigated [11–14].

Even though cosmetically impacting, elbow limitations have been scarcely faced, possibly for the poor outcome of surgical procedures in the long term and minor functional impairment compared to those of the shoulder.

Up to now, a new attention has been paid to study the consequences of neonatal brachial palsy on the elbow joint. During growth, patients suffering from OBPP can develop severe elbow involvement, primarily expressed as a weakness of both extension and flexion motion; however, the most typical anomaly is limitation of elbow extension due to a flexion contracture [15]. In our opinion, elbow flexion contracture combines skeletal deformity and soft tissue retraction, primarily due to neonatal palsy and secondarily to combined factors acting on elbow joint during growth, i.e. forced position of the upper extremity and joint contractures.

In 1994, Ballinger and Hoffer [16] recognized elbow flexion contracture as the most common elbow deformity after Erb’s palsy; they also underlined the lack of explanation in its etiology. Since then, many authors have speculated on possible etiopathogenic mechanisms, but the solution still seems to be far away [15]. The most common theory is based on muscular imbalance between elbow flexors and extensors [17, 18], which could be stem from a weakening of extensors [11] or either a precocious or anomalous reinnervation of flexors [16].

According to Al-Qattan, a contributing cause of the contracture might be the typical shoulder posture in internal rotation and slight abduction that determines elbow positioning in flexion [19]. Other hypotheses to explain flexion contracture of the elbow consider the altered muscular growth induced by denervation [20, 21] or an overactivity of long head of the biceps muscle reflecting on elbow joint [22].

However, the weakest point of the above-mentioned theories lies in the fact that only soft tissue involvement was addressed, neglecting bony deformity. In this perspective, a recent study on elbow flexion contracture by Oka and collaborators considers 3D CT scan to assess bony morphology of the distal humerus in patients affected by OBPP. Those authors demonstrated that the olecranon fossa of the affected side was consistently hypoplastic and shallow relative to that on the normal side [23]. In line with these findings, we the authors sustain that bony deformity plays a key role in elbow flexion contracture. The malfunction of denervated muscles in OBPP leads inevitably to abnormal use of the joints and, during developmental age, this anomaly could affect the normal growth process of articular bone ends. At the level of the elbow, the olecranon tends to overgrow and widen, while the olecranon fossa interrupts its natural development remaining shallow. The result is a permanent bony deformity that causes an untimely contact between olecranon process and humeral fossa for olecranon preventing the full active and passive extension of the elbow [9, 24]. Basing on these presuppositions, our surgical procedure includes two phases: the first implies the resection of the tip of olecranon through a posterior approach, while the second phase comprises the incision of brachialis muscle aponeurosis and anterior elbow capsular release through an anterior approach. Relating to the posterior approach, a basic suggestion would be to cut the tip by approximately one centimeter and remodel olecranon remnant, checking its congruence with the olecranon fossa in the distal end of humerus.

Ulnar nerve should be accurately spared but rarely isolation of the nerve trunk is required. In the anterior approach, median nerve and vascular bundle should be protected during brachial aponeurosis cut. During anterior capsular section, it is mandatory to meticulously follow the line of the incision to safely reach the other portion of the joint without damaging small vessels around the joint, so preventing from

![Fig. 6 Pie chart showing patients' satisfaction](image)
hematoma formation. The medial and lateral collateral ligaments of the elbow are incised only in their anterior components, preserving most of the lateral bands to avoid creating elbow instability. The aim of the procedure is to solve both soft tissue contracture and bony deformity, diverging from previous treatment strategies like serial casting and splinting [18, 25], possibly additioned with botox injection of the biceps and brachialis muscles [26], progressive arthro-dystasis with external fixator [17], biceps tendon lengthening [27] or anterior elbow release [28], which all address only soft tissue retraction. Because of the high rate recurrence of deformity, many of the procedures aimed at correcting elbow deformities during growth have proved to be temporarily effective but inefficient in a long term. In particular, many different studies reported good results with serial casting and splinting. This technique could be advantageous in younger patients to procrastinate surgery and preventing deformity progression, but the same authors underlined the high recurrence rate up to 49% [18, 25]. Anyway, our series included only young adult patients with a mean age of 16.7 years who presented late at our observation and, in our opinion, were no more eligible for conservative treatment.

Comparing our study to that of Garcia et al., it is possible to find that elbow anterior release alone gives results similar to our technique, but mean follow-up is only 3 years in their study compared to our 7-year follow-up; furthermore, they consider only 10 patients compared to 29 in our study. We sustain that adding bone resection could favour the maintenance of the obtained correction.

Speculating on the role of mechanical factors leading to deformity we performed the procedure we are now presenting.

In our opinion, the age at surgery plays a crucial role in recurrence risk. In this study, all the subjects were 13 years old or more at surgery. At this age, patients are particularly motivated especially for cosmetic and social reasons and are enough mature to understand the importance of compliance. Furthermore, given that elbow flexion contracture tends to aggravate at puberty, it is advisable to operate on when the skeletal structure is fully developed, to avoid recurrence. As we stated in our previous paper about the technique, it is likely that fully elbow extension is impossible to reach due to the severity of most elbow flexion contractures. The aim of the procedure is to achieve an improved elbow range of motion and a better cosmetical appearance. Moreover, the correction has to be achieved without losing function, so the complete elbow extension is not sought.

The results of the present study demonstrate the efficacy of this surgical technique, even in long term. Elbow extension has improved of 22° on average (Fig. 7), without any increase of instability or loss of active flexion. After a mean follow-up of 7 years, about 77% of patients are still satisfied or very satisfied with their outcome and would recommend this treatment to other patients. The achieved degree of extension in most cases is maintained or slightly decrease; the same conclusions can be drawn in terms of functional results as documented by DASH scores. If run by an experienced surgeon, the procedure results safe, devoid of major complications and not time-consuming.

A possible limitation of this study is the lack of control groups to compare different treatment modalities. Moreover, the impossibility to uniform the postoperative rehabilitation program, as each patient is treated by a personal physiotherapist at home, represents a further restriction. Post-operative orthoses with graded range of motion are essential to maintain and progressively improve surgical achievements. Non-compliant patients can show different outcome. A further limitation could be the use of a generic test for assessing functional results, like DASH score does. A more specific rating system could be useful in such pathologic condition where several segments of the upper limb are involved.

Conclusions

In our opinion, elbow flexion contracture in OBPP results from the combination of bony deformity and soft tissue retraction. Our surgical procedure that comprises olecranon osteotomy and anterior capsular release addresses both issues and proved to be a successful treatment in 26 patients. This surgical technique associated with adequate postoperative physical therapy yielded satisfying long-term outcomes and is particularly indicated for adolescent and young adult patients. Showing long-term results in a large sample
of patients, this paper seems to sustain the efficacy of this surgical approach for managing elbow flexion contracture in OBPP.

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Compliance with Ethical Standards

Conflict of interest The authors declare that there is no conflict of interest.

Ethical standard statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent For this type of study informed consent is not required.

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Healing of Artificially Created Gap Non-union Using Autologous Cultured Osteoblasts Impregnated Over Three-Dimensional Biodegradable Scaffold: An Experimental Study (Rabbit)

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Abstract
Background The large bone defect often require bone transplant or its substitutes to restore bone integrity which have some limitations. The study was conducted to analyze role of autologous osteoblast that are amplified in vivo and impregnated in a synthesized three-dimensional gelatin hydroxyapatite scaffold for treating artificially created critical size defect in rabbit’s iliac crest.

Methods In this research, 4-month-old ten healthy white male rabbits of average weight 2–3 kg were chosen. Osteoblasts cells were isolated from the rabbit iliac crest and were taken in transfer medium to the laboratory and cultured for 2–3 weeks. These osteoblast cells were seed on 3-dimensional scaff old and culture the construct for 2 weeks. The cultured autologous osteoblasts over the scaff old were transplanted into the defect by reopening the iliac crest of the same rabbit from which is cells were extracted. Serial radiograph of pelvis was done to see progressive signs of union.

Results Out of ten rabbits chosen for study two rabbits were passed during study. Gross and radiological examination of rabbits was done at 0, 4, 8 and 12 weeks. Features of union was seen in six rabbits on follow-up. There is no signs of union or minimal new bone formation around the implant material were seen in two case.

Conclusion The study demonstrated using autologous cultured osteoblasts impregnated over three-dimensional biodegradable scaffold for large bone defect is a good option. The importance of three-dimensional biodegradable scaffold is that it provide scaffolding for sufficient interval for new bone formation.

Keywords Three-dimensional biodegradable scaffold · Autologous cultured osteoblast · Gelatin hydroxyapatite scaffold

Introduction

The large bone defects whether caused by trauma, tumor excision, congenital malformation or aseptic loosening of prosthesis often needs bone graft or bone substitute to restore bone integrity. Bone grafting procedures, segmental bone transport, distraction osteogenesis or biomaterials are applied for reconstruction. Autologous bone grafts are currently considered to be the gold standard for bone repair and reconstruction. The repair of bone defects in reconstructive surgery is subject to significant limitations, including donor site morbidity, risk of infection, limited supply of autograft, immune rejection of allograft [1] and poor osteogenic effect of synthetic bone substitutes [2]. In addition, bridging of a large bone defect by callus distraction requires a long-term follow-up and usually an external fixator, both very inconvenient for patients [3–5]. However, there is a great
need for the development of new approaches for reparative osteogenesis.

Cell therapies and tissue engineering are advances made in recent past to treat large bone defects. Cell therapies involving use of any kind of cells to repair damaged or destroyed bone tissue are unique in that the active component consists of living cells. One of the biggest cell therapy areas is tissue engineering, defined by Langer and Vacanti (1993) that applies the principles of engineering and the life sciences to develop biological substitutes that restore, maintain or improve tissue function [6]. Tissue can be engineered in two ways either in vivo by stimulating the body’s own regenerative mechanism with the appropriate biomaterial or ex vivo cells can be expanded in culture, attached to a scaffold and then re-implanted into the host. Depending on the source, cells may be heterologous (different species), allogeneic (same species, different individual) or autologous (same individual). Every type of graft cells has its own complications and limitations. Autologous cells are preferred, because they will not evoke any immunologic response and the potential risks of pathogen transfer are also eliminated [7]. Osteogenic cells are an integral part of any bone tissue engineering strategy. These cells are either transplanted along with the appropriate scaffolds into the bone defects or attracted from the host by osteoinductive factors [8].

Since there are major limitations for treating large bone defects according to standard protocols, there is great need for development of new approaches for reparative osteogenesis. Hence, the purpose of this study was to investigate whether cells isolated from bone marrow and bone could restore the stability of the fractured area and differentiate into normal bone tissue.

Materials and Methods

The experimental study was performed on rabbit model. All animal procedures were approved by Ethical Committee (EC Registration no. ECR/562/Inst/UP/2014) and conducted as per norms laid down by Ethical Committee.

Selection of Animal

4-month-old healthy white ten male adult rabbits of average 2–3 kg weight were chosen and left for 1 week before starting experiment. The rabbits were kept in smooth walled stainless-steel colony cage (1 animal per cage) in comfortable environment and maintained under pathogen free condition. They had free access to standard diet (pellet) and water. The principle of laboratory care, feeding and sacrifice was followed as per ICMR guidelines on care of experimental animals.

Operative Procedure

Surgery on rabbits was performed under anesthesia using ketamine and midazolam injection intramuscularly. In each rabbits, both iliac crest were shaved and disinfected with spirit and betadine and sterile draping was done. Postoperative antibiotic was given. The right-sided iliac crest is exposed using incision over the anterior superior iliac spine extending posteriorly over iliac crest and full thickness $1 \times 1 \text{cm}^2$ bone defect is created (Fig. 1). Care must be taken not to damage much of soft tissue and any neurovascular structure. The incision site was sutured and dressed and rabbits were transferred back to their cages and allowed to ambulate freely.

Cell Isolation

The osteoblasts lies subperiosteally, so the bone piece is transported to lab in sterile condition using phosphate buffer solution (Fig. 2). Transfer medium and growth medium were prepared in the same way except that the transfer medium is serum free. The bone pieces were placed in alpha minimal essential medium (MEM) solution with 10% penicillin and streptomycin. Soft tissue and periosteum were removed through scrapping and extensive washing. The bone samples were washed, and then finally cut into 1–2 mm length. Bones were then again placed in hanks balanced saline solution. The bone samples were incubated in collagenase solution for 25 min, and then the solution was aspirated and kept for cell plating. This was repeated for two more times, for a total of three digestions. For osteoblast cells to properly grow in the medium, the following constituents were added: fresh Dulbecco’s Modified Eagle Medium, fetal bovine serum (FBS), 50 μg/ml of glutamine solution, 50 μg/ml of gentamycin, and 2 mg/ml of amphotericin B.

Fig. 1 Removal of segment of iliac crest for creating gap non-union
Bone Cell Culture

Cell suspension resulting from primary isolation procedure were cultured in type I rat tail collagen coated six-well plates at a seeding density of approximately 250,000 cells per 9.5 cm square in an alpha-MEM medium supplemented with 5% fetal bovine serum, 5% calf serum and 1% penicillin and streptomycin. Cells were maintained at 37°C centigrade in a humidified incubator for 2–3 weeks.

Cell seeding onto Gelatin Hydroxyapatite Scaffold

This scaffold was prepared using 95% gelatin and 5% hydroxyapatite. The osteoblasts cells were grown in batch mode for 30 days to check their viability using haemocytometer. The cells showed a near linear growth for 21 days and after the completion of 21 days, there was a decrease in the number of cells. Therefore, it is better to delink the cells after a certain interval of time and seed them into the scaffold.

Bioreactor Enhancement

Cell polymer construct was transferred into 110 cm³ volume airlift bioreactor. Vessel was cleaned with 70% ethanol and double distilled water, and autoclave sterilized. Construct has been placed in down corner as well as riser of airlift. Airlift reactor was provided with gas supply. Sterile incubator gas pumped through the riser at a flow rate of 0.7–1.2 L/min. Construct has been cultured for 2 weeks in 37 °C/10% CO₂ incubator.

Transplantation

The cultured autologous osteoblasts over the three-dimensional scaffold were transferred into the defect by reopening the iliac crest of the same rabbit from which cells were extracted (Fig. 3). Biocompatibility of the scaffold material was tested in one of the control limbs. The same procedure was repeated in left limbs without osteoblast transplantation. Thus, the defect in the right iliac crest of each rabbit was transplanted with scaffold impregnated with autologous osteoblasts and the left iliac crest serves as control. The scaffold was cut in such a size that it tightly fit into the defect so no additional stability is required. The iliac crest was then closed in layers using aseptic precautions. The rabbits were
followed up at period of 0, 4, 8 and 12 weeks by gross and X-ray examination (Fig. 4).

**Result**

The study was performed in ten rabbits. Out of which two rabbits were passed during study period. Rabbits were examined grossly and radiologically at specific interval. Features of union was seen in six rabbits on follow-up. No sign of union or minimal new bone formation around the implant material was seen in two cases.

At immediate postoperative X-ray there was good bonding between the scaffold and the bone defect so created on experimental side of iliac crest. The scaffold is less radio opaque as compared to surrounding bone. At 4 weeks of follow-up, there was increase in the radio opacity indicative of calcification all around the margin of the scaffold. At 8 weeks, there was formation of bridging mass in the created defect on X-ray. The radio opacity of this bridging mass was gradually increasing. At 12 weeks of follow-up, there was still increase in the girth reaching up to the periphery of the created defect. There was either no evidence of new bone formation or little amount of callus formation seen on control side of iliac crest in same rabbit at final follow-up.

Post-operatively on radiological examination, they could be easily demarcated from the surrounding bone as they are less radio opaque. The new bone formation started from the periphery of the scaffold by about 4 weeks and then with time it involved the central part of scaffold and replaces it. Post-operatively the scaffold implant was resorbed by 8–12 weeks duration which was evident radiologically and by gross examination. It was seen that the consistency of the implant material within the encased fibro-collagen gradually diminished and the thickness of the encasing callus increased suggesting the bioactivity of the implant cell construct. The importance of gelatin hydroxyl appetite implant is that it provide scaffolding for sufficient interval of time for new bone formation.

**Discussion**

Bone is the second most common tissue transplanted in human body, next to blood. Bone grafts are necessary to provide support, fill defects, and enhance biologic repair of skeletal defects. Currently, fresh autologous bone is the most effective graft material available for most clinical situations. However, autologous bone has a number of major disadvantages: (1) the availability of transplantable bone is often insufficient for large defects; (2) there is significant risk of postoperative morbidity at the donor site like pain hemorrhage wound problems, cosmetic disability, infection and nerve damage; and (3) the ability to fabricate a functional state from transplanted tissue often is limited, resulting in less than optimal filling of the defect [10].

Despite increase in the number of procedures that require bone grafting, there has not been a single ideal bone graft substitute. In the light of these inadequacies, numerous investigators in their search for suitable alternatives to autologous bone have explored such diverse substances such as homologous bone (allografts), heterologous bone (xenografts), demineralized bone, deproteinated bone, and synthetically derived organic and inorganic constituents of bone [11]. Yet these alternatives have been largely ineffective in fulfilling the basic mechanisms underlying bone regeneration such as osteogenesis, osteoinduction and osteoconduction [12]. Biomedical scientists and surgeons thus, have a tremendous responsibility to develop biologic alternatives that will enhance the functional capabilities of the bone graft substitute.

The results of our study demonstrate that new bone formation can be elicited in critical-sized defects in iliac crest of Rabbit by the implantation of autologous cultured...
osteoblast impregnated in a three-dimensional biodegradable scaffold. Under the conditions used in the present study, the implantation of autologous osteoblasts in hydroxyapatite scaffold led to the formation of new bone. The new bone was not distributed uniformly throughout the cell–matrix implant but became integrated with the host bone. Radiology of the implanted iliac crest revealed that there was progressive resorption of the implant. Previously similar studies done using bioactive glass ceramics, carbon fiber glass implants, fiber-composites and various other ceramic implants did not show any change in the consistency of the implant even after 20 weeks of follow-up, since none of the implants were biodegradable [13]. Hence, the biodegradability of the implant was a desired and good sign; however, the resorption of the implant was not associated with a corresponding new bone formation which could be appreciated radiologically. This discrepancy could be assumed to be due to the failure of the gelatin in the implant to provide the required scaffold for a longer duration.

The design and selection of an ideal carrier for the delivery of osteoblast cells is based on several criteria [14].

1. The material should allow for uniform loading and retention of cells.
2. The carrier should support rapid vascular ingrowth.
3. The matrix should be composed of radiolucent materials that are resorbed and replaced by bone as new bone is formed.
4. The material should allow or enhance osteoconductive bridging of host bone by the new bone.
5. Finally, the cell–matrix combination should be easy for the physician to handle in a clinical setting.

The scaffold (gelatin 95% + hydroxyapatite 5%) used in this study degraded slowly in the initial hours and rate of degradation increased with time [15]. The rate of growth of osteoblast increased with time in culture medium up to 21 days when the amount of cell is highest and this was the time for seeding the cells on scaffold. The viability of the cells in scaffold decreased with time and therefore it was important to implant the scaffold as early as possible. This would impart a three-dimensional architectural similarity to that of natural bone, thus the scaffold that we provided as our implant should help in the new bone formation in a better way. The aligned structure helped the mineralization of the newly formed bone in an oriented fashion thus hastening the process of bone remodeling at a faster rate. This was due to two broad reasons, first the time taken for reorientation of the newly formed bone to that of the natural bone texture almost vanished and the presence of hydroxyapatite at the site of new bone formation helped healing process of bone regeneration.

Easy availability, large size, easy handling due to their docile nature and a suitable anatomy for the present study; made rabbits as the most suitable species for this study. The hip bone in rabbits, i.e. iliac crest was easily palpable and prominent structure so it is quite easy to create defect for experimental studies.

Commercially, many bone graft substitutes are available such as Pro-osteon 500R (interporous hydroxypatite), Osteoset (surgical grade calcium sulfate), Vitoss (porous pure beta-tricalcium phosphate) and Collagraft. The most noteworthy of them is Collagraft (Zimmer Corporation, Warsaw, IN), which is a composite of porous calcium phosphate granules and bovine-derivered fibrillar collagen to which autogenous bone marrow aspirate is added [16]. Approved by the FDA in 1993, it can be used as a paste or strips. In both formulations, the ceramic component contains 0.5–1 mm diameter granules of 65% hydroxyapatite and 35% tricalcium phosphate. The pore volume of the ceramic granule is approximately 70%. An equal volume of highly purified, bovine-derived collagen (95% Type I collagen) serves as the carrier for the porous ceramic and the autologous marrow. Collagraft possesses no structural strength and therefore is used most frequently in conjunction with internal fixation. Preclinical trials of Collagraft in rat and dog models showed it to be effective in bridging segmental long bone defects. Tricalcium phosphate is rapidly absorbed compared with hydroxyapatite but the granules of ceramic are evident radiographically and histologically years after implantation and the rate of bioresorption of Collagraft has not been studied accurately.

Human trial in Chinese population using bio-derived bone scaffold with allogenous cultured periosteum-derived human osteoblasts showed achievable union in 3–4.5 months after creation of bone gap and followed till 7 years for any evidence of loosening. However, in the study by Peng et al., 60% of fractures of long bones were fresh and comminuted. They could not generalize the results for gap nonunion [17]. Another Chinese trial on 52 patients showed excellent results and union in bone defects followed for a period of 18.5 months by allogenous periosteum-derived osteoblast over a bio-derived bone scaffold. However, the composition of the scaffold was not specified [18].

**Conclusion**

In this study, we have analyzed the role played by autologous osteoblast that are amplified in number in vivo and impregnated in a biomimetically synthesized three-dimensional gelatin hydroxyapatite scaffold for treating artificially created bone defect in rabbit’s iliac crest. The importance of three-dimensional biodegradable scaffold is that it provide scaffolding for sufficient interval for new bone formation.
Compliance with Ethical Standards

Conflict of Interest  The authors declare that they have no conflict of interest.

Ethical Standard Statement  The experimental study was performed on rabbit model. All animal procedures were approved by Ethical Committee (EC Registration no. ECR/562/Inst/UP/2014) and conducted as per norms laid down by Ethical Committee.

Informed Consent  For this type of study, informed consent is not required.

References


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A Novel Tracker-Less, Universal, Image-Based, Computer-Assisted Navigation in Orthopaedic Trauma - A pilot Study

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Abstract
Background Computer-assisted navigation system is well-known orthopaedic advancement which allow surgeon to obtain a real-time feedback during surgeries, thus helps to reduce intraoperative errors. Currently used navigation systems are tracker based, invasive and non-universal. Therefore this study was conducted to test novel tracker-less, image-based, non-invasive, universal, real-time navigation system to predict future position of the guide wire, K wire, screws and plates in orthopaedic trauma surgeries.

Methods Firstly, the software was tested and validated on bone model. Then utilized for non-randomised comparative study conducted on 81 adult patients with stable intertrochanteric fracture treated by dynamic hip screw and barrel plate fixation. In one group, C-arm was used and in other, software navigation was used in addition to C-arm. Parameters such as time to insertion, number of C-arm shoots and number of attempts for guide wire insertion were documented and compared.

Results Use of the navigation software for guide wire positioning in bone models and in the DHS barrel plate surgery proved to be significantly beneficial as compared to not using navigation.

Conclusion Intraoperative use of this new navigation system eliminates trial and error improving accuracy and reducing the operative time and radiation exposure. Thus this novel trackerless, C-arm image-based navigation system have potential to replace existing tracker-based navigation systems because of its universal nature, noninvasive and more effective properties.

Keywords Navigation · Novel · C-arm · Computer assisted · Tracker-less · Trauma

Abbreviations
- AP Anterioposterior
- CAOS Computer-Assisted Orthopaedic Surgery
- IT Intertrochanteric
- DHS Dynamic Hip Screw
- 3D 3 Dimension

Introduction
Currently, orthopaedic is in the era of innovations and evolution. Advance researches in orthopaedic develops new effective techniques which improve the intraoperative precisions, ultimately yielding better results. One of these innovations in orthopaedic is the use of computer assisted navigation systems in planning and carrying out various orthopaedic procedure.

Computer-assisted navigation was first introduced in spine surgery for pedicle screw placement in the year 1998. Since then, it gained wide acceptance among orthopaedic surgeons for various procedures like reconstructive hip and knee surgery, sports injury, trauma, spine and tumour surgery. It allows the surgeons to obtain real-time feedback which can be used to modify the operating technique, thus decreasing the intraoperative errors and improving overall surgical result [1].

Computer-assisted navigation systems can be active or passive [2]. Active navigation prevents the surgeon from moving beyond predetermined safe zones. Passive
navigation is used intra-operatively. It display images on a monitor, with the help of which the operating surgeon can modify their decisions in more precise manner.

Computer-assisted navigation systems are further classified on the basis of reference used such as computed tomography-based navigation systems, fluoroscopy-based navigation systems and imageless tracker-based navigation systems in which there is no radiation exposure [2].

In spite of many advances, the currently used navigation systems suffer from serious drawbacks. Many studies have shown improved accuracy and better postoperative image using navigation techniques, but clinically the results were almost same when compared with old conventional technique [3].

Excessive radiation in 3D-image intensifier, its invasive nature (due to the need to drill pins in bones) and its non-universal nature (not useful for all fractures, bones and implants) are additional drawbacks of the current computer navigation systems observed in day to day practice [4].

Also, instruments and systems are not cross compatible. For example Stryker (Stryker ADAPT, a computer-assisted navigation Adaptive Positioning Technology for Gamma 3) navigation system used for positioning of head screw in proximal femoral nailing is compatible only with the company’s own nail. Smith and Nephew system (TRIGEN SHOT Distal Targeting System) used for distal interlocking works only for the company’s nail (author’s disclosure at the end).

Keeping these drawbacks in mind and as per recommendations in the literature [4], a passive type fluoroscopy-based navigation system was developed called “System for accurate guide wire and implant positioning”. This system is based on intra-operative C-arm or X-ray images. It is a trackerless, non-invasive and universal system that can be used for all fracture and for all bones and also it is compatible with implants of various manufacturers.

Currently, navigation systems are used for the insertion of pedicle screws in the lumbar spine (its first use), distal locking of the intramedullary nail, femur neck fracture fixation with screws, iliac wing and sacroiliac joint screw fixation, acetabulum fracture fixation, proximal tibia or humerus fracture fixation [5].

Intertrochanteric femur fracture is one of the commonest fractures happening in young and geriatric population. During treatment of such stable intertrochanteric fractures using dynamic hip screw with barrel plate, optimum positioning of lag screw is of utmost important, which is considered as slightly superior in anterioresposterior view and central in lateral view, which if not achieved properly increases the chances of screw cut out significantly [6].

Lots of research has happened over various aspects to improve the results of DHS for IT fracture fixation but none of the study describes use of navigation in it which can help to guide and modify the techniques intra-operatively and improve the results postoperatively.

Thus, this pilot study was carried out using new trackerless image-based universal navigation system in case of Dynamic hip screw with barrel plate fixation for stable IT fractures.

It was expected that intraoperative use of this new navigation tool can help to reduce radiation exposure to patient and surgeon, eliminate trial and error, improve accuracy, reduce surgical time and complication rates.

**Functioning of Trackerless Navigation System**

Software imaging and image manipulation is the heart of this system. For example, for an intertrochanteric femur fracture, the C-arm or X-ray image is captured. The software then performs the image processing. It then predicts and displays future position of the guide wire inside the bone on a separate monitor without driving the actual wire inside the bone. (Fig. 1).

Based on this, the surgeon can adjust the position of the guide wire outside the bone itself, so that when the actual guide wire is driven in, it will assume the ideal position.

The software then superimposes virtual dynamic hip screw on the future guide wire position. Similarly, other implants like the barrel plate and cortex screws are suitably superimposed and displayed. (Fig. 2).

Thus, the surgeon is able to visualize the future position of implants inside the bone even before actual guide wire is inserted.

By use of an appropriate scaling method, the software also helps to predict various parameters of the implants like screw length, number of screws required, and appropriate plate angle.

**Material and Methods**

**Part 1**

As it was the new software system-based study and as per literature guidelines [4], it was mandatory to test and validate this system in laboratory before using it on the patients. Therefore, initially, the system was tested and validated on plastic femur heads, tibia and humerus bone models in the operation theatre environment. Guide wires were passed in bone models in the operation theatre under C-arm control with and without the use of navigation system.

First, Benchmark was established by inserting the guide wire without the use of navigation software and parameters were noted. For benchmarking, a total of three models were used, one each for the femur, tibia and humerus.
Then the guide wires were inserted using the navigation software and the results of it were compared to the benchmark parameters. For navigation-assisted guide wire insertion, a total of 26 models were used: 20 for the femur, 3 for the tibia and 3 for the humerus.

The percentage error between the predicted guide wire position and actual guide wire position was also calculated in bone models by superimposing two images of predicted guide wire position and actual guide wire position using the adobe Photoshop software version CC 2018 (19.1.7) which was freely available on internet. Measurements were taken in both AP and lateral view C-arm images. The maximum difference (in mm) between the predicted guide wire position and actual guide wire position were expressed as percentage of maximum bone width.

Part 2

After testing and validating the software system on bone models the software was utilized on adult patients with stable intertrochanteric fracture who were to be fixed with DHS and barrel plate.

This non-randomised comparative study was carried out on adult patients aged 20 years or above with stable intertrochanteric fracture (Boyd and Griffin type 1 or 2). High-risk individuals, patients with polytrauma, unstable intertrochanteric fractures, compound fracture and medically unfit patients were excluded.

Intraoperative C-arm monitoring was used in all patients. Navigation software was used in patients depending upon the availability of compatible C-arm in addition to C-arm monitoring.

Thus, there were two groups: one in which only C-arm was used and the other, in which navigation was used in addition to the C-arm.

The following data were collected for each surgery:

1. Number of attempts for guide wire positioning
2. Radiation exposure as measured by number of C-arm shoots for guide wire positioning
3. Time required in minutes for guide wire positioning

We included 81 patients and navigation was used in 24 patients. Use of the software or not was left over to surgeons preference.

Approval of Institutional Ethics Committee was obtained. Patient consent was waived by the Ethics Committee as the study was considered to carry minimal or no risk there being no intervention, but only image manipulation and visual feedback.
Fig. 2 Virtual implant superimposition and templating of DHS barrel plate
Results

In the bone models, the values obtained using navigation system with regards to number of C-arm shoots, time and number of attempts taken for ideal guide wire positioning are significantly better when compared with non-navigated benchmark values as represented in Table 1.

When various parameters like percentage reduction in time, number of shoots, number of attempts, percentage errors in AP and Lateral view were studied in the bone models, the use of navigation demonstrated favourable

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reductions in all of them as represented in Table 2. Thus navigated system helped in getting more precision and accuracy in bone models.

After validating the software in bone models, it was used to compare the results between two study groups of patients, we found that the mean number of attempts required for guide-wire insertion was significantly less when navigation was used as compared to when navigation was not used (3 ± 1.7 Vs. 5.3 ± 2.1, respectively, \( p = 0.014 \)). Similarly, when navigation was used, it was found that the mean duration (in minutes) required for guide-wire insertion was significantly less as compared to when navigation was not used (9.9 ± 6.5 min Vs. 19.63 ± 10 min respectively, \( p = 0.019 \)). The number of shoots required was also lesser when navigation was used, but this difference was not statistically significant (20.9 ± 9.5 Vs. 37.8 ± 23.2, respectively, \( p = 0.059 \)) (Table 3).

**Discussion**

Computer-assisted navigation system has been playing an important role in orthopaedics and traumatology since the last two decades. Although Navigation systems continue to evolve and improve, the currently used systems are not devoid of drawbacks.

In a review article by Mavrogenis et al. [1], they stated that currently used navigation systems are still in their infancy with the drawbacks of increase of operative time for arrangement of set up, high learning curve, risk of fractures (which is now minimized, but not eliminated, due to smaller pins), an inherent error of 0.1 to 1 mm in the tracking system of commercially available navigation markers, lack of improvement in clinical outcomes.

Zheng and Nolte [4] also concluded that even after about two decades since the introduction of the first robot and navigation systems for Computer-Assisted Orthopaedic Surgery (CAOS), it is still at the beginning of a rapid process of evolution. There is a need to eliminate the drawbacks of the currently available optical tracking systems and to stimulate the development of non-invasive registration methods and referencing tools. All the new techniques and devices will need to be carefully evaluated first in a laboratory setting and then clinically. More prospective and retrospective studies comparing the outcome of CAOS versus non-CAOS procedures with long follow-up time will have to be conducted.

In the study, conducted to fix the trochanteric fractures with gamma nail [7], significant improvement were found in parameters of surgical time, wound size, number of X-ray shoots and accuracy of implant placement using navigation system. Similarly, a study on navigated sub-capital fracture fixation allowed improved screw positioning and reduced radiation to both the surgeon and the patient [8]. These results are more or less comparable to our study.

In our study, when percentage error between the predicted guide wire position and actual guide wire position was calculated, the error was found to be less than 4% in almost all cases of bone models. The tracking system of commercially available navigation markers has an inherent error of 0.1 to 1 mm for each of the three coordinates in space [2]. In our tests, the deviation in mm ranged from a minimum of 0 to a maximum of 2.8 mm in one plane (with an average of 1.31 mm).

In today’s practice, existing computer navigation systems also have drawbacks of morbidity such as fractures and infections due to the placement of bony reference arrays [10], or have excessive radiation exposure [9] and are non-universal [9]. The new navigation software which we used in our study is non-invasive, universal and its working is based as add-on to the C-arm images without actually replacing it.

Our study has demonstrated that the use of this new navigation software has significantly improved the parameters, namely, the time required for guide wire insertion, the number of C-arm shoots and the number of attempts ultimately reducing the radiation exposure to both patients and surgeons.

This same navigation system can be used for other surgeries as well, for example, distal end radius K-wire fixation/plate fixation, proximal femoral nailing, radius ulna shaft plate fixation and proximal humerus plate fixation. The software detects the position of guide wire (or sleeve) on C arm image while its end is touching the bone surface (not driven in) by edge detection and further image manipulation described earlier is effected. This universal nature, compatibility with various implants of different manufacturers and ability to be used in many trauma surgeries makes this new trackerless navigation system more handy and useful. The software is simple to use and does not require any specific learning curve, just understanding of the basic procedure.
Limitations

It is a non-randomized study conducted on small sample size.

Only two fracture types were considered (though, among the most common ones).

Conclusion

The use of trackerless navigation system proved to be beneficial when compared to the fixation done without navigation in various aspects. The universal nature of this new software makes it compatible to be used for various trauma surgeries with implant of different manufacturers. The non-invasive nature of this software also helps to prevent the complications of previously used systems.

Thus we conclude that, this tracker-less, image-based navigation system is a handy tool to improve precision and results both intra and postoperatively. Also it does have a potential to replace existing tracker-based navigation systems.

Further long-term multi-centric studies on a larger number of patients and in other fracture types are required to conclusively prove its benefit.

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Author Contribution Conception of work, NG and VP, acquisition of data NG and VP, data analysis and interpretation NG. Drafting of manuscript NG and VP. Critical revision of articles NG and VP, final approval of the versions to be published NG and VP.

Declarations

Conflict of interest Author has received grant from Government of India for development of the navigation software.

Ethical approval Studies have been approved by the appropriate ethical committee and have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. Patient consent was waived by the Ethics Committee as the study was considered to carry minimal or no risk there being no intervention, but only image manipulation and visual feedback. Manuscript has been read and approved by all the authors and represent our original work which has not been published anywhere or under consideration.

References

Pin Leverage Technique: A Simple Percutaneous Technique for Elevation of Posterolateral Tibial Plateau Fractures

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Abstract
Depressed lateral tibial plateau fractures with a large central or posterior fragment can be seen in isolation or association with complex proximal tibia fractures. Conventionally elevation of the large depressed fragment is done by bone tamp through a medial metaphyseal window in isolated fractures, or the fractured window in associated complex fracture scenarios. Though various instruments have been devised for this purpose, reaching the posterior aspect of lateral condyle through the medial metaphyseal window is not always easy, considering the difficulty in aiming and trajectory. Excessive maneuvering can result in the widening of the medial metaphyseal window, leaves a large metaphyseal void, intraarticular penetration of elevating device, and comminution of the depressed fragment. Described herein is an alternate percutaneous technique for effective reduction of selected lateral tibial plateau depression fractures using Steinmann pin. Twenty-one patients with at least 1-year follow-up with successful outcomes have benefitted from this reduction technical tip thus far.

Keywords  Pin leverage technique · Proximal Tibia · Lateral Plateau · Depressed fracture · Posterolateral fracture · Percutaneous · Elevation

Introduction
The lateral plateau depression fracture is a common injury of proximal tibial fractures encountered either in isolation or in combination with complex injury patterns. The common mechanism involved in lateral condyle depression is axial loading with the valgus moment with a knee either in flexion or extension. With the knee in flexion, the central and posterior aspect of the lateral plateau is involved and is usually not comminuted, unlike in pure axial load-valgus injuries [1]. The incidence of these fractures is approximately 15% of the total tibial plateau fractures and 44% of all bicondylar tibial plateau fractures [2, 3].

Traditionally displaced shear fracture of the posterolateral condyle is approached through the more invasive procedures like the posterolateral approaches, which are well described in the literature [4]. For depressed fractures of a posterior and central aspect of lateral tibial plateau with intact or minimally displaced posterior cortex are usually treated by less invasive techniques like elevation using the metallic tamps and elevators through the medial metaphyseal window [5, 6], arthroscopic assisted reduction [7] and more recently using inflatable bone tamps [8]. Irrespective of the technique used, the elevation device should be placed perpendicular to the depressed articular surface in all the planes for accurate elevation, which is not always possible from the medial aspect, considering the difficulty in aiming and trajectory. Excessive
maneuvering can result in a widening of a medial metaphyseal window, intraarticular penetration of elevating device, the comminution of the depressed fragment, and large metaphyseal void at times requiring a bone graft. So the elevation technique should be tailored to the morphology of the depressed articular surface.

Described herein is an alternate percutaneous pin leverage technique to simply and effectively reduce selected central and posterior depression fracture of the lateral tibial plateau without the need for bone grafting. This technique can be used for isolated lateral plateau fractures or those associated with complex proximal tibia fractures. The paper discusses the indications, surgical technique, and limitations in detail, and the outcome of 21 patients treated with this technique.

**Preoperative Planning**

Standard anteroposterior (AP) (Fig. 1a) and lateral (Fig. 1b) radiographs are evaluated carefully for fracture morphology and the location of the depressed articular surface. The depressed lateral condyle can be seen as a “double density sign” on the lateral view in isolated fractures. CT scan is recommended for all cases that fit into the percutaneous technique, for accurate assessment of the location of a depressed plateau in all three planes, to look for a number of fracture fragments, and to study the associated complex fracture (Fig. 1c, d). The important prerequisite is the intact or easily restorable lateral cortical rim with percutaneous methods.

**Surgical Technique**

**Position**

The patient is supine on a radiolucent top table with the involved extremity elevated over a rectangular cushion. The procedure is routinely done under tourniquet, and the limb is prepped and draped at least to the middle of the thigh. The fluoroscopic C-arm is placed on the contralateral side. Access for fluoroscopic images including AP, lateral, and AP view in the plane of a plateau (10–15° caudal view) are confirmed.

**Equipment**

4 mm Steinmann pin with T-handle, 6.5 mm and/or 4 mm cancellous screw set, in addition to a standard proximal tibial periarticular instrumentation set, is required.

**Elevation of Plateau**

The skin incision is marked under fluoroscopic guidance—in AP view a K-wire is placed centering the depressed lateral plateau articular surface and in lateral view just below the dense articular margin of the depressed fragment. A 1 cm skin incision is made at the intersection point and deepened using hemostat up to the bone. A 4 mm Steinmann pin (pilot pin) is inserted using a power drill under fluoroscopic guidance centering the depressed fragment in AP view, and 1–2 cm below and parallel to the lateral plateau articular surface. The direction of the pin should be cephalad to caudal in the sagittal plane (Figs. 2a, a’ and 3a). The pilot pin

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**Fig. 1** A 50-year-old male presented to the emergency room following self-skid and fall from a bike. AP (a) and lateral (b) radiograph of the left knee shows the large noncomminuted depression fracture of the posterolateral tibial plateau. Arrowheads in b represent the depressed posterolateral condyle (double density sign). Sagittal (c) and coronal (d) CT images show the single large posterolateral depressed fragment with the intact posterior cortex.
**Fig. 2** Diagrammatic representation and a corresponding clinical picture showing the position of pilot pin and reduction maneuver. Note the direction of the pilot pin before \((a, a')\) and after \((b, b')\) reduction. Curved arrow in \(a\) and the straight arrow in \(b'\) represents the direction of levering of the pilot pin from cephalad to caudal direction. Arrowheads in \(a\) represent the normal medial tibial plateau. The dotted red line in \(a\) represents the depressed posterior-lateral tibial plateau which has been elevated to normal height in \(b\). Arrow in \(a\) and \(b\) represent the position and direction of the pilot pin before and after reduction.

**Fig. 3** Fluoroscopic images showing the sequence of reduction and fixation using pin leverage technique. Arrowheads represent the depressed convex lateral plateau; the dotted line represents the intact slightly concave medial plateau, pilot pin inserted parallel to the depressed articular surface. \(b\) Note the position of the pin, inserted up the posterior cortex but not engaging it. \(e\) The lateral plateau is elevated to the reference medial plateau. \(d, e\) Temporary fixation with K-wire with the pilot pin in position. \(f\) Definitive fixation using a cancellous screw with the pilot pin in position. Note the position of a screw placed as posterior as possible in the depressed fragment. \(g, h\) Final intraoperative fixation with two screw construct and anatomical reduction.
should be inserted up to the posterior-most aspect of the depressed plateau, but should not penetrate the articular margin or engage the posterior cortex of the tibia. Engaging the posterior tibial cortex prevents the effective leverage of the depressed plateau. Once the pilot pin is in the desired position, the T-handle is attached to it for an adequate grip (not shown in the figure). Next is to lever the pilot pin in a sagittal plane from cephalad to the caudal direction (Figs. 2b, b’ and 3b, c). This maneuver is done in a controlled fashion under fluoroscopic guidance until the depressed lateral plateau is completely elevated and matches the level of dense medial plateau articular surface. If the initial pin position is not adequate for complete elevation, repositioning of the pilot pin or usage of second pin adjacent to the pilot pin to provide a wide buttress for elevation can be done.

Obtaining the true AP (caudal tilt view) and lateral view (with both femur condyles overlapped) is key to assess the location of the depression and adequacy of elevation intraoperatively. Smaller size pins less than 4 mm is not recommended as they may bend and does not provide adequate leverage force for elevation.

Internal Fixation

Once the elevation was done, one or two 1.8 mm subchondral K-wires are placed from lateral to medial, engaging the opposite cortex (Fig. 3d, e). Final fixation completed with the pilot pin in position using two subchondral 4 mm/6.5 mm cancellous screws, depending on the size of the fragment. We believe that two screws construct with one positioned posteriorly (Fig. 3f) and other in the center of the depressed articular surface gives more stability and prevent rotation of fragment on a single screw on loading during early passive knee flexion (Fig. 3g, h). The pilot pin is then removed and the wounds are closed in a standard fashion. Standard AP and lateral radiographs are taken (Fig. 4a–c).

For lateral plateau depression associated with complex proximal tibia fractures, a similar pin leverage technique can be used in combination with the appropriate reduction and fixation of the involved columns. Pin leverage technique in our experience greatly facilitates indirect access to the central and posterior aspect of a lateral plateau and avoids the need for additional surgical exposures in these cases (Fig. 5).

Postoperative Protocol

A postoperative femoral nerve block is given to all patients, and continuous passive motion is started on the immediate postoperative day. Patients were kept on non-weight bearing walking for 6 weeks at which time radiographs were repeated and gradually progressed to full weight-bearing walking during the next 6 weeks. All patients received clinical examination, radiographic analysis, and knee society score evaluation at the final follow-up.

Results

Between 2015 and 2018, we identified 21 tibial plateau fractures that were selectively treated using the described technique. All are closed injuries. There were 14 males and 7 females. The average age at the time of presentation is 42.4 years (24–56). Of 21 cases, 13 are isolated lateral plateau fractures which needed only screw fixation. Eight cases were associated with complex proximal tibia fractures requiring additional plate fixation. Of eight associated fractures, six had posteromedial condyle shear fracture and two are bicondylar fractures with metaphyseal comminution.

All 21 cases (100%) were successfully reduced intraoperatively using this technique. The average duration of follow-up was 19 months (12–34). The average knee flexion at the final follow-up was 136°. The average knee society score was 92. There were no intraoperative complications. No patient developed a superficial or deep infection. At the final follow-up, none had a loss of reduction or osteoarthritic changes (Fig. 6). Three patients had the prominence of an implant on the medial aspect, but none underwent hardware

![Fig. 4 a Intraoperative clinical image showing the incision for the pilot pin (yellow circle) and screw placement (black arrow). Note the small size of the incisions needed for the pin leverage technique. b, c Final postoperative AP and lateral radiographs were showing the anatomical reduction](image)
removal. The use of appropriated screw length should have avoided this problem. All patients returned to their pre-injury activity level.

Discussion

With the advent of the CT and a better understanding of the mechanism of injury and fracture morphology, various novel approaches and techniques have been described for the plateau fractures of the proximal tibia. There is always a dilemma in the case of lateral and posterolateral plateau depression fractures regarding the choice of approach and technique of elevation. Various lateral and posterolateral approaches have been described in the literature; all these are justified when there is a sheared and displaced condyle [4, 9–14]. In scenarios like depressed fracture of the central and posterior aspect of a lateral plateau with an intact or nondisplaced posterolateral cortex, less invasive techniques can be used. Traditionally described less invasive techniques are elevation through a medial metaphyseal window using the various bone tamps or elevation rods, arthroscopic assisted reduction techniques, or balloon tibioplasty [5–8, 15]. Though elevation through the medial metaphyseal window is routinely used, approaching the posterior aspect of lateral condyle through a medial metaphyseal window is not always easy, considering the difficulty in aiming and trajectory. This technique is useful in cases where the depression is predominantly in the coronal plane, were the elevation rod can be place perpendicular to the depressed articular surface in all planes and can be elevated anatomically. But in cases where the articular depression is mainly in the sagittal plane, the elevation rod from the medial side cannot be placed perpendicular to the
depressed articular surface and may lead to inadequate elevation or fragmentation of the articular surface (Fig. 7). On the other hand, arthroscopic assisted techniques and balloon tibioplasty are handy for most trauma surgeons. We propose a Pin leverage technique in these cases, where

![Fig. 6](image)

**Fig. 6** A 30-year female presented after a motor vehicle accident. **a, b** AP and lateral radiograph of a left knee showing the depression of the central and posterior part of lateral tibial plateau with nondisplaced fracture of the lateral condyle. Axial (**c**), coronal (**d**), and sagittal (**e**) CT sections showing the single large depression of lateral plateau with nondisplaced shear fracture of the posterolateral cortex. Three months postoperative AP (**f**) and lateral (**g**) radiograph showing the anatomic reduction. At 6 months, she sustained a repeat fall and distal femur medial condyle fracture. CT scan, axial (**h**), coronal (**i**) and sagittal (**j**) sections taken at that point show the maintenance of anatomic reduction

![Fig. 7](image)

**Fig. 7** a Diagrammatic representation showing the lateral plateau depression predominantly in the coronal plane (shaded area with dotted outline), which are amenable for the elevation through the medial metaphyseal window (arrow directed from medial to lateral). The bone tamps (arrow) can be placed perpendicular to the depressed fragment and can be easily elevated. b Shows the depression mainly in the sagittal plane. In these scenarios, the elevation rod from the medial side cannot be placed (arrow with cross mark) in the plane of depression and may lead to inadequate elevation or comminution of articular fragments. The ideal placement of the elevation rod for these cases is in the sagittal plane (black arrow)
the pilot pin can be placed in the plane of the depressed articular surface, and controlled elevation can be done.

The success of this technique depends on a good understanding of its indications and limitations. Pin leverage technique is recommended for lateral plateau depressed fractures with single large posterior or central fragment with depression predominantly in the sagittal plane. For the fragments depressed predominantly in the coronal plane, this technique can be used with appropriate positioning of the pilot pin and carefully choosing the direction of leverage. Pin leverage technique is difficult to perform in comminuted depressed fractures, severe osteoporotic fractures, and those requiring the bone graft after elevation. In elderly osteoporotic fractures, the anterior tibial cortex may not provide an adequate fulcrum to lever the depressed fragment and leads to cut through of the pilot pin. It is also not indicated in fractures with displaced posterolateral condyle, in which case direct posterolateral approach and fixation are needed.

The advantages of this technique are minimally invasive, no specialized instruments are needed and avoid separate metaphyseal window for elevation. It also allows for more controlled elevation without risk for intra-articular penetration of elevating instrument or iatrogenic comminution of the depressed fragment. As the single pin is used to elevate the depression, it avoids the creation of an iatrogenic metaphyseal void akin to the medial metaphyseal window, where the entire tract is left with a void after elevation, at times requiring bone grafting. In carefully selected cases it avoids the extensive and technically demanding posterolateral approaches. In associated complex proximal tibia fractures, the pin leverage technique avoids additional surgical exposure. No major complications related to the technique were noted in our series. Though the concerns may be the breach of intact anterior proximal tibia cortex by the pilot pin during elevation, it is in the safe corridor and thus not clinically significant.

In summary, we describe a percutaneous pin leverage technique for the elevation of a single large central and posterior depression fracture of the lateral tibia plateau. In this small series, clinical and radiographic data suggest that the pin leverage technique as an alternative for more invasive approaches in selected cases of posterolateral tibial plateau fractures.

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**Declarations**

**Conflict of interest** All the authors declare no conflict of interest.

**Ethical approval** Study is approved by an institutional review board.

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New Technique for the Proximal Leg Reconstruction: Medial Sural Artery-Based Cross-leg Flap

Ahmet Kaplan · İpek Allı · Hasan Murat Ergani · Burak Yaşar · Çağdaş Duru · Ramazan Erkin Ünlü

Abstract
Reconstruction of the lower extremity, especially the proximal lower leg, is known to be a challenge for reconstructive surgeons. When there is extensive vascular damage, the use of local flaps and microsurgical methods will be limited, so there are few reconstructive options available. We want to define the use of medial sural artery-based cross-leg flap for the reconstruction of the proximal lower leg. A 51-year-old male had a soft tissue defect on the proximal leg region because of a gun-shot injury. We observed that there was no chance of a local flap as a result of CT angiography. We considered free flap to be risky because of extensive vascular damage and medial sural artery-based cross-leg flap was planned. A 12*20-cm-sized medial sural artery-based cross-leg flap was elevated from the contralateral leg and adapted to the defect without tension.

Keywords Cross-leg · Knee · Limb salvage · Medial sural artery · Wounds

Introduction
Reconstruction of the lower extremity is known to be a challenge for reconstructive surgeons [1]. The lower limb has poor wound healing, and combined with the limited amount and mobility of the soft tissue, reconstruction of this area becomes even more difficult. There are many solutions to these problems, ranging from local flaps to free flaps. Reconstruction of the proximal 1/3 of the leg may be more challenging, especially if gastrocnemius muscle flap or reverse-flow anterolateral thigh flap cannot be used. Even though free tissue transfer is accepted as a gold standard treatment for such situations, patients with extensive vascular damage may force the surgeons to seek different solutions.

The cross-leg flap was first described by Hamilton in 1854 to reconstruct a chronic ulcer, and it has been used ever since. Even though it was replaced by free flaps after the rise of the microsurgery, a cross-leg flap is still an effective alternative for reconstruction of the lower extremity, especially with patients who are unsuitable for free tissue transfer or the salvage procedures after flap failures [2]. In the last decades, classic cross-leg flaps are abandoned for the pedicled cross-leg flaps [3]. These flaps are mostly described for the defects in the middle-distal 1/3 of the leg. Cross-leg flaps that are described for the reconstruction of the defects in the proximal 1/3 of the leg has not been seen in the literature.

One of the many options for reconstruction of the lower extremity is medial sural artery-based flap. It is a fasciocutaneous flap and was first described by Cavadas et al. in 2001 [4]. This flap is most commonly used as a pedicled flap for knee defects or as a free flap for head and neck reconstruction.

In this case, we reconstruct a defect in the proximal 1/3 of the right crural area, with contralateral medial sural artery-based cross-leg flap.
Case Presentation

The patient is a 51-year-old male with no known chronic disease, who has suffered from a gun-shot wound to the proximal 1/3 of the right tibia, and also knee joint had been totally destructed. The patient was treated for popliteal artery injury with an alloplastic vascular graft about 20 cm between the popliteal artery to the posterior tibial artery in another hospital, and after the wound fail to heal; he was referred to our hospital about 1.5 months later. The wound was situated in the proximal 1/3 of the right crural area, and a large necrotic area was present (Fig. 1). After a series of debridement, a defect of about 8 × 12 cm was present, and an alloplastic vascular graft was exposed. For the assessment of vascularity, a CT angiography was performed. Of about 10 cm proximal and distal to the poplitea, a vascular allograft was present and it was decided to be unsuitable to plan a pedicled or a local flap.

In the CT images, we noticed contralateral medial sural artery, and we thought that a medial sural artery-based flap can be used as a cross-leg flap for the reconstruction of the defect (Fig. 2). After soft tissue reconstruction, knee arthroplasty was performed by the orthopedics department, as the knee joint was destructed.

Surgical Technique

First, we marked the medial sural artery on the contralateral leg preoperatively. A line was drawn from the midpoint of the popliteal crease to the medial malleolus [5]. The pivot point was determined as the area that the medial sural artery was emerging from the gastrocnemius muscle (Fig. 3). A flap with a size of 12 × 20 cm was planned around the pre-drawn line. The flap was elevated from distal to proximal and adapted to the defect without tension (Fig. 4). The donor site was reconstructed with a split-thickness skin graft. After surgery, both legs were held together by bandages only. The donor leg could be mobilized since the bandages were not too tight. The pedicle was divided 2 weeks later (Fig. 5). In this period, the patient could be mobilized with a wheelchair. During this period, anticoagulant medication was given to our patient.

There was no complication in the late postoperative period (Fig. 6).

Discussion

There are different reconstructive options for the defects in the proximal 1/3 of the leg including local, distant, and free flaps. Local flaps are options, but the surrounding tissue may be in the injury zone or simply there may not be enough adjacent tissue to cover the whole defect. The second option is free tissue transfer, and this procedure has been the gold standard for reconstruction, but patients with any limitation for microvascular surgeries create a challenge for this approach [6].

In our case, the location, damaged vascularity and overall nature of the defect made it difficult to reconstruct with these two options. In such a patient, the first option is the gastrocnemius muscle flap [7], while the second option can be a reverse-flow pedicled anterolateral thigh flap [8]. These options could not be applied, because the pedicles of the flaps cannot be relied on in CT-angiography images. Likewise, the free flap was not considered at this stage, as
no suitable recipient vessel could be seen. Therefore, we preferred to use a cross-leg flap. However, no cross-leg flap was defined for the reconstruction of proximal leg defect in the literature.

Peroneal artery and posterior tibial artery perforator flaps, or reverse sural flaps were used as pedicled cross-leg flaps but they were defined mostly for the defects of the distal 1/3 leg or rarely for the middle 1/3 of the leg [9]. Also, the conventional cross-leg flap is not used in the proximal leg. Since these flaps originate from the distal or middle 1/3 of the opposite leg, it is not possible to reach the proximal part of the injured leg. Even if it reaches, there may be dehiscence as there will be tension, and the comfort of the patient is seriously reduced.

Medial sural artery-based flap is most commonly used as a pedicled vascular island for the reconstruction of the knee defects [10]. However, its use as a cross-leg flap has not been found in the literature. In this case, after excluding the free flap option, there were not many choices except medial sural artery-based cross-leg flap, and we believe that it is a safe option to consider in challenging cases such as this one.

Cross-leg flaps are historically valuable reconstruction options. No wonder the use of cross-leg flaps has naturally decreased with the advancement of microsurgery. However, it can still be used in challenging cases and salvage procedures. This cross-leg flap, which we defined for proximal leg defects, can be used in patients with an extensive knee injury or exposed knee prosthesis when other options are not available.
**Fig. 4** Intraoperative image just after flap inset: make sure that the flap adapts without tension

**Fig. 5** Early postoperative image: just after pedicle division, 14 days later
Fig. 6  Late postoperative image, 3 months later, department of orthopedic was planned knee arthroplasty
Isolated Fracture Dislocation of Medial Humeral Condyle Without Elbow Dislocation: Mechanism of an Unreported Injury

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Abstract
Dislocations of elbow are often associated with fractures in proximal radius and/or ulna. In adults, fracture dislocations involving humeral condyle are exceptional and have been reported only in association with lateral humeral Condyle. Medial condyle Fracture dislocations have not been reported in adults. We present a curious case of isolated fracture dislocation of medial humeral condyle in an adult in a setting of supracondylar—intercondylar fracture of distal humerus in which elbow joint remains in position, while medial condylar fracture fragment gets dislodged from olecranon notch. A possible mechanism of injury is explained.

Keywords Medial condyle humerus fracture · Condylar fracture dislocation elbow · Partial dislocation elbow · Isolated fracture dislocation of medial humeral condyle · Fracture avulsion and dislocation of medial condyle of humerus

Introduction
Fracture dislocations of elbow in adults, have associated fractures usually in radius and/or ulna [1]. Fracture dislocation involving humeral condyle are common in paediatric population, but complex elbow dislocations with associated distal humeral fracture have been reported only exceptionally in adults [1]. Most common type of such dislocations is lateral condyle fracture dislocations [1]. Dislocations with supracondylar-intercondylar component are rare [2]. Medial condyle fracture dislocations in adults have never been reported.

We report a curious case of isolated anterior dislocation of the medial condyle of humerus in a case of supracondylar-intercondylar bi-column fracture of distal humerus, wherein lateral condyle fragment along with part of trochlea stays within its position in olecranon notch without any disruption of either the humeroulnar articulation or radio-capitellar articulation.

Case Report
A 20-year-old female reported to our hospital 6 days after slipping in a Sarson field (Mustard field), landing on left elbow and sliding for a few feet. Injury was closed with bruise on medial aspect. X rays (Fig. 1) and CT scan (Figs. 2 and 3) films are shown. Please note isolated anterior dislocation of Medial condyle fragment, with rest of articular surface still within olecranon notch. Also note minimally displaced, very low, lateral column fracture with intact radio-capitellar articulation. Fracture is classified as OTA 1.3 C1 with medial condyle dislocation. Closed reduction of dislocation had already been tried at secondary care centre and had been unsuccessful. No immediate attempt was made for any closed reduction at our centre. Patient had no other associated injury.

After pre-anæsthetic work up, patient was taken up for surgery under general anaesthesia. A gentle closed reduction was attempted but it was difficult to get any hold on dislocated fragment which was locked against the coronoid process and reduction attempt was unsuccessful. No aggressive attempts at achieving closed reduction were made to avoid any aggravation of mildly displaced lateral column.

Surgery was done in lateral decubitus position with arm supported on a post with forearm hanging free to permit elbow flexion up to 120°–130°. A standard midline posterior incision was made. An olecranon chevron osteotomy
was done under Image Intensifier control to place level of osteotomy at most distal part of bare area of olecranon notch to permit more direct access to the coronoid process, where dislocated fragment was locked.

The dislocated fragment was found rotated and carrying the attachments of common flexor origin and medial collateral ligament. Dislocated fragment could be unlocked from coronoid process in 100 to 110 degree of flexion. Moderate valgus force was applied to the elbow for relocation of dislocated fragment into the Olecranon Notch. The manoeuvre was not particularly difficult and reduction was achieved easily after de-rotation in hyperflexion.

Intercondylar fragments were converted into single fragment using two intercondylar wires passed from lateral to medial. Anatomical reduction of supracondylar component was then achieved and provisionally fixed with multiple K wires. Lateral column fracture was very low and only two 2.4 mm screws could be accommodated in capitellar area around already placed Intercondylar K wires.

Fine tuning of the reduction of medial fragment to stabilized lateral column was then done. Stable fixation of medial fragment to reconstructed lateral column was achieved with three Interfragmentary screws passed from lateral column to medial column (Fig. 4). Medial column plate was avoided to prevent stripping of attached muscles and ligaments from thin medial condylar fragment. One 2.4 mm Lag screw was finally inserted from medial to lateral above the attached tissues close to the beak of medial fragment to secure the fixation. The ulnar nerve transposition could be avoided because of absence of any major implants medially.

Reattachment of the olecranon osteotomy was done with tension band wiring. The elbow joint was assessed and was found stable to varus or valgus stress as well as flexion and extension range. The surgical wounds were closed on a drain, sterile dressing was applied, and a posterior splint was applied. Drain was removed after 24 h of surgery.

Post-operative and follow up X-ray (complete follow up of 18 months is available) are shown in Fig. 4. Patient achieved an arc of motion from 5° to 160° flexion. Patient asked for removal of implant before her marriage, due in a few months, and was obliged. Range of motion is shown after removal of Implant (Fig. 5).

Discussion

Terrible triad of Elbow is a recognised common injury pattern comprising of elbow dislocation associated with fractures in proximal radius and/or ulna [1]. However, complex Elbow dislocations with associated fractures in distal humerus in adults are much less common [1]. Results of open reduction and internal fixation are reported as good to excellent in such dislocations [1].

Compared to lateral condyle fracture dislocation; bi-column fracture dislocation is a rarity [2]. Only solitary case report in literature is of a 43-year-old female who sustained injury after falling from a height of 20 ft onto a concrete surface. Elbow dislocation was open. Whole of articular surface, separated from shaft fragment at Supracondylar fracture line, was dislodged out of Olecranon notch as intercondylar fracture line was un-displaced. Patient had associated fractures in acetabulum and bilateral radii. Fractures of the
Fig. 2 3D-CT Spots: views from anterior and medial aspect. Please note Mildly displaced Supracondylar Fracture line. Medial Condylar Fragment is dislocated anteriorly and locked against coronoid process. Please note empty medial part of olecranon notch.

distal humerus was managed by ORIF. The dislocation was treated with closed reduction and splint stabilization in a manner identical to the approach used if the dislocation had presented as an isolated injury. Functional results were not reported.

Compared to reports in literature our case has few rare and unique features which can be enumerated as (1)
Supracondylar fracture of humerus with dislocation of elbow in an adult (2) Dislocation is partial with isolated dislocation of medial condyle out of olecranon notch, while rest of joint remains congruent (3) Dislocation occurred in anterior direction. (4) Trauma causing the injury pattern was moderate with no other associated injuries or any open wound.

Furthermore, supracondylar—intercondylar distal humerus fracture line was very low. The Intercondylar fracture line was passing through medial third of Trochlea leaving radio-capitellar articulation completely undisturbed. The lateral 2/3 of the trochlea containing trochlear groove, lateral trochlear ridge along with capitellum formed the lateral articular fragment. This lateral articular fragment stayed within olecranon notch. Such a bi-column fracture with closed partial anterior elbow dislocation is so far an unrecognised entity.

From treatment point of view, except the reduction of anteriorly dislocated fragment which required unlocking from coronoid process in hyperflexion, de-rotation and relocation of the fragment into olecranon notch by opening medial joint line by valgus force; the treatment was by standard lateral column fixation using posterior midline trans-olecranon approach. Medial condylar fragment was much smaller and thinner than usual, and hence plate fixation of medial column was avoided. However, we could insert four Inter-fragmentary screws into the small fragment; three from lateral to medial and one 2.4 mm from medial to lateral and fixation was assessed to be adequate and stable. Avoidance of plate fixation helped us to leave all the muscle and ligament attachments to the small medial condylar fragment undisturbed.
Our case being first of its kind to be reported is off-course noteworthy, but the injury may have been caused by unusual mechanism as explained hereinafter. Elbow dislocations with distal humerus fracture described in literature result from violent trauma ranging from car accident to fall from heights on hard concrete surface. There was always high frequency of associated injuries in the same limb, other upper limb and other parts and dislocations may be compound. Our case was a slip in a Sarson (Mustard) field, where surface is neither hard nor there was any associated injury, nor was it open.

Historically mechanism of supracondylar—intercondylar fractures has been accepted to be an axial load on the elbow, with the olecranon acting as wedge, splitting the medial and lateral columns of the distal humerus. Mechanical studies have shown that bi-column fractures are produced with elbow flexed beyond 90°.

Milch [3] and Bentounsi [1] described mechanism of dislocations of elbow associated with isolated condylar fractures without supracondylar component. Milch emphasised importance of lateral wall of trochlea and explained how, when lateral wall of trochlea remains attached to the fracture fragment, fracture dislocation occurs; and simple fracture occurs when lateral wall of trochlea remains unseparated from humerus. Classically these dislocations are posterior with medial and lateral displacement depending upon the

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**Fig. 4** Post Op (Upper row) and Union X rays (Lower row): Please note that no major implant has been placed on medial column other than a 2.4 mm IF screw.
condyle fractured with fracture fragment displacing superi-
orly towards humerus.

In our case, the dislocated fragment does not have any part of lateral wall of trochlea. Intercondylar fracture line is far medial, leaving all of trochlear groove as well as some part of articular surface medial to it remaining attached to lateral wall of trochlea as part of lateral fragment. Milch [3] beautifully explained the stability provided by accurate fit of contiguous ridges and grooves on articular surfaces of distal humerus and proximal radius and ulna. This may be the reason why humeroulnar and radio-capitellar joints did not dislocate in our case.

Most curious in our case is dislocation of medial condylar fragment with fragment displacing inferiorly towards coronoid process, and therefore, we believe that the axial force was not the reason for dislocation in our case. The inferior displacement has been recognised by Milch in fractures but not fracture dislocations. He explains that when force is applied to extended elbow “tension on ulnar collateral ligaments leads to an abduction avulsion fracture with downward displacement of medial condyle.” It is logical to conclude that avulsion force either by Ulnar collateral Liga-
ment or attached Flexors was the underlying mechanism in displacement of the medial condyle fragment in our case.

In Milch description, the condylar fracture line extends obliquely, upwards and medially from joint surface; (1) from Trochlear Groove in Simple Fractures (2) Lateral to lateral wall of Trochlea in fracture dislocations. It is easy to understand why forearm bones will go with fracture fragment in either of these two situations, because accurate fit of contiguous ridges and groves on articular surfaces of distal humerus and proximal radius and ulna remains mostly Intact. In our case, because dislocated fracture fragment was separated medial to the contiguous fit of Trochlear groove and Olecranon-coronoid ridge, the forearm stayed with main articular Fragment in the elbow joint and did not dislocate.

It is interesting to note that intercondylar fracture line in our case was a clean vertical split and not oblique as anticipated in Milch description. Smaller than usual size of medial condylar fragment with verticality of fracture line along with location of the fracture line, medial to trochlear groove, may be the reason that avulsion force was able to pull out the fragment out of joint in our case unlike the scenarios described in Milch paper. Actively contracting flexor muscles may have provided the rotatory and tilting force necessary to ease out the medial condylar fragment out of sigmoid notch of olecranon. In con-
text of active role of flexor muscles in the avulsion in this case, a parallel with epicondylar fracture avulsion seen with elbow dislocation in children and adolescents is difficult to miss [4].

One point of contradiction still remains. From foregoing description, it would imply that avulsion of medial condyle required extended position of elbow, while supracondylar fracture required flexed position of 90°. And our case had both components. From our understanding by detailed discussion with the patient, patient stumbled and fell in flexed position on the point of elbow and then the elbow got extended as the patient slid for a few feet on the slippery field.

**Conclusion**

A hitherto unrecognised closed, fracture- partial dislo-
cation of elbow is described. various components of the injury viz partial isolated medial condyle elbow dislocation,
Intra-articular fracture with fracture dislocation of humeral condyles, supracondylar fracture in combination with elbow dislocation are described in detail with reference to reported cases/case series. The possible mechanism of injury of this unrecognised entity is explained with reference to the existing understanding of mechanism of various components of complex injury.

Author contributions All authors have contributed to study design, collection and interpretation of data, literature search, preparation of manuscript and proof reading. Study design: RKM, RT, KM. Data collection: RKM, RT, KM. Data interpretation: RKM, RT, KM. Literature search: RKM, RT, KM. Manuscript writing: RKM, RT, KM. Proof reading: RKM, RT, KM.

Compliance with Ethical Standards

Conflict of Interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

References


Consent to Publish Informed consent was taken from all the individuals regarding publication of their identifying information.

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Release of Extensive Post Traumatic Radio-Ulnar Synostosis with Vascularized Free Flap Interposition

Gopal Malhotra1 · Rahul Patil1,2 · Ghassan Al Yassari1,3 · Emad Salah Ibrahim1 · Venkata Nageshwara Reddy Komma1

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Abstract
Radioulnar synostosis is a rare complication after a forearm or elbow injury. The severity of initial trauma, associated head injury along with timing and the type of surgical treatment have been implicated in the formation of extra bone leading to synostosis. Surgical intervention is the standard treatment and is recommended after the maturation of synostotic bone. Surgery involves resection of the extra bone with or without tissue interposition. Materials used for interposition may include synthetic materials, allografts, and vascularized and non-vascularized autologous tissue superiority of one material over the other has not been demonstrated. Reported is a case of extensive soft-tissue defect and severe type II synostosis, with a relevant review of the literature.

Level of Evidence Level IV.

Keywords Radioulnar synostosis · Heterotopic ossification · Open fractures of the forearm

Introduction
Radioulnar synostosis is a rare but disabling complication following fractures and crush injuries of the forearm and elbow [1]. Bone overgrowth, subsequently leading to synostosis, can occur anywhere along the forearm and is not specific to the fracture site or the type of intervention. The reported incidence of post-traumatic radio-ulnar synostosis in the literature varies from 0 to 9.4% [2–4].

Case Report
Thirty-five years old Mr. A presented to us with limited prono-supination of his right forearm, while wrist and elbow range of motion were well preserved. The original injury was sustained during a road traffic accident nearly 12 years before presentation. Back then, he had open fractures of the right radius and ulna and significant soft tissue loss. Fractures were managed with intramedullary nails, while the soft-tissue defect was covered with a skin graft at another hospital. The patient also had a significant head injury and was under neurosurgical intensive care for 14 days. His
mentation was subsequently altered and had recovered gradually over the next few months. While the patient was recovering from his head injury, his forearm movements had gradually decreased. Patient though having some residual signs of head injury, was now relatively independent, striving for gainful employment and came seeking correction of his deformity.

At presentation, the patient had a grafted area involving almost 3/4th of the volar forearm and a significant limitation of prono-supination. The arm was locked in around 35° supination. Distal sensory and motor examination was within normal limits except for the loss of flexor pollicis longus (FPL) function (Fig. 1a, b).

The X-ray revealed three bony blocks extending from just distal to the radial tuberosity proximally to the distal 1/4th of the forearm and extensive heterotrophic calcification. Both proximal and distal radioulnar joints were spared (type II) (Fig. 2a, b). A Computer tomogram (CT) was obtained to assess further details about the extent of the bony block, and other tissues involvement (Fig. 3a–d). Both radial and ulnar vessels were well felt in the distal forearm. Allen’s test

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**Table 1** Predisposing factors for post-traumatic radio-ulnar synostosis

<table>
<thead>
<tr>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensive soft tissue damage</td>
</tr>
<tr>
<td>Comminution at the fracture site</td>
</tr>
<tr>
<td>Fractures involving both bones at the same level</td>
</tr>
<tr>
<td>Monteggia fractures</td>
</tr>
<tr>
<td>Delay in surgical intervention</td>
</tr>
<tr>
<td>Single access incision for fixing both bone injury/injury to interosseous membrane</td>
</tr>
<tr>
<td>Traumatic brain injury</td>
</tr>
<tr>
<td>Prolonged immobilization with late rehabilitation</td>
</tr>
</tbody>
</table>

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**Fig. 1 a, b** Patient with post-traumatic radio-ulnar synostosis. The graft can be appreciated to be adherent to the underlying soft tissues. Long flexors had full function while the FPL was not functional
confirmed the communication between the radial and ulnar vessels. No angiogram was performed pre-operatively.

In a two-team approach, while one team excised the skin graft, secured the vessels, and released synostosis, the other team harvested the anterolateral thigh flap, with a fascia lata extension from the contralateral thigh (Fig. 4a). The block involved central 3/5th of the interosseous space and had significant volar soft tissue involvement. After excision of the skin graft, the pronator insertion was released from the radius, and the muscle was reflected ulnarly. The flexors of the fingers and wrist also were released and retracted ulnarly, along with the median nerve. The anterior interosseous nerve and vessels could not be identified and isolated from the scar, as was the central part of the interosseous membrane. The critical central oblique band of the interosseous membrane and other accessory bands could not be identified separately from the bony block. The proximal oblique cord and distal oblique bundle were uninvolved while the dorsal accessory cord could be carefully dissected out and preserved.

The ALT flap was harvested based on septocutaneous perforators. A cuff of fascia was harvested along with the flap. The pedicle was dissected and kept ready but undivided to minimize the ischemia time. After confirming adequate excision of the bony block, the tourniquet was released, and hemostasis was achieved. No.1 nylon sutures were placed from the dorsum of the forearm and were brought to the volar forearm through the interosseous space (Fig. 4). Three such sutures were preplaced. The flap was then brought into the defect, aligned appropriately and secured with a few sutures. The sutures pre-placed earlier were now passed through the vascularized fascia and were passed back through the interosseous space over the dorsal forearm (Fig. 4). While the surgeon held the fascia interposed between the bones, the assistant tied the knots over the dorsum of the forearm drawing and retaining the interposed vascularized tissue in its new place (Fig. 4). Radial vessels served as donor distally in the forearm. End-to-end anastomosis was performed. Skin paddle was then used to cover the volar skin defect. Total surgical time was around 6 h.

Fig. 2  a, b X-ray images showing extensive heterotrophic ossification and extensive synostosis involving the shafts of radius and ulna, the proximal and distal joints were spared though
Range of motion exercise was started from the fifth post-operative day and involved active and assisted pronation and supination. The flap survived completely and follow up x-rays revealed complete resolution of the synostosis (Fig. 5). The vascularised tissue interposed between the bones also could be appreciated (Fig. 4). After four years of follow-up, there has been no recurrence. His forearm pronation is 10° from −35° pre-operatively, and supination is around 80° (35°, pre-operatively) (Fig. 5) (Video 1). His DASH score improved from 36.7 pre-operative to 16 postoperatively.

The patient subsequently underwent flap debulking and transfer of flexor superficialis of the ring finger to the FPL for the restoration of the thumb flexion. During surgery, the FPL tendon was found avulsed from the proximal attachment and tethered to scar tissue in the middle 1/3rd of the forearm. The patient is satisfied with the overall outcome (Fig. 6a–d).

Discussion

Radio-ulnar synostosis is a rare but disabling complication following significant crush injury to the forearm. Vince and Miller [3] have proposed a classification system based on the anatomic location of the bone block. Jupiter and Ring [4] have further modified this classification by sub-classifying the proximal (type III) synostosis. These classifications are helpful guides for documentation, communication, and surgical approaches.

Surgical treatment is the gold standard in the management of post-traumatic radioulnar synostosis. The surgical goal is to release the bony block to improve the function while minimizing possible recurrence. Care should be observed to prevent any further soft tissue injury. Conservative management is rarely sufficient, when the arm is in a functional position, the patient is either very low demand or has significant co-morbidities, precluding any surgical intervention. Preoperative counselling is essential explaining possible complications, including neurovascular injury, recurrence and need for the postoperative therapy.

Optimal timing of surgery is still being debated [1, 3, 9]. Traditionally, a waiting period of twelve months to allow fracture healing and maturation of synostosis was advocated. While serial radiographs, bone scans, and serum alkaline phosphatase levels, are used to monitor the maturation process, none are completely reliable. Recently, authors have tried early release, with better functional outcome and similar recurrence rates [4].

Careful assessment of the radiographs and CT scan helps to determine the extent of the block. The anatomic classification proposed by Vince and Millar also describes the neurovascular structures to be expected around the bony blocks [3]. Any neurovascular injury can lead to further
disablement and must be prevented with careful dissection under magnification.

Proposed materials for interposition include vascularized or non-vascularized autologous tissue, allografts, silicone, and polypropylene [1]. Free non-vascularized fascia has been proposed by a few authors but has higher recurrence rates and is no longer recommended [4].

Jupiter and Ring reported eight cases treated with free fat flap and ten cases with no interposition. Adjuvant therapy was not used in any of their patients. The results in both their groups were comparable [4]. Bell proposed the interposition of vascularized anconeus muscle with excellent results [10]. Free vascularized fat transfer also has been proposed in the past with good results. Recently, Pfanner et al. [11] presented two cases where a full range of motion was restored following the release and interposition of allogenic fascia lata graft. There has been no consensus regarding the benefit of interposition, neither regarding material to be used for interposition. Most of the studies, though suggested that some form of interposition gives a better outcome than isolated resection.

Among other treatment options, Kamineni et al. [12] have suggested a technique of removal of part of radius to create pseudoarthrosis, where excision of the bony block was not possible. Other authors have proposed a similar approach to proximal synostosis [13]. Adjuvant therapies following surgery include non-steroidal anti-inflammatory drugs (NSAIDs) and low-dose radiation; their efficacy is unproven.

Fig. 4  a Schematic representation of the synostosis. The incision marked in green, shows de-epithelialization of the skin, further the interosseous space is approached from radial side and the forearm muscles along with the median nerve reflected radially to expose the bone block. b The ALT flap being inset, the fascia is fed between the two bones with help of a suture placed from the dorsum of the forearm. c Showing the fascia interposed between all the volar muscles and the radius and further between radius and ulna (median nerve was deep in the muscle mass, protected from the harms way). d The vessel running in the fascia can be appreciated in a film with contrast. Letters d and v indicate dorsal and volar side of the limb for orientation.
with only a limited number of studies available [14]. Indomethacin also has been used to prevent heterotopic ossification following a total hip replacement. Unfortunately, it also reduces bone healing, making it less desirable [14]. Few reports suggest that the radiation following surgery was successful in preventing recurrence [14]. Regular use of either radiation or Indomethacin is not recommended, though, it could be considered in patients with a greater possibility of recurrence.

After resection, the risk of recurrence has been proposed to be around 6–35%. The risk factors include extensive soft tissue injury or associated head injury [3, 4, 9].

While we review our case considering the available information, this patient presented very late. The synostosis had already matured, allowing immediate intervention. He had a loss of volar soft tissue cover and had residual symptoms of head injury, both increasing the risk of recurrence. After adequate release, the vascularized tissue helped to maintain a curtain of tissue between the separated bones and provided added vascularity for tissue healing. Soft tissue flap helped in achieving pliable and vascular cover to multiple vital structures, that were adherent to the skin graft earlier. A vascularized skin flap also paved the way for the future tendon transfer for FPL reconstruction, that would have been difficult to pass under the skin grafted area. Flap allowed both, easy access for the second surgery and the adipose tissue plane for the easy tendon glide and helped restore function without adhesions. The flap and the vessel running between bones could be appreciated in postoperative CT scan (Fig. 4). Smooth outline of both forearm bones without signs of recurrence, maintained range of forearm movements, and good excursion of tendon transfer under the flap suggested scar re-modulation and attested usefulness of the vascularized interposition and cover. The absence of a definite interosseous membrane and avulsed FPL muscle (loose tendon) at later exploration may indicate a severe original injury to these structures. This also suggests why AIN could not be found, that normally should be protected and retracted as shown in Fig. 4. Nearly four years of

\[ \text{Fig. 5 a–c Well settled flap and pronation and supination range of 10/80 degrees respectively while a complete resolution of the heterotrophic ossification can be observed} \]
post-surgery, the patient enjoys a useful function and there is no radioulnar instability.

Critical factors in the management of this case were the complete release of the bone block, vascularized fascial interposition and cover, early mobilization and stretching. Careful planning and execution of these principles is key to a successful outcome even in cases with extensive multilevel synostosis.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethics Approval This is an observational study. The Khoula Hospital Research Ethics Committee has confirmed that no ethical approval is required.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Patient Consent Patients signed informed consent regarding publishing their data and photographs. The participant has consented to the submission of the case report to the journal.

References


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CASE REPORT

Bilateral Fracture Neck Femur in Child with Bilateral Delayed Union and Bilateral AVN: A Rare Occurrence and Literature Review

Premal Naik1,2, Nihit Mantri3, Parag Tank2, Ravi Bhesaniya4

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Abstract
A bilateral neck of femur fracture in children is a rare occurrence with only twelve cases reported till the date. We report a case of a 3-year-old schoolgirl with bilateral Delbet type 2 fracture neck femur after a fall from height. She was managed elsewhere by bilateral closed reduction and screw fixation within 24 h. She presented to us three months after surgery with painful hip movements and inability to walk. Her X-ray showed bilateral Ratliff type three avascular necrosis and bilateral delayed union with visible fracture lines. We placed her in double hip spica for three months. Fortunately, on both sides fractures united well with complete resolution of avascular changes. At one year follow-up, she had no functional limitation, no limb length discrepancy, and an x-ray showed mild coxa vara on left. Bilateral delayed union and avascular necrosis of fracture neck femur has not been reported till date.

Keywords Avascular necrosis · Bilateral fracture neck of femur · Delayed union · Ratliff type III AVN · Coxa vara

Introduction
Fracture neck of femur (FNOF) in children is quite uncommon, comprising less than 1% of all pediatric fractures [1]. Bilateral FNOF is even rarer, with only 11 reports (12 cases) in the literature [2–12]. We report a case of a 3-year-old school girl who presented with bilateral FNOF after a fall from a height. Closed reduction with percutaneous cannulated screws fixation (PCSF) was done elsewhere. She presented to us after 3 months with inability to walk and her X-rays showed signs of bilateral avascular necrosis and bilateral delayed union with clearly visible fracture lines.

Case Details
A 3-year-old school girl fell from a 10 ft high wall under construction and developed bilateral Delbet type 2 FNOF. There was no associated head injury or other limb or visceral injury. She was managed within 24 h by closed reduction with PCSF on both sides simultaneously. She was immobilized in hip spica for 6 weeks. After the removal of spica, she was mobilized without radiological confirmation of the union. After mobilization, she developed painful hip movements and could not bear weight; she went back to the primary orthopedic surgeon after six weeks of mobilization. X-ray at that time showed incomplete union and bilateral fracture lines still visible; there was no mention of AVN changes in their notes. The child was advised to undergo bilateral proximal femoral valgus osteotomy and was referred to us for the same.

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At the time of presentation to our center three months after the surgery, parents were concerned about the inability of the child to stand and walk and painful hip movements. On clinical assessment, her bilateral hip movements were painful and restricted. She could not bear weight on either side. X-ray on presentation showed bilateral FNOF fixed with single 4 mm cannulated cancellous (CC) screw on both sides, screws were short of physis; left side screw appeared to be cutting out of the superior part of the neck. X-rays also revealed Ratliff type III AVN in both hips with clearly visible fracture lines on both sides in both views. There was bilateral coxa vara with a neck-shaft angle of 113° on right and 107° on left (Fig. 1).

A gentle assessment was done under fluoroscopy without anesthesia in the available range of movements without pain. A parent was kept with the patient to pacify her and improve her co-operation. During fluoroscopic assessment both side screws were found to hold fragments and provide partial stability. By rotating the C-arm in multiple directions, we found the left-sided screw to be sufficiently placed in the proximal fragment and provide some stability; both fragments moved as one piece on either side. Hence, decision was taken to give additional stability with spica rather than revise fixation. We also felt that revising the screw in the osteopenic bone (due to prolonged lack of weight-bearing) will not give sufficient stability to allow mobilization. She was given double hip spica and the possibility of future surgical intervention was discussed with parents. Parents were also informed that data concerning the case would be submitted for publication and they consented to it.

At 6 weeks follow-up, radiographs out of plaster showed signs of healing. The left side screw which appeared cutting out of the neck, to our surprise now appeared to be within the neck. This was probably due to improvement of ossification in osteopenic bone around the screw. Even AVN changes showed improvement (Fig. 2). As the 6 weeks, post-spica X-ray showed early signs of the union, there was an option of placing the child in an abduction brace and start gradual supervised mobilization. But considering the socioeconomic and educational background of parents coming from a remote rural area and their questionable ability in managing the child in abduction brace, we chose to further extend the plaster immobilization for six more weeks. The second spica was also given without anesthesia.

After three months of spica, her X-ray showed sound union and complete resolution of AVN changes on both sides (Fig. 3). The superior portion of the neck on the left side was well-formed and both screws appeared to be well placed. She was allowed gradual mobilization with the resumption of normal activities and sports at 6 months from the initial presentation to us.

At the final follow-up after 1 year, she had no functional limitations. She had a normal gait without any limp or lurch and full hip movements on both sides without pain. She could sit cross leg and squat (which is very essential in Indian customs for activities of daily living). There was no limb length discrepancy (Fig. 4a). Her X-ray showed sound union and no telltale signs of AVN with an improvement of the neck-shaft angle (NSA) to 116° on the left and 122° on the right (Fig. 4b).

**Fig. 1** AP and Frog lateral X-ray of the pelvis 3-month post-surgery showing visible fracture line both sides in both views and bilateral Ratliff type 3 AVN, note left side screw cutting out of neck

**Fig. 2** Six weeks follow-up X-rays showing signs of healing and improvement in AVN changes both sides, the left side screw now appear to be well placed and holding
Discussion

Bilateral posttraumatic FNOF in children is one of the rarest injuries, we could trace only 11 reports with 12 cases so far [2–12]. Of these 11 reports, we could not trace the full-text of two articles [2, 4], but their case details were available in other paper [11]; one report did not mention adequate patient details [12]. Relevant details of all cases are summarized in Table 1. Togrul et al. reported only a single case of traumatic bilateral FNOF in their retrospective study of 103 femoral neck fractures over 16 years [8]. The age range of the children with bilateral FNOF in reported literature is 4–11 years; our patient was three years old and the youngest in published cases. Kozlowski reported a case of a four and half months old child with bilateral slipped capital femoral epiphysis following epilepsy; the child developed widening of the same fracture on both sides at age of 20 months [13]. Bilateral FNOF is more commonly reported in children with seizures and osteogenesis imperfecta [14–16]. Scheerlinck reported bilateral stress fractures in an 8-year-old girl [17].

The most common injury leading to bilateral FNOF is a fall from height followed by road accidents [11]. Saied A and Jalili reported a case of bilateral FNOF by direct injury by cement block [2]. For bilateral FNOF, three mechanisms are hypothesized [11]. Our patient probably had the axial load type of injury after falling from a height; the fall was

Fig. 3 Three months follow-up X-ray showing sound union and complete resolution of AVN changes on both sides.

Fig. 4 a Function at one year follow-up, b X-ray at one year showing sound union and no telltale signs of AVN on both sides, note coxa vara on left side (neck shaft angle left—116°, right—122°).
Table 1  Reported bilateral FNOF in children

<table>
<thead>
<tr>
<th>Author</th>
<th>Age (y)</th>
<th>Sex</th>
<th>Mode of injury</th>
<th>Delbet type</th>
<th>Associated injury</th>
<th>Delay in fixation</th>
<th>Fixation method</th>
<th>Post op spica (wk)</th>
<th>Union time (wk)</th>
<th>Follow-up</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upadhyay et al. [6]</td>
<td>Case 1</td>
<td>11</td>
<td>FFH</td>
<td>Right</td>
<td>Head inj</td>
<td>11 wks</td>
<td>Screws</td>
<td>No</td>
<td>18</td>
<td>20 m</td>
<td>Lt hip – delayed union, AVN + coxa vara Rt—normal</td>
</tr>
<tr>
<td></td>
<td>Case 2</td>
<td>8</td>
<td>FFH</td>
<td>Right</td>
<td>Pelvic inj</td>
<td>1 d</td>
<td>Screws + plates</td>
<td>No</td>
<td>12</td>
<td>30 m</td>
<td>Nil</td>
</tr>
<tr>
<td>Gilban et al. [7]</td>
<td>6.5</td>
<td>M</td>
<td>FFH</td>
<td>Left</td>
<td>Tibia fracture</td>
<td>4d</td>
<td>Sliding screw + plate</td>
<td>No</td>
<td>14</td>
<td>24 m</td>
<td>16 m Bilat. Coxa valga L &gt; R, ↓ joint space Rt hip</td>
</tr>
<tr>
<td>Togrul et al. [8]</td>
<td>6</td>
<td>F</td>
<td>FFH</td>
<td>Left</td>
<td>Nil</td>
<td>NR</td>
<td>Screws + plates</td>
<td>No</td>
<td>16</td>
<td>30 m</td>
<td>Nil</td>
</tr>
<tr>
<td>Kumar [9]</td>
<td>8</td>
<td>M</td>
<td>RTA</td>
<td>Right</td>
<td>Pelvic inj</td>
<td>10d</td>
<td>Screws</td>
<td>No</td>
<td>12</td>
<td>24 m</td>
<td>9y</td>
</tr>
<tr>
<td>Saied and Jalil [2]</td>
<td>4</td>
<td>M</td>
<td>FFH</td>
<td>Left</td>
<td>Radius fracture</td>
<td>12 h</td>
<td>Screws</td>
<td>No</td>
<td>16</td>
<td>24 m</td>
<td>30 m Bilat. Coxa valga L &gt; R, ↓ joint space Rt hip</td>
</tr>
<tr>
<td>Mazurek et al. [10]</td>
<td>5</td>
<td>M</td>
<td>FFH</td>
<td>Right</td>
<td>Nil</td>
<td>3d</td>
<td>Screws + plates</td>
<td>No</td>
<td>8</td>
<td>5 m</td>
<td>24 m</td>
</tr>
<tr>
<td>Gopinathan [5]</td>
<td>10</td>
<td>M</td>
<td>Direct impact</td>
<td>Left</td>
<td>Tibia fracture, pelvic inj, head inj</td>
<td>2d</td>
<td>Screws</td>
<td>No</td>
<td>6</td>
<td>28 m</td>
<td>18 m SCFE left hip–fibula grafting + screw fixation, normal at final follow-up</td>
</tr>
<tr>
<td>Dhar [3]</td>
<td>9</td>
<td>F</td>
<td>FFH</td>
<td>Left</td>
<td>Nil</td>
<td>9</td>
<td>Screws</td>
<td>No</td>
<td>9</td>
<td>28 m</td>
<td>24 m</td>
</tr>
<tr>
<td>Sané et al. [4]</td>
<td>9</td>
<td>F</td>
<td>FFH</td>
<td>Right</td>
<td>Nil</td>
<td>9</td>
<td>Screws</td>
<td>No</td>
<td>9</td>
<td>28 m</td>
<td>24 m</td>
</tr>
<tr>
<td>Dakouré et al. [11]</td>
<td>9</td>
<td>F</td>
<td>FFH</td>
<td>Right</td>
<td>Nil</td>
<td>9</td>
<td>Screws</td>
<td>No</td>
<td>9</td>
<td>28 m</td>
<td>24 m</td>
</tr>
<tr>
<td>Goddemir et al. [12]</td>
<td>5</td>
<td>F</td>
<td>FFH</td>
<td>Right</td>
<td>Nil</td>
<td>5</td>
<td>Screws</td>
<td>No</td>
<td>5</td>
<td>28 m</td>
<td>18 m SCFE left hip–fibula grafting + screw fixation, normal at final follow-up</td>
</tr>
<tr>
<td>Our case</td>
<td></td>
<td></td>
<td>FFH</td>
<td>Right</td>
<td>Nil</td>
<td>3</td>
<td>Screws</td>
<td>No</td>
<td>3</td>
<td>12 m</td>
<td>Nil</td>
</tr>
</tbody>
</table>

FFH fall from height, Inj injury, h hours, wk week, d day, cr closed reduction, or open reduction, m months, y years, RTA road traffic accident, NR not reported
not witnessed by anyone. Children with bilateral FNOF tend to have associated injuries like pelvic injury, associated limb injuries, head injury, and visceral injury [2, 3, 6, 7, 9, 10].

Although the timing of surgery is the subject of debate, many authors favor the urgency of fracture reduction following a pediatric hip fracture. Dial noted that the literature suggests that an early anatomic reduction reduces the risk of AVN [18]. Our patient was one of the few patients who had fixation of both fractures within 24 h [2, 3, 6]. In bilateral FNOF cases, few authors have preferred preoperative traction [11], while in others, delay in fixation was due to associated injuries [9] and delayed presentation or referral [7]. The highest delay in fixation was one month due to delayed presentation following a delay in the diagnosis [6].

The Delbet classification is the most commonly used classification for FNOF in children, it relates the location of fracture to the risk of AVN [18]. In bilateral FNOF cases, fracture type may not be the same on both sides [2–5, 11]. Our patient had Delbet type 2 fracture on both sides; there is only single report of two cases with bilateral Delbet type 2 injury in both patients (radiograph of a single patient was documented) [6]. Bilateral Delbet type 3 injury appears to be the most common pattern in bilateral FNOF [7–10].

Treatment options for FNOF include closed reduction and cast immobilization, closed or open reduction with fixation, and primary valgus osteotomy [19]. Bilateral FNOF has been treated with either closed or open reduction and fixation by pins, screws, screws + plates, DHS, and blade plate [11]. No child with bilateral FNOF was treated conservatively. Dial noted that in adult FNOF three screws in inverted triangle formation provide optimal stability on biomechanical studies but for the pediatric FNOF hardware selection guidelines do not exist, and the type of fixation is dictated by the surgeon’s preferences. They recommended the use of at least two screws or pins prevents rotation at the fracture site [18]. Unfortunately, our patient had stabilization with a single 4 mm CC screw fixation on either side with 6 weeks of spica immobilization. Successful union on both sides after single screw fixation in bilateral FNOF after preoperative traction for 17 days and one month of spica immobilization has been reported [11]. The majority of bilateral FNOF were closed reduced. No child with Delbet type 2 fracture in cases of bilateral FNOF had an open reduction. Two authors used open reduction for bilateral Delbet type III fractures. Mazurek [10] used anterolateral and posterolateral approach according to the displacement of fragments three days after injury and Kumar [9] also used bilateral open reduction after a delay 10 days due to associated abdominal injury.

It is recommended that following Delbet type II and III fractures, hip spica or hip abduction brace should be used for up to six weeks [18]. Postoperative immobilization following bilateral FNOF varies considerably as per the surgeon’s choice. Hip spica cast was used for 4–18 weeks [2–5, 7, 8, 10, 11]. Upadhyay reported two cases of bilateral FNOF treated with cancellous screw fixation, one of which was 1 month old and another had pelvic injury; no postoperative immobilization was used except for a pelvic binder in the case with pelvic injury. Both cases went on to a successful union without complications [6].

FNOF is prone to major complications like avascular necrosis (AVN), non-union, coxa vara, and premature physeal closure [18, 20, 21]. Yeranosian in their meta-analysis study of FNOF reported an overall incidence of nonunion was 10.8% and reported that nonunion and coxa vara was not affected by reduction methods [21]. Sanghvi et al. noted that the definition of nonunion of FNOF is not standardized. If the failure of fixation is identified within 3 months and adequate bone contact is retained, they recommended removal of implant with refixation and valgus osteotomy [22]. For our case, we have a dilemma if we should call this a nonunion or a delayed union? The child presented to us after three months post-fixation without any signs of radiological union and inability to bear weight and painful movements. At the same time due to some stability provided by the implants, there was no abnormal mobility at the fracture site under fluoroscopic assessment. This finding encouraged us to offer conservative treatment to the patient. There is no report of bilateral delayed union or nonunion of FNOF. Gilban treated bilateral Delbet type III fracture with closed reduction and plate + screw fixation and noted delayed union on one side after 2 months of spica immobilization, union was achieved after another 2 months of hip spica. The same side developed AVN (involving about 50% of the head) with coxa vara [7]. We found the following deviations from the recommended treatment in our patient, which probably led to problem in union.

1. Single screw fixation short of physis leading to suboptimal stabilization
2. Premature mobilization without confirmation of radiologic union.

Posttraumatic AVN is commonly classified by Ratliff’s classification [1]. Ratliff reported AVN incidence of 42%, of which few patients had an undisplaced fracture [1]. Moon et al. identified fracture type and age as significant predictors of AVN and noted that older children were 1.14 times more likely to develop AVN for each year of increasing age. They also found type I to III fractures were 15, 6, and 4 times, respectively, more likely to develop AVN than type IV fractures [20]. Yeranosian et al. from a meta-analysis of FNOF reported overall 23% AVN, with incidence reducing from about 40% in Delbet type I fractures to around 5% in Delbet type IV. They found surgical intervention and open reduction to be associated with higher rates of AVN; capsular decompression did not affect AVN [21].
Interestingly, bilateral posttraumatic AVN of the hip in bilateral FNOF has not been reported to date but two cases of unilateral AVN is reported. Gilban reported unilateral AVN in a case of bilateral Delbet type III FNOF, which resulted in coxa vara and permanent limp [7]. Diallo also reported AVN and coxa vara following Delbet type III FNOF; seven months follow-up radiograph showed Ratliff type III AVN but no specific treatment was offered for AVN [11]. Venkatadass reported the case only of bilateral AVN following postictal bilateral Delbet type II FNOF in a 16-year-old autistic child; the patient developed FNOF one after another with nine months interval. They did not discuss the treatment of AVN but noted a lack of clear treatment guidelines for posttraumatic AVN and found majority of AVN culminating into hip arthritis[14].

Ratliff reported type 3 AVN as uniform increase in density of femoral neck limited between fracture site distally and physeal plate proximally with no fragmentation of neck; most of the children in his series were < 11 years. He postulated type 3 AVN resulting from damage to superior metaphyseal vessels with intact lateral epiphyseal vessels [1]. There are only a few reports of Ratliff type III AVN, many of them resolved without any treatment with good outcome [1, 11, 23]. Forlin reported 11 cases of posttraumatic AVN, out of which four had Ratliff type III AVN. They found Ratliff type 3 AVN difficult to classify but reported good results in 2, fair and poor results in one each. They also noted lack of effectual treatment of an established AVN and treated one patient with varus osteotomy [23]. AVN changes take some time to resolve, but time range for resolution of AVN changes in children is not clearly reported. In both reports of AVN in case of bilateral FNOF, details regarding appearance and resolution of AVN changes in not mentioned. Many authors have questioned existence of type 3 AVN because radiological changes appear very early and it does not interfere with union [24, 25]. Very similar sequence of event happened in our patient; three months post-injury X-ray showed changes of Ratliff type 3 AVN, which showed significant resolution at six months post-injury with sound union. Sanghvi has reported the ability of the femoral head to revascularize after the successful healing of nonunion [22]. It is possible that Ratliff type III AVN resolves spontaneously like in our case and is under-reported.

Coxa vara is defined as a reduction in NSA compared to the opposite side or NSA < 120° in skeletally immature child. Coxa vara may develop following a loss of reduction or following AVN, nonunion, and premature physeal closure [18]. Yeranosian reported 18.5% overall incidence of coxa vara with significantly lower incidence in the operated group [21]. In our patient NSA at the time of presentation was 113° on right and 107° on the left, which improved to 122° and 116°, respectively.

The limitations of our case include the nonavailability of initial records and short follow-up of 1 year. We know that complications like premature physeal fusion may not be evident at such short follow-up and the child may need correction of coxa vara if it progresses. At the same time, to the best of our knowledge this is the first case of posttraumatic bilateral Ratliff type III AVN and delayed union, which healed without operative intervention with complete resolution of bilateral AVN, hence reported. Patient’s final Ratliff score was good on both sides with mild coxa vara on left side [1].

**Conclusion**

Our case with bilateral FNOF with bilateral delayed union and bilateral Ratliff type III AVN is the rarest of a rare case and has not been reported to date. Successful conservative management of bilateral AVN and delayed union also makes it a unique case. We are very well aware that, just one case is not enough to give this message emphatically but, in very young children with some stability, and good healing potential, conservative treatment may be offered. Parents must be informed regarding the possibility of surgical intervention if the conservative trial fails.

**Declarations**

**Conflicts of interest** Authors do not have any conflict of interest.

**Ethical standard** Informed consent from the parents for this study which is in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**References**


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CASE REPORT

Pediatric Anterior Transolecranon Fracture-Dislocation of the Elbow: A Case Report and Review of Literature

Dheeraj Batheja1 · Pratyush Shahi1 · Manish Chadha1 · Apoorv Sehgal1

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Abstract
A five-year-old female child came to us with complaints of pain, swelling and deformity of the left elbow following fall on flexed elbow. Radiographs showed an anterior transolecranon-fracture dislocation of the elbow. After an unsuccessful attempt at closed reduction, open reduction and internal fixation with a tension band construct using two 1.5 mm Kirschner wires and a 20-gauze stainless steel (SS) wire was done. Active assisted mobilisation was started 2 weeks postoperatively. At 2 months after the surgery, the child had regained unrestricted and painless elbow movements. All the wires were removed at 6 months. Anterior transolecranon-fracture dislocation of the elbow is an extremely rare entity with only 11 cases reported till date, none being from India. We, hereby, report new observation, discuss the mechanism of injury and management protocol for such cases, and highlight the causes of under-reporting and importance of early intervention and mobilisation.

Keywords Transolecranon fracture-dislocation · Paediatric · Anterior · Tension band wiring · Elbow

Introduction
In children, due to the presence of strong ligamentary and capsular components, traumatic dislocation of the elbow is rare, accounting for only 3–6% of all elbow injuries [1]. Anterior transolecranon fracture-dislocations, although prevalent in adults, are rare in children. These occur due to disruption of the ulnohumeral joint with maintained radioulnar alignment secondary to a blow to the posterior elbow in a flexed position. Till date, only 11 cases have been reported in literature, out of which seven are isolated transolecranon fracture-dislocations [2–7]. This is the eighth case report on isolated transolecranon fracture-dislocation and the first from India. We, hereby, report new observation, discuss the mechanism of injury and management protocol for such cases, and highlight the causes of under-reporting and importance of early intervention and mobilisation.

Case Report
A five-year-old female child presented with complaints of pain, swelling and deformity of the left elbow. She had a history of fall on flexed elbow with the forearm in supination a few hours back. Clinical examination revealed tenderness, swelling and deformity of the left elbow with normal overlying skin and no distal neuromuscular deficit. Radiographs of the left elbow taken in the anteroposterior and lateral views showed disruption of the ulnohumeral joint via a proximal, transverse fracture of the olecranon leading to an anterior transolecranon fracture-dislocation of the elbow. The radioulnar alignment was maintained. The secondary ossification centre of the olecranon had not appeared yet (Fig. 1). Closed reduction was attempted, but unsuccessful. After obtaining informed consent from the parents, the patient was taken up for surgery in the lateral decubitus position under general anaesthesia. Standard midline posterior approach for olecranon was used. Under image-intensifier control, the dislocation was reduced (gentle axial traction, sustained posterior force to proximal forearm and anterior force to distal humerus, and elbow flexion to about 30 degrees) and the fracture was fixed with a tension band construct using two 1.5 mm Kirschner wires (entering from the olecranon tip and having the distal hold in the anterior cortex of ulna) and a 20-gauze stainless steel (SS)
wire (Fig. 2). The capsuloligamentous restraints of the elbow were intact. Post-fixation, the stability of the elbow was checked with full flexion–extension and pronation-supination. The elbow was splinted in 90 degrees of flexion for 2 weeks in a Plaster of Paris slab. Active assisted mobilisation was started two weeks postoperatively and the patient was put on a physiotherapy regimen. The wires did not cause any irritation or interfere with elbow motion. After about 2 months, the child could do all his regular activities and had a painless range of motion with no instability or significant limitation of the movement in flexion and extension (0–130 degrees), pronation (85 degrees) and supination (80 degrees) when compared to the other side (Fig. 3). All the wires were removed at 6 months.

**Discussion**

When a child falls on the outstretched hand with elbow hyperextended, the olecranon fully engages and forcefully pushes into the olecranon fossa and acts as a fulcrum, while the anterior capsule simultaneously provides a tensile force on the distal humerus at its insertion. The resulting injury is an extension-type supracondylar fracture of the humerus, which is the most common type of injury after fall on outstretched arm in a child. On the other hand, when a child falls on flexed elbow with direct impact on the posterior aspect, it forces the olecranon anteriorly as it is not engaged into the fossa in flexion. If
the force continues, there may be an epiphyseal separation or a fracture of the olecranon depending upon the site of trauma, which can further lead to an anterior transolecranon dislocation of the elbow (Fig. 4).

Tiemdjo et al. classified this injury into four types and proposed different treatment modalities [2] (Table 1). But they did not explain any possible mechanism of injury for such fracture-dislocations. Our case, due to a proximal, transverse fracture of the olecranon, was a Tiemdjo’s type I fracture-dislocation with an intraoperative finding of disrupted periosteum.

Thorough literature search was done on Medline, using Thesaurus, with key words ‘elbow’ or ‘elbow joint’ or ‘olecranon’ and ‘fracture dislocation’ and ‘anterior’ and ‘child’ or ‘children’ or ‘paediatric’. Pubmed search was also done using key words transolecranon, fracture, dislocation. We could find only seven articles with 11 cases of anterior transolecranon fracture-dislocation in children. Different treatment protocols have been used, and unlike in adults, all are associated with excellent long-term outcome [2–7] (Table 2). This can be attributed to the strong capsuloligamentous restraints of the elbow and absence of extensive metaphyseal comminution or any coronoid fragment in this injury pattern in children. In addition, the paediatric population shows better fracture healing and remodelling properties. We used a tension band construct in our case as it was a proximal, transverse fracture of the olecranon with no metaphyseal comminution. Both No. 2 Ethibond suture and SS wire have been used in the tension band construct in different cases, depending on the surgeon’s preference. However, Guitton et al. stated that the added instability due to the associated soft tissue injury made tension band construct insufficient and therefore, preferred screw-and-plate fixation [3]. Arain et al. stated that in spite of the chances of displacement of the fracture with casting, a nonoperative management can be attempted if the alignment is near-anatomic, owing to the good remodelling potential in children.

![Fig. 3](image1.png) Clinical assessment at 2 months postoperatively. a Full extension; b full flexion

![Fig. 4](image2.png) Mechanism of injury. (1) Forward force after fall on the flexed elbow causing (2) an anterior transolecranon fracture-dislocation. A: humerus, B: ulna, C: radius

<table>
<thead>
<tr>
<th>Classification</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I: epiphyseal splitting or proximal fracture of the olecranon</td>
<td>Reduction + tension band wiring</td>
</tr>
<tr>
<td>Type II: transverse fracture</td>
<td>Reduction + tension band wiring</td>
</tr>
<tr>
<td>Type III: oblique fracture</td>
<td>Reduction + screwed plate</td>
</tr>
<tr>
<td>Type IV: fracture of the olecranon + associated injury to radius or humerus</td>
<td>Reduction + osteosynthesis of fracture of the olecranon and associated injury</td>
</tr>
</tbody>
</table>
Galvez et al. proposed closed reduction and fixation with a single Kirschner wire, thus highlighting the importance of avoiding aggressive fixation in young children [5]. We propose a treatment algorithm for children with this injury which is shown in Fig. 5.

Making a correct diagnosis in a case of anterior transolecranon dislocation of elbow is a challenge for medical personnel. The secondary ossification centre of the olecranon appears around the age of 10 years [8]. The diagnosis can be missed in case of an occult fracture of the olecranon before its appearance. Also, the injury can be misdiagnosed as a Monteggia-type fracture-dislocation. These possible factors of underdiagnosis might be the reason that only a few cases of this injury have been reported till date.

Table 2  Review of literature of anterior transolecranon fracture-dislocation of the elbow in children

<table>
<thead>
<tr>
<th>Author</th>
<th>Cases</th>
<th>Sex</th>
<th>Fracture management</th>
<th>Complications</th>
<th>Long-term result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butler et al. (2012) [4]</td>
<td>3</td>
<td>2 M, 1 F</td>
<td>Open reduction and tension band construct</td>
<td>None</td>
<td>Excellent</td>
</tr>
<tr>
<td>Tiemdjo et al. (2015) [2]</td>
<td>1</td>
<td>–</td>
<td>Close reduction and plaster</td>
<td>None</td>
<td>Excellent</td>
</tr>
<tr>
<td>Galvez et al. (2018) [5]</td>
<td>1</td>
<td>M</td>
<td>Closed reduction and 1 Kirschner wire fixation</td>
<td>None</td>
<td>Excellent</td>
</tr>
<tr>
<td>Bouazziz et al. (2018) [6]</td>
<td>1</td>
<td>M</td>
<td>Open reduction without internal fixation</td>
<td>None</td>
<td>Excellent</td>
</tr>
<tr>
<td>Arain et al. (2019) [7]</td>
<td>1</td>
<td>M</td>
<td>Closed reduction and plaster</td>
<td>None</td>
<td>Excellent</td>
</tr>
<tr>
<td>Our case (2020)</td>
<td>1</td>
<td>F</td>
<td>Open reduction and tension band construct</td>
<td>None</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

Fig. 5  Treatment algorithm for pediatric anterior transolecranon fracture-dislocation of the elbow
An inadvertent delay in management of such articular injuries may lead to serious complications and poorer final outcome. Early intervention and anatomical reduction are required. Also, early mobilisation is recommended to minimise elbow stiffness.

Conclusions

We conclude that physicians need to have a high level of awareness to detect anterior transolecranon fracture-dislocations of the elbow in children. Although, the treatment modality of these injuries should be individualised, early intervention, anatomical reduction and early mobilisation are necessary for good outcome.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human or animal subjects performed by the any of the author.

Informed consent Informed consent was taken from the parents.

References


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Iatrogenic Renal Artery Injury Necessitating Nephrectomy Following Lumbar Interbody Fusion for Tubercular Spondylodiscitis

Gurpremjit Singh1 · Pankaj Kandwal2 · Vikas Kumar Panwar1 · Sunil Kumar1 · Ankur Mittal1 · Shiv Charan Navriya1

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Abstract
Percutaneous pedicle screw fixation and transforaminal lumbar interbody fusion is a popular minimally invasive technique for fixation and fusion of vertebrae for a variety of indications. It is associated with infrequent but serious well-recognized vascular, visceral and neurological complications. Hereby, we present a case of left main renal artery injury necessitating nephrectomy during lumbar transforaminal interbody fusion of pott’s spine.

Keywords Pedicle screw · Complication · Renal artery · Nephrectomy

Introduction
Percutaneous pedicle screw fixation is an increasingly performed technique since its first use by Magerl, used for fusion and fixation of thoracolumbar vertebrae [1]. With advances in the technology and surgical expertise, minimal invasive surgeries like percutaneous pedicle screw fixation and transforaminal lumbar interbody fusion (TLIF) have been commonly performed for various post-traumatic and infectious spinal pathologies [2–4].

Iatrogenic vascular injury is infrequently reported complication in spine surgery. The mortality rate is as high as 15–65%. The prevalence of vascular complications is between 1 and 5 per 10,000 lumbar disc operations [5]. Several authors have reported aortic, common iliac artery, inferior vena cava, common iliac vein and accessory renal artery injuries in spine surgeries [5, 6]. The management depends on the type and the site of injury. Herein, we describe a case of left main renal artery injury leading to nephrectomy during Minimally invasive TLIF of T12–L1 and L1–L2 in a patient of pott’s spine.

Case Report
A 55-year-old woman presented with severe pain in the lower back (VAS 8/10) radiating to bilateral thighs for 7 months. She was diagnosed with tubercular spondylodiscitis of L1–L2 based on radiological findings (Fig. 1). Patient was planned to undergo minimally invasive TLIF of L1–L2 with posterior instrumentation. While removing the disc material for interbody fusion of L1–L2, pituitary rongeur slipped anteriorly and was accompanied by a gush of fresh blood from the incision site followed by a drop in blood pressure. Intraoperative episode of hypotension with tachycardia raised the suspicion of vascular injury. The patient responded to bolus of intravenous crystalloid fluids and transfusion of two units of packed red blood cells. After consultation with cardio-thoracic and intervention radiology, CT angiography was planned. The patient was stabilized and shifted to the critical care unit postoperatively. Bedside Ultrasonography showed moderate collection diffusely spreading in the retroperitoneal space. CT angiography was
done which showed pseudoaneurysm near the renal artery without any active contrast extravasation with a minimal enhancement of renal parenchyma. (Figs. 2, 3) Diagnosis of left renal artery laceration with the formation of a left renal artery pseudoaneurysm was made and decision of endovascular stent placement was taken. The patient’s relatives were explained about the procedure, the possible complications and the need for a nephrectomy if the need occurs. A written informed high-risk consent was taken. Patient was hemodynamically stable; however, there was a drop of hemoglobin from 10 to 7.9. Patient was planned for digital subtraction angiography (DSA) and stenting of the renal artery by intervention radiologist. On DSA, it showed large pseudoaneurysm communicating with the renal artery. No distal renal artery track visualized and guidewire was unable to cross to the distal segment. So a plan was made for immediate exploration because of renal artery injury after taking a high-risk consent from the patient and the relatives. Midline laparotomy incision given and retroperitoneum was entered after incising the peritoneum just medial to inferior mesenteric vein, dissecting over the mid dorsum of aorta. Intraoperatively large hematoma was noticed on left side. Vascular control was taken over left renal vein, suprarenal and infra-renal aorta. Left renal artery identified and vascular slings placed at origin just flushed to aorta. Hematoma evacuated, large rent with near-complete transection and thrombus at rent site was noticed in the left renal artery. Left kidney was nonviable on assessment so nephrectomy was done after ligation of renal artery proximal to the injury site (Fig. 4). Postoperative period was uneventful and patient discharged in clinically satisfactory condition on 10th post-operative day. Histopathology of left nephrectomy specimen showed acute tubular injury. On follow-up at 6 and 9 months, patient is doing well with stable renal function.

**Fig. 1** A 55-year-old female presented with severe low back pain. Pre-op CT sagittal cut (a) and Coronal cut (b) showing destruction of L1 and L2 vertebra. Pre-op MRI: T1 sagittal cut (c), T2 sagittal (d), Coronal STIR sequence (e) and T2 Axial cut (f, g) showing involvement of L1 and L2 vertebrae along with intra and peri-vertebral collection, suggestive of Infective spondylodiscitis L1–L2.

**Fig. 2** a Axial CT images showing the path of the right side screw fixation (bold blue arrow), left non-enhancing renal parenchyma (bold yellow arrow) and b Axial CT images showing left renal artery pseudoaneurysm (red bold arrow), left side screw (blue arrow), left non-enhancing, non-excretory renal parenchyma (yellow arrow), right kidney with good enhancement and contrast excretion (dotted red arrow).
Discussion

Major vessel injury following spine surgery is a rare but devastating complication. The vessels may be injured while performing anterior spinal procedures and less commonly during posterior surgeries like discectomy, malpositioned pedicle screw or interbody fusion [7–9].

Percutaneous pedicle screw fixation and MIS TLIF is the increasingly popular and preferred technique because of its minimally invasive nature and it can be used for a variety of etiologies including degenerative, post-traumatic and infectious pathologies like tubercular spondylodiscitis [7, 10, 11].

Many vascular injuries like aortic, inferior vena cava and common iliac vessels have been reported in the literature. A systemic review by Papadoulas et al. reported arteriovenous fistula (AVF) in 67%, vessel laceration in 30% and pseudoaneurysm in 3% cases, commonly at L4–5 disc level with 10% overall mortality [5].

Main renal artery injury resulting in nephrectomy has never been previously reported in the literature as per the best of our knowledge. The MIS TLIF was performed from the right side. Destruction of the body along with annulus and ALL could explain slip of pituitary rongeur anteriorly and injuring the opposite renal artery. Disruption or degeneration of the anterior annulus fibrosus and anterior longitudinal ligament or peri-discal fibrosis, both associated with chronic disc pathology, is one of the known risk factors for iatrogenic vessel injury [5].

Renal vascular injuries in the form of accessory renal artery injury and renal visceral injury have been reported previously [12]. Yuan et al. reported a case of a nicked renal vein in one patient [13]. Isaacs et al. reported one case of renal visceral laceration in his study of 107 patients who underwent extreme lateral interbody fusion for treatment of adult scoliosis [14]. Sugimoto et al. reported a case of lumbar artery injury which was managed by emergency embolization [15].

Clinical manifestations of a vascular injury include a drop in hemoglobin, persistent hypotension, tachycardia and abdominal pain depending on the injury type. It may
present immediately or may remain undetected for a long time. Contrast-enhanced computed tomography (CECT) and angiography can help to localize the site of bleeding and in early diagnosis.

Depending on the severity of the injury, the vessel injured and the timing of presentation, the treatment can be planned. In case of an aortic laceration, lateral suturing or graft interposition can be done. In case of an arteriovenous fistula, closure or resection of the fistula has to be undertaken; whereas in the case of a pseudoaneurysm, endovascular repair can be attempted [5]. Lumbar artery injury was traditionally managed by exploration and direct repair but, nowadays, it is being managed with selective embolization of the bleeding vessel after evaluation with computed tomography and angiography [15].

In this index case, the vascular injury was suspected intraoperatively and CT angiography was planned but the patient’s vitals were stable which lead to continued conservative management. On further evaluation based on USG findings and fall of hematocrit, a CT angiogram was done which revealed left renal artery laceration with the formation of a pseudoaneurysm. A left nephrectomy was planned for this patient. In such a case if vascular injury with active bleeding is suspected, a post-operative CT angiography should be done and assessed immediately. If the treatment is delayed, patient can have severe anemia and shock due to continuous bleeding from the injured vessel [15]. The primary goal in such a case should be definitive hemostasis, even though it may necessitate a nephrectomy as the renal function can be adequately preserved with a single opposite renal unit also [12].

Preventive strategies should be followed during posterior lumbar spine approaches. An intact anterior annulus and anterior longitudinal ligament protects against vascular complication but in some cases, these structures might be weak making these patients more prone to injury. Risk factors for increased chance of injury include overaggressive primary discectomy, revision discectomy, degenerative disc diseases, retroperitoneal adhesions and increased intra-abdominal pressure [16]. Careful surgical technique may reduce the risk of complications. Any overaggressive complete discectomy with blind pituitary use should be avoided [17]. The surgeon should maintain an adequate depth assessment and feel of vertebral endplates using instruments. There should be evaluation of relationship with nearby organs and major vessels as well as use of instruments with depth markings for performing interbody procedures may avoid anterior extrusion. Inappropriate trajectories and screw sizes should be avoided. Early recognition and treatment of such injuries should always be done to prevent any catastrophic outcomes [18].

Conclusions

Vascular injury following MIS TLIF is a rare but serious complication. Any episode of hypotension or fall in hematocrit should warrant an immediate search of vascular injury to avoid catastrophic consequences. Prompt detection with urgent intervention either surgical exploration or embolization has chances of better outcomes.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Standard Statement All standard procedures were followed in compliance with the ethical standards.

Informed consent Informed consent was obtained from the patient.

References


Usual and Unusual Musculoskeletal Sequelae of COVID 19!

Vaibhav Bagaria

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Abstract

Today the orthopedic world with respect to COVID remains focused on resumption of elective surgery and impact of the pandemic on scientific activities. However, it is equally important that we keep our eyes on the phenomenon that is quietly unraveling in front of the eyes. The phenomenon of post-COVID musculoskeletal sequelae may become a major orthopedic public health problem in coming months and needs to be investigated in depth. The usual post-COVID symptoms include arthralgia and myalgia that are common in many viral diseases. It is the unusual symptoms like occurrence of primary septic joint infection and elevated rates of post-operative infections that warrant attention and further investigation. Could this be attributed to immune consumption leading to a phase of temporary immunosuppression is a matter of speculation and hypothesizing. A short communication here reveals a glimpse of musculoskeletal sequelae that COVID may bring in coming months. These could be usual arthralgia or myalgia which are self-limiting but could also be more sinister like spontaneous osteonecrosis and primary joint infections.

COVID 19 virus and disease has shown to affect various systems in affected individual. This affliction has been patient specific and for reasons unknown the impact has been non-uniform. There are numerous studies reflecting on the clinical manifestations of COVID 19. Orthopedic manifestations of COVID 19 infection in patients who presented with the disease or in the immediate aftermath of disease, however, is also not well documented.

A total of 6200 patients were seen in the pandemic period (15th March 2020 to 31 March 2021) in the orthopedic OPD and emergency department of a tertiary care hospital. Of these 90 patients who reported (RTPCR positive in last 3 months) or investigated and found (elevated Ig G titers) having recent COVID came for an orthopedic consult for possible post-COVID Sequelae. Following were the clinical manifestations of the disease from the orthopedic standpoint:

1. Arthralgia and Myalgia: 62
2. Synovitis: 14
3. Acute Primary septic joint: 2
4. Spontaneous osteonecrosis: 2
5. Soft tissue Abscess: 4
6. Postoperative infection: 6

Arthralgia and myalgias are not very specific and may be a chance occurrence [1]. These maybe considered usual symptoms for any viral disease. However, the high rate of post-operative infections in those operated in post-COVID period, occurrence of primary septic arthritis, spontaneous osteonecrosis and soft tissues abscess is unusual and noteworthy. While no causal relationship between the symptoms and disease could be established, the association of certain rare condition like acute primary septic joints and spontaneous necrosis is a cause of worry and should be a subject of further investigations. It is pertinent to note that not all patient had symptomatic COVID infection or received steroids. In light of these, the cause is hypothetically attributed to phenomenon of ‘Consumption Immunosuppression’ in which the COVID infection utilizes the available immune defense mechanism of the body leaving the patient vulnerable to infections. Similarly, a hypercoagulable state may be responsible for spontaneous osteonecrosis.

Today the orthopedic world with respect to COVID understandably remains focused on resumption of elective surgery and impact on scientific activities [2]. However, it is equally important that we keep our eyes on the phenomenon that is unraveling quietly in front of the eyes. The phenomenon of post-COVID musculoskeletal sequel that may
become a major orthopedic public health problem in coming months needs to be investigated in depth to reach a meaningful conclusion and to design a preemptive strategy.

Declarations

Conflict of Interest The article has not been submitted anywhere else and the authors do not declare any conflict of interest.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent For this type of study, informed consent is not required.

References


To the Editor,

The article by De et al. [1] on peri-operative outcomes and mortality in COVID-19-positive patients with hip fractures holds great relevance with the current worldwide situation with respect to the pandemic. Hip fractures especially those occurring in the elderly (fragility fractures) are a leading cause of morbidity and mortality in orthopaedic patients. We would like to give our opinion about the following points:

1. In the study protocol, COVID-19 tests were done only for patients who fulfilled clinical or radiological criteria of COVID-19 infection. The inclusion of only symptomatic patients for testing would lead to underreporting of infection in this cohort of patients. Patients who were asymptomatic would also logically have lower rates of pulmonary complications and mortality, and their exclusion would lead to higher mortality being attributed to COVID-19. A possible solution would be to label the study sample as ‘symptomatic COVID-19 positive patients’.

2. The study protocols mentioned that patients were operated in ‘COVID-designated theatres’. But results from Table 1 have divided the patients into two groups—those who were operated in ‘COVID-designated theatres’ and those who were operated in ‘clean trauma theatre’. We request the authors to provide a clarification for this point, with respect to how allocation was done for patients to any specific theatre. We also request the authors to give their opinion on where they feel these patients should be operated, both from the patients’ point of view and in view of restricting transmission to healthcare workers.

3. An international multicentre cohort study conducted in over 35 hospitals has found that 30-day mortality in patients undergoing surgery with COVID-19 infection was 23.8% (268 of 1128) [2]. They opined that higher thresholds should be set for deciding on operative intervention, especially in the older age group. They also felt that non-operative treatment measures should be used to delay or avoid surgery in high-risk patients. The treatment protocol in our institution for hip fractures has been to treat them in the same category as other closed fractures—to be operated once the patient is COVID negative. We feel that further research is needed, to ascertain whether non-operative treatment has better/comparable outcomes in COVID positive patients specifically, or whether we need to develop more protocols and resources for urgent treatment of these patients.

We would like to thank the authors for their pioneering work in the field of hip fractures in COVID-19-positive patients, and await their comments.

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Conflict of interest The authors declare no conflict of interest.

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