

# Variables affecting complication rates in type III paediatric supracondylar humerus fractures

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#### **Abstract**

Purpose Unstable supracondylar humerus (SCH) fractures may have different outcomes as a result of direction of displacement and pin configuration. This study evaluates the impact of fracture displacement, pin configuration and fellowship training on clinical and radiographic outcomes in unstable fractures.

Methods A total of 99 patients with completely displaced type III fractures were identified at an academic centre and a local community hospital. Patient characteristics and the fellowship training of the treating surgeon were recorded, and injury films documented the direction of displacement. Pin configuration, coronal and sagittal alignment were recorded from postoperative radiographs and at healing. Radiographic outcomes including coronal, sagittal and rotational malunion as well as clinical complications were analyzed.

Results Fractures with direct posterior displacement had a lower composite malunion rate compared with those with posterolateral (PL) or posteromedial (PM) displacement (6.9%, 36.4%, 29.2% respectively; p = 0.019). PM displacement had a higher rate of coronal malunion compared with PL (18.2% versus 0%; post hoc p = 0.024). All-lateral constructs resulted in more rotational malunions (20.9% versus 1.8%; p = 0.002) compared with crossed pinning. PL fractures treated with all-lateral fixation showed a trend toward increased rota-

tional instability or malunion (23.8% versus 1.3%; p = 0.073). Higher composite complication rates were noted in patients treated by surgeons with non-paediatric, non-trauma fellowship training.

Conclusion For displaced SCH fractures, all-lateral fixation is associated with higher rates of rotational instability and malunion. Posteromedially and posterolaterally displaced fractures have higher rates of malunion compared with fractures with straight posterior displacement. Fellowship training other than paediatric or trauma was associated with increased complications.

Level of Evidence: Level III

Cite this article: Livermore AT, Sansone JM, Machurick M, Whiting P, Hetzel SB, Noonan KJ. Variables affecting complication rates in type III paediatric supracondylar humerus fractures. *J Child Orthop* 2021;15:546-553. DOI: 10.1302/1863-2548.15.210101

**Keywords:** fellowship training; supracondylar humerus fractures; pin configuration; complications; direction of displacement

## Introduction

Supracondylar humerus (SCH) fractures are among the most common elbow fractures in paediatric patients, comprising up to 58% of fractures.1 They are classified according to the direction of displacement as described by Gartland.<sup>2</sup> Completely displaced type III fractures are treated surgically with reduction and pinning to prevent malunion and mitigate neurovascular compromise.2 There has been a trend to refer patients with SCH fractures to paediatric specialty hospitals to be cared for by paediatric fellowship-trained specialists. Despite an assumption that a paediatric fellowship-trained surgeon is more likely to use contemporary pinning strategies, it is unknown if results between paediatric orthopaedists and other fellowship-trained surgeons differ. Previous studies show a difference only in rates of open reduction between training groups, without a difference in overall outcomes, though radiographic data were not included.3

The importance of periosteal disruption in paediatric fracture patterns is well-described, and the periosteum is variably damaged by fracture displacement in different directions.<sup>4</sup> Intact periosteum acts as a tether to prevent

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further displacement and can serve as a reduction aid. In the case of SCH fractures, posterolateral (PL) displacement at the time of injury disrupts the medial periosteum, whereas posteromedially displaced fractures result in lateral periosteal disruption. Straight posterior displacement may have some intact medial and lateral periosteum.

Several studies have evaluated biomechanical differences and clinical outcomes in fractures managed with all-lateral pinning or crossed pinning.<sup>5,6</sup> Despite numerous studies, there is no clear data on outcomes framed by direction of displacement and pin configuration in displaced fractures.<sup>7-10</sup> Closed reduction with all-lateral pin fixation is a common method of treating displaced SCH fractures. However, in the setting of PL displacement with disrupted medial periosteum, an all-lateral pin configuration would only restore stability to the lateral column of the humerus.

The aim of our study is to investigate radiographic outcomes and complications in completely displaced type III SCH fractures, taking into consideration the direction of displacement and pin configuration. We further hypothesize that posterolaterally displaced type III fractures treated with all-lateral pinning will have higher rates of malunion. Another aim is to determine whether radiographic outcomes and complications in completely displaced type III SCH fractures vary by fellowship training of the treating surgeon.

# Materials and methods

Institutional review board approval was obtained for this retrospective cohort study. Patients between two and 12 years of age with SCH fractures over a ten-year period (2003 to 2013) were identified by ICD-9 (International Classification of Diseases-9)11 codes at two institutions within the same community: an academic Level 1 paediatric trauma centre (University of Wisconsin Hospitals and Clinics, Madison, Wisconsin) and a high-volume, private Level 3 hospital (St. Mary's Hospital, Madison, Wisconsin). All completely displaced, extension Gartland type III fractures were included if they had complete clinical data and radiographs of sufficient quality for accurate measurement. As a primary outcome of our study was malunion rates, we included all patients with a minimum follow-up of six weeks and with complete radiographic union, given that little coronal plane remodelling occurs at the distal humerus after union occurs. Exclusion criteria included flexion-type fractures, history of prior SCH, ipsilateral forearm fracture, metabolic bone disease and closed physes.

Patient and injury characteristics including age, sex, laterality, skin status, presence of compartment syndrome and preoperative neurological and vascular status of

the extremity were recorded from the initial encounter. Patients were considered to have vascular compromise if they had decreased or absent pulses, decreased perfusion of the injured hand or required vascular exploration. Injury radiographs were reviewed and the direction of displacement of the completely displaced distal fragment was noted for type III fractures as either direct posterior (P), posteromedial (PM) or PL. Those patients with P displacement had no cortical continuity as seen in type II fractures. All completely displaced fractures with extension were included, and exam under anaesthesia was not undertaken to distinguish type III from type IV. Surgical details were also recorded, including the type of reduction (closed, medial mini-open and open) and type of fixation (all-lateral versus crossed pinning). Postoperative neurovascular status was recorded, and radiographs were analyzed for pin configuration, Baumann angle and the location of the anterior humeral line as it intersected the capitellum on the lateral radiograph. Measurements were made from final fluoroscopic views as these were of superior quality to postoperative plain radiographs in a cast. Pin spread at the fracture site was measured with the distance functionality on our institution's picture archive and communication system (PACS) (McKesson, Irving, Texas) (Fig. 1). The Baumann angle and anterior humeral line measurements were repeated at final radiographic follow-up.

Pin configuration and technique was at the discretion of the treating surgeon and was not controlled for in this retrospective study. While the semi-extended, mini-open technique as described by Edmonds et al<sup>12</sup> was utilized frequently for medial pin placement, it was not used universally and was not used in the two iatrogenic ulnar palsies that occurred in this series. Prior studies have examined the biomechanical stability of various starting points for all-lateral pinning, suggesting improved stability with a capitellar starting point *versus* true-lateral.<sup>13</sup> Our series contained a combination of both techniques at the discretion of the surgeon.

Radiographic and clinical complications were recorded at final follow-up. Clinical complications included reoperation, infection and iatrogenic nerve palsy. Extension malunion was diagnosed if the capitellum remained posterior to the anterior humeral line on the lateral radiograph at the time of healing. Coronal malunion was defined as a healed fracture with a final Baumann angle > 90° or < 60° (75° sd 15°). Rotational malunion was diagnosed at final healing when there was a difference in width of 5 mm between the distal humerus and the metaphysis proximal to the fracture on the lateral radiograph. This measurement was chosen based on the lateral rotation percentage from prior studies, in which a measure of 20% was defined as significant 15-17 (Fig. 2). Our choice of 5 mm of



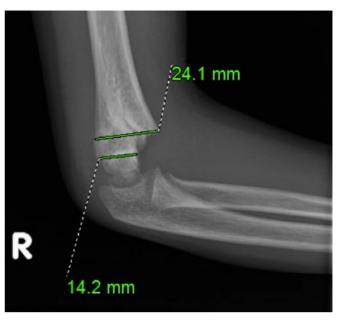
**Fig. 1** Pin spread at the fracture site on the anteroposterior view. Measurements were made with picture archive and communication system software.

displacement yielded a lateral rotation percentage of at least 30% in our series, indicating a significant rotational malunion in these patients.

At the time of the study, fractures at the academic centre were treated by paediatric fellowship-trained surgeons, trauma fellowship-trained surgeons and surgeons with other fellowship training. At the community hospital in the study, fractures were treated by one paediatric fellowship-trained surgeon and eight surgeons with nontrauma, non-paediatric fellowship training.

# Statistical analysis

Statistical analysis for the comparison was carried out with chi-squared tests or analysis of variance where appropriate. *Post hoc* two-way comparisons were adjusted for multiple testing with Holm p-value adjustment. Comparison of two groups was carried out with chi-squared tests, Fisher's exact tests, or t-tests where appropriate, p < 0.05 was considered significant. Power was calculated based on an analysis of outcomes between the two sites, which are not presented in this paper; the results presented herein are secondary outcomes of that power analysis. All analyses were carried



**Fig. 2** Rotational malunion of a supracondylar humerus fracture. Malunion was present when there was a difference in width of > 5 mm between the capitellum and the metaphysis proximal to the fracture.

out by a biostatistician using R version 3.1 or higher (The R Foundation for Statistical Computing, Vienna, Austria).

## Results

In total, 151 completely displaced type III SCH fractures were identified, and 99 met inclusion criteria. In all, 52 patients were excluded primarily for insufficient follow-up or poor-quality radiographs precluding measurement, and two flexion type injuries were excluded. There were 59 female and 40 male patients included in the study, and the left arm was involved in 63% of cases. The mean age was 6.3 years (2 to 12; SD 2.0). A total of 12 patients had signs of vascular compromise on arrival, and two of those required vascular exploration to free an entrapped brachial artery from the fracture site after reduction; in neither case was reconstruction required. One patient developed compartment syndrome. Mean follow-up was 6.6 months (1.5 to 68).

There was no difference in the age or laterality based on direction of displacement (Table 1). There was a 21% rate of anterior interosseous nerve (AIN) injuries on initial exam in the PL group, compared with 3.4% and 4.5% in the P and PM groups, respectively (p = 0.05). There were no other differences in incidence of specific nerve injury or vascular compromise by direction of displacement. One preoperative AIN palsy had not fully resolved when the patient was lost to follow-up, but all remaining inju-



Table 1. Demographics, neurovascular status, and outcomes by direction of displacement

Demographics	Р	РМ	PL	p-value
n	29/99	22/99	48/99	
Sex (% female)	13 (44.8)	11 ( <i>50.0</i> )	35 (72.9)	0.030*
Arm (% right)	12 (41.4)	8 (36.4)	17 (35.4)	0.866
Age (years, mean)	6.6 (sd 1.9)	6.6 (sd 1.9)	5.9 (sd 2.0)	0.239
Neurovascular status (%)				
Median palsy	3 (10.3)	1 ( <i>4.5</i> )	11 (22.9)	0.119
AIN palsy	1 (3.4)	1 (4.5)	10 (20.8)	0.050*
Radial palsy	1 (3.4)	3 (13.6)	3 (6.3)	0.455
Ulnar palsy	0 (0.0)	1 (4.5)	2 (4.2)	0.596
Vascular anomaly	5 (17.2)	0 (0.0)	7 (14.6)	0.098
Compartment syndrome	0 (0.0)	0 (0.0)	1 (2.0)	1
Outcomes				
Paediatric fellowship (% yes)	15 ( <i>51.7</i> )	11 ( <i>50.0</i> )	26 (54.2)	0.944
Fixation (% crossed)	15 ( <i>51.7</i> )	14 (63.6)	27 (56.2)	0.695
Total complications (%)	7 (24.1)	8 (36.4)	19 (39.6)	0.391
Rotational malunion	2 (6.9)	2 (9.1)	6 (12.5)	0.907
Extension malunion	0 (0.0)	2 (9.1)	8 (16.7)	0.035 <sup>†</sup>
Coronal malunion	0 (0.0)	4 (18.2)	0 (0.0)	0.002 <sup>‡</sup>
Combined malunion	2 (6.9)	8 (36.4)	14 (29.2)	0.019**

<sup>\*</sup>post hoc pairwise comparison with Holm adjusted p-value revealed no significant two-way comparisons

ry-related neurovascular abnormalities resolved by final follow-up. One patient in the PL group developed compartment syndrome and had normal function after undergoing fasciotomy.

Direction of displacement impacted malunion rates (Table 1). Posteromedially and posterolaterally displaced fractures had a higher rate of extension malunion (9.1% and 16.7%, respectively) compared with fractures with P displacement (0.0%) (p = 0.035; post hoc pairwise analyses; p > 0.05). Pooled PM and PL fractures compared with P fractures showed a significant difference in extension malunion (14.3% *versus* 0% respectively; p = 0.032). PM displaced fractures had an 18.2% rate of coronal malunion, all in varus, compared with no coronal malunions in the P or PL groups (p = 0.002; post hoc pairwise analysis PM to PL; p = 0.024). The combined malunion rate in the P group was 6.9%, which was significantly lower than the PM (36.4%) or PL (29.2%) groups (p = 0.019; post hoc pairwise analyses; p > 0.05). For combined malunions, pooling PM and PL groups versus the P group again showed a significant difference (31.4% versus 6.9% respectively; p = 0.010). Rotational malunion was similar regardless of displacement (p > 0.9). Pooled complications did not differ by direction of displacement (p = 0.391).

When examining displacement groups by fixation type, there were no differences in demographics or total complications between all-lateral and cross pin fixation (Table 2). All-lateral fixation was associated with a significantly higher rate of rotational malunion (20.9% *versus* 1.8%; p =

0.002) and a higher combined malunion rate (34.9% *versus* 16.1%; p = 0.036) compared with cross-pinning. Four iatrogenic nerve palsies were identified, three of which occurred with a crossed pinning construct (two ulnar, one AIN, 5.6% rate of injury), and one with a lateral construct (radial, 2.3% rate of injury) (p = 0.6). One patient was lost to follow-up at two months prior to resolution of an ulnar nerve palsy, while the remaining three iatrogenic nerve palsies resolved fully.

There were ten fractures that healed with rotational malunion. While not significant, there was a trend toward higher rates of rotational malunion in PL fractures stabilized with an all-lateral pin configuration (23.8%) versus a crossed pin construct (3.7%; p = 0.073) (Table 3). There was no difference by fixation method in P and PM fractures. For all-laterally pinned fractures, those that developed rotational malunions (nine fractures) had a mean pin spread of 9.3 mm (SD 6.5) at the fracture site as measured on PACS, as compared to a mean pin spread of 15.2 mm (SD 4.6) in the 34 fractures that maintained appropriate rotational alignment (p = 0.026) (Table 4). No patients required corrective osteotomy for malunion in our series. Of the 24 combined malunions present in the study, 12 of them were deemed to be inadequately reduced at the time of surgery. With these removed from analysis, there were two combined malunions (4.3%) in the crossed pinning group and ten malunions (25.6%) in the all-lateral group, presumably due to interval loss of reduction (p = 0.005) (Table 5).

<sup>†</sup>post hoc pairwise comparison with Holm adjusted p-value revealed no significant two-way comparisons. Pooled PM and PL compared with P showed significant difference (0% versus 14.3%; p = 0.032)

 $<sup>\</sup>ddagger$ post hoc pairwise comparison with Holm adjusted p-values showed significant difference between PM and PL; p=0.024

<sup>\*\*</sup>post hoc pairwise comparison with Holm adjusted p-value revealed no significant two-way comparisons. Pooled PM and PL compared to P showed significant difference (6.9% versus 31.4%; p = 0.010)

P, direct posterior displacement; PM, posteromedial displacement; PL, posterolateral displacement



Table 2. Demographics and outcomes by fixation type

Demographics	Crossed	All lateral	p-value*	
Number	56/99	43/99		
Sex (% female)	35 (62.5)	24 (55.8)	0.642	
Arm (% right)	24 (42.9)	13 (30.2)	0.281	
Age (years, mean)	6.4 (sd 1.9)	6.1 (sd 2.0)	0.375	
Outcomes				
Paediatrics fellowship (% yes)	28 (50.0)	24 (55.8)	0.711	
Total complications (%)	15 (26.8)	19 (44.2)	0.089	
Rotational malunion	1 (1.8)	9 (20.9)	0.002	
Extension malunion	6 (10.7)	4 (9.3)	1	
Coronal malunion	2 (3.6)	2 (4.7)	1	
Combined malunion	9 (16.1)	15 (34.9)	0.036	
Compartment syndrome	1 (1.8)	0 (0.0)	1	
latrogenic palsies	3 (5.6; 2 ulnar, 1 AIN)	1 (2.3, radial)	0.631	

AIN, anterior interosseous nerve

Table 3. Rotational instability by direction of displacement and fixation type

Direction	P	PM	PL
Crossed, n (%)	0 (0)	0 (0)	1 (3.7)
Lateral, n (%)	2 (14.3)	2 (25)	5 (23.8)
p-value*	0.224	0.121	0.073

P, direct posterior displacement; PM, posteromedial displacement; PL, posterolateral displacement \*p-values are from Fisher's Exact test

Table 4. Mean pin spread at fracture site in posterolaterally displaced type III fractures treated with all-lateral fixation

	Rotational malunion	No rotational malunion	p-value*
Number	9/43	34/43	-
Max pin spread	9.3 mm (sd 6.45)	15.2 mm (sd 4.61)	0.026

<sup>\*</sup>p-value is from t-test

Table 5. Malunion rates by pin construct when initial reduction is radiographically adequate

Pin construct	n (%)
Crossed	2 (4.3)
Lateral	10 (25.6)
p-value*	0.005

<sup>\*</sup>p-value is from Chi-square test

Paediatric fellowship-trained surgeons cared for 54% of fractures in our series (Table 6). There was a higher rate of composite complications for the non-paediatric, non-trauma fellowship group compared with the paediatric fellowship and trauma fellowship trained groups (29.4% *versus* 19.2% *versus* 15.4%; p = 0.038). There were three iatrogenic palsies (8.8%) in the group with non-trauma, non-paediatric fellowship training, compared with one in the paediatric group (1.9%) and none in the trauma group

(p = 0.346). This was coupled with a significantly lower rate of mini-open reduction technique in the other fellowship group for crossed fixation at 40.9%, compared with 75.0% for the paediatric group and 100.0% for the trauma group (p = 0.002). All iatrogenic palsies in the other fellowship group occurred with crossed fixation methods, and this group had the lowest rate of all-lateral fixation (35.3%), compared with 46.2% and 53.8% for the paediatric and trauma fellowship groups, respectively (p = 0.45).

<sup>\*</sup>p-values are from Fisher's Exact Test



Table 6. Outcomes by fellowship training for type III fractures

Outcomes	Other fellowship (n = 34), n (%)	Paediatric (n = 52), n (%)	Trauma (n = 13), n (%)	p-value*
All-lateral fixation	12 (35.3)	24 (46.2)	7 (53.8)	0.45
Mini-open reduction (for crossed fixation)	9 (40.9)	21 (75.0)	6 (100.0)	0.002
Additional surgery	2 (5.9)	2 (3.8)	0 (0.0)	0.800
Extension malunion	3 (8.8)	5 (9.6)	2 (15.4)	0.798
Coronal malunion	2 (5.9)	2 (3.8)	0 (0.0)	0.800
latrogenic palsy	3 (8.8)	1 (1.9)	0 (0.0)	0.346
Composite complication**	10 (29.4)	10 (19.2)	2 (15.4)	0.038

<sup>\*</sup>p-values are from Fisher's Exact test

## **Discussion**

This study is the first to examine outcomes of completely displaced type III SCH fractures stratified by direction of displacement as well as pin configuration. All-lateral pinning is a relatively newer approach to fracture stabilization; despite this there was no significant difference in the rate of lateral pinning according to fellowship training (Table 6). While all-lateral pinning does mitigate the risk of iatrogenic ulnar nerve palsy, 18-20 in the present study it was associated with higher rates of rotational malunion, regardless of direction of displacement. It was also associated with higher combined malunion rates in patients with adequate initial reductions (Table 5). Recent literature has documented a method of internal rotation stress testing prior to cast application as a means of detecting fracture instability; during the course of this study, this technique was not routinely performed.<sup>17</sup> The risk of rotational instability was higher when the maximal pin spread at the fracture site was low, in accordance with biomechanical and clinical studies demonstrating less resistance to torsional forces with narrow pin spread.<sup>5,6,21</sup>

Fractures displacing directly posteriorly have a lower rate of malunion, and we hypothesize that having some portion of both the medial and lateral periosteum intact leads to increased stability upon reduction and stabilization with pins from either direction. PM and PL displacement had higher rates of both extension malunion and combined malunion. PM fractures had a higher rate of varus malunion than P or PL fractures, regardless of fixation type. This may be due to unrecognized medial comminution from the initial injury, resulting in shortening of the medial distal humerus and resultant varus alignment.

One primary hypothesis of our study was that posterolaterally displaced fractures treated with all-lateral fixation would have more malunions compared with fractures managed using a crossed pinning construct. The difference was not significant though it trended towards significance in the setting of rotational malunion, with a rate 23.7% in all-lateral fixation *versus* 3.7% with crossed fixation (p = 0.073). This difference is likely due to underpowering. The clinical significance of rotational malunion (without coronal plane deformity) in the distal humerus remains unclear at this time. SCH fractures may remodel slightly in the sagittal plane but less so in the coronal plane.<sup>22</sup> The ability to remodel in the axial plane is not well-studied. Shoulder rotation may compensate for rotational malalignment of the distal humerus and may not restrict the individual's ability to position the hand in space in a meaningful way. This remains an area for future study.

One previous study has examined outcomes based on direction of displacement. Ernat et al<sup>7</sup> prospectively examined outcomes in type II and III fractures, also stratifying by direction of displacement in type III fractures. There were no significant differences in their patient-reported outcome measures. Our study found radiographic differences in alignment between groups, though the functional impact of these differences remains unknown. The previous study did not include treatment or radiographic data, and thereby the correlation to our data remains unclear.

In our series, we found no significant differences in individual categories of radiographic or clinical outcomes when stratifying by the training of the treating surgeon. However, there was a significantly different increase in pooled complications in fractures treated by non-trauma, non-paediatric fellowship trained surgeons at our centres. This is in contrast to prior work by Farley et al,3 who found the only difference between training groups to be in the rate of open reduction. Of note, the other fellowship group had the highest rate of iatrogenic palsies and the highest rate of crossed pin fixation (both not significant), with the lowest rate of mini-open reduction technique in crossed pin fixation cases, which was significant. This suggests that by adopting this technique when using crossed-pin fixation, further palsies may be mitigated and the overall complication rates would be very similar when stratified by fellowship training.

Our study carries with it the limitations inherent to any retrospective cohort study. Periosteum is known to play an important role in fracture stability in children,<sup>4</sup> and our

<sup>\*\*</sup>composite outcome of additional surgery, extension malunion, coronal malunion or iatrogenic palsy



study used direction of displacement as a surrogate for periosteal injury. Nevertheless, presenting radiographs may underrepresent the magnitude and possibly the direction of displacement present at the time of injury, and as such, radiographs remain an imperfect proxy for underlying periosteal injury. As no patients with radiographic malunions required corrective osteotomy in our series, the functional impact of this radiographic finding is not known. Our use of unilateral Baumann angle as a measure of coronal alignment is imperfect and subject to high variability. Ideally, we would have had comparison Baumann angles from the uninjured side but did not have frequent contralateral comparison films. A more functional measure of coronal alignment would have been carrying angle, but with anteroposterior radiographs shot in varying degrees of elbow flexion, we did not have adequate data to include this. Furthermore, our follow-up period is short and may miss some remodelling over time, thereby offering a possible explanation of the lack of need for corrective osteotomy. This is likely especially true for juxtaphyseal fractures, in which growth disturbances may not manifest for longer periods. This short follow-up may be in part due to patients travelling long distances to a level I referral centre for paediatric-specific care who then have challenges following up, though our finding of higher complication rates in non-paediatric, non-trauma trained surgeons may argue in favour of seeking specialty care. Additionally, nearly one-third of patients had to be excluded due to inadequate follow-up or poor-quality radiographs. This likely impacted our outcomes, and is again likely due to lengthy travel distances for many referred patients included in the study. Numerous variables were included for analysis in this study, making the individual contributions of each somewhat challenging to delineate. The fellowship of a treating surgeon is likely to be a proxy for the surgeon's learning curve with treating supracondylar fractures, and we do not have data for how many such fractures were treated by each surgeon.

In conclusion, all-lateral fixation is associated with higher rates of rotational instability and combined malunions. Coronally displaced fractures have higher rates of malunion, while fractures with P displacement are more stable. Fellowship training other than paediatric or trauma was associated with increased complications.

Received 26 May 2021; accepted after revision 05 November 2021.

## **COMPLIANCE WITH ETHICAL STANDARDS**

## **FUNDING STATEMENT**

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

#### **OA LICENCE TEXT**

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#### **ETHICAL STATEMENT**

**Ethical approval:** This retrospective chart review underwent review and approval by the institutional review board. This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed consent:** No informed consent was obtained as there was no patient identifying information included.

### **ICMJE CONFLICT OF INTEREST STATEMENT**

The authors have no conflicts to report. This study did not receive separate funding.

#### **AUTHOR CONTRIBUTIONS**

ATL: Study design, Institutional review board preparation, Data acquisition, Radiographic measurements, Manuscript preparation, Statistical analysis.

JMS: Study design, Data acquisition, Manuscript preparation.

MM: Data acquisition, Radiographic measurements, Statistical analysis.

PW: Study design, Manuscript preparation.

SBH: Study design, Statistical analysis, Manuscript preparation.

KJN: Study design, Institutional review board preparation, Manuscript preparation.

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