Do anatomical contoured plates address scapula body, neck, and glenoid fractures and can these fractures be classified? – A multi-observer consensus study

by

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This study was conducted from March 2019 to March 2021 under the supervision of Professor Stephen Roche, Department of Orthopaedic Surgery, University of Cape Town.

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Abstract

Background: The surgical management of scapula body, neck and glenoid fractures remains a challenge. This study focusses on templating an available anatomical pre-contoured plating system using 3D printed scapulae to assess the ability of these plates to address the aforementioned fractures and to determine consensus on classifying scapula body, neck and glenoid fractures.

Methods: We used a cohort of twenty-two 3D printed fractured scapulae prototypes and an available anatomical pre-contoured plating system to determine anatomical congruency and fit. Nine investigators templated the scapula fractures using four pre-contoured plates and the investigators classified the twenty-two fractured scapulae using the Ideberg and AO/OTA classification system.

Results: Eleven out of twenty-two fractures were found to be fixable using the plates under study. The long lateral plate addressed 83.3% of fractures involving the lateral border, while the glenoid plate was unable to adequately address any glenoid fractures. We observed good to excellent ($p \leq 0.001$) inter-observer reliability for three of the four plates. The inter-observer reliability was moderate (ICC = 0.74) for the AO/OTA classification and good (ICC = 0.88) for the Ideberg classification.

Conclusion: We believe that the anatomical pre-contoured plating system does not address all the fracture patterns encountered in clinical practice and further development in plate design is required. Good to moderate interobserver reliability were observed using the Ideberg fracture classification for intra-articular fractures and the AO/OTA classification for extra-articular fractures involving the body.

Acknowledgements

I would like to thank my supervisor, Professor Stephen Roche, and all the co-authors for their assistance and guidance throughout the whole process. Secondly, I want to acknowledge Doctor Roopam Dey for his assistance with manufacturing and printing of the scapula prototypes and also the statistical analysis and interpretation of the data. Lastly, I would like to thank Professor Sudesh Sivarasu and the team at the Division of Biomedical Engineering for granting me access to the laboratory and their invaluable input with data collection and manufacturing of the scapula prototypes.

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Abbreviations

3D - Three dimensional

2D - Two dimensional

AO/OTA - Arbeitsgemeinschaft für Osteosynthesefragen

CAG - Classification Advisory Group

CT - Computer tomography

DICOM - Digital Imaging and Communication in Medicine

HREC - Human Research Ethical Committee

ICC - Intraclass correlation coefficient

NICSF - New International Classification for Scapula Fractures

ORIF - Open reduction and internal fixation

OTA - Orthopaedic Trauma Association

PART A: MANUSCRIPT IN ARTICLE FORMAT

Do anatomical contoured plates address scapula body, neck-, and glenoid fractures? – A multi-observer consensus study.

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Keywords

Scapula fracture, open reduction and internal fixation (ORIF), South Africa, scapula plate analysis, 3D printing, fracture classification.

Introduction

Isolated scapula fractures are rare, accounting for 3% to 5% of upper limb fractures and 0.7% of all fractures[1–3]. They commonly occur in the polytraumatized patient and are generally associated with significant trauma. Low energy scapula fragility fractures sustained after falls may be found in the geriatric population[4].

The scapula plays a pivotal role in maintaining the resting position of the shoulder girdle and together with the clavicle, provides the anchor for the upper limb to the thorax[3]. The rotator cuff muscles originate from the scapula and function not only as a dynamic glenohumeral stabilizer, but also in the initiation of gleno-humeral motion. Loss of motion at the glenohumeral joint is well tolerated through increased scapulothoracic movement and displaced fractures may affect this movement. The aim of scapula fracture management should be to restore shoulder function by correcting alterations in anatomy that cannot be compensated for[3].

Non-surgical management of minimally to moderately displaced scapula body and neck fractures has rendered clinically acceptable and favourable long-term outcomes. However, the displaced and intra-articular fractures types still pose a clinical dilemma due to a lack of comparative literature and well defined surgical indications[2,3,5]. Displaced and malunited intra-articular fractures lead to glenohumeral joint incongruency and increased degeneration, resulting in early onset (accelerated) arthrosis of the glenohumeral joint[1–3,6,7]. Shoulder deformity with chronic pain, and stiffness are frequently encountered in malunited scapula fractures[8,9]. Rotator cuff weakness and disfunction with impingement have also been described[3,4,9].

The surgical management of scapula fractures can be difficult and challenging. Adequate fixation options are limited not only by the osseous anatomy and anatomical variability of the scapula, but also by zones of poor bone stock and the lack of bone thickness[1]. The complexity of fracture patterns, challenging surgical approaches and implant limitations may lead to hesitance from surgeons to perform open reduction and internal fixation (ORIF)[1,10]. Limited implant options and pre-contoured plating systems have often led surgeons to use alternate fixation systems designed for other bones to fix scapular fractures[11,12].

Historically, several classification systems were proposed, attempting to guide the surgeon in decision making and fracture management. The most used classification system was developed by the OTA Classification Committee in 1996 and revised ten years later[13].

To address the limitations of the existing classification systems, the OTA Classification Committee and the AO Classification Advisory Group (CAG) collaborated to develop a new validated classification system[14,15]. Although validated and reproducible, the AO/OTA classification system does not determine surgical indications, operative approaches or implant choice[14].

The primary aim of this study was to quantify the anatomical congruency and fit of the only available plating system in the country and to determine its fracture fixation capability. The secondary aim of the study was to determine the interobserver reliability of scapula fracture classifications and consensus among the investigators using 3D printed scapulae.

Methods

Recruitment and enrolment:

Ethical approval was obtained from the host institute's HREC (Human Research Ethical Committee). The Phillips Electronics iSite Electronic Radiology System database was used to search for all shoulder (three-dimensional) CT scans performed from January to 2016 with to 2018. Twenty-six patients with closed scapula body, neck and glenoid fractures were identified.

The inclusion criterion:

1. Closed scapula body, neck and glenoid fractures

The exclusion criteria:

1. Any patient younger than 18 years
2. Penetrating gunshot wounds
3. Isolated acromion and/or coracoid fractures

Twenty-two closed scapula body, neck and glenoid fractures met the inclusion criteria while, four scapula fractures were excluded as they were isolated acromion fractures. The mean age of the cohort was 46.6 years (range: 26 – 71 years) and was predominantly male.

Research procedure:

The Digital Imaging and Communication in Medicine (DICOM) files of the 22 fractured scapulae were used to create 3D models (*Figure 1*) using Materialise Mimics® (Leuven, Belgium), and then printed using additive manufacturing process.

Each fracture fragment was anatomically reduced and glued in place to maintain the reduction. The 3D models were used to template and determine the anatomical congruency of the available pre-contoured anatomical plating system. Templating was performed with the only locally available plating system[16] from Acumed® (Hillsboro, OR, USA).

The pre-contoured anatomical plating system has four plates designed to address the different anatomical locations of the scapula. The plate options were a long and a short medial plate for the medial scapula border, a long lateral plate and short lateral (glenoid) plate for the lateral border and the glenoid respectively. All four plates were templated on appropriate anatomical locations, determined by the fracture propagation through the scapula anatomy, to attain the best anatomical fixation (*Figure 2).*

Data collection:

Nine investigators (five surgeons and four engineers) templated four plates on twenty-two scapulae on two separate occasions, one month apart. A scoring system, similar to our previous study[17], was applied to this study where plates were defined in an ordinal scale of fit or no-fit depending on their ability to adhere around the fractured region (Table I). Templating of the plates, around fracture regions was performed similar to Malhas *et al.* [18].

The scoring system considered three factors:

Plate overhang: Defined as plate overhang on either the medial or lateral border of the scapula, preventing the placement of a screw.
Plate offset*:* Defined as the distance (in millimetres) from the inferior border of the plate from the bone.
Adequate fixation: Defined as the ability of the plate to allow for placement of three screws proximal and three screws distal to the fracture line as advocated by the AO society fracture fixation guidelines[19].

Each plate was scored and subdivided into a fit or no fit group:

Fit: Defined as plate offset of less than 3 mm with no plate overhang and adequate fixation (six cortices) proximal and distal to the fracture line.
No-fit: Defined as plate offset of more than or equal to 3 mm with plate overhang (as defined by the aforementioned definition) and/or inadequate fixation (less than six cortices) either proximal or distal to the fracture line.

The surgeons (six) classified each scapula fracture pattern using the Ideberg classification[20] for the glenoid fractures and the AO/OTA classification for all fractures except the glenoid[21]. Five senior shoulder and elbow surgeons and one trainee registrar classified the fracture patterns of the twenty-two scapulae at a single sitting.

Data analysis:

To determine the dependency of plate types and its ability to fit the fracture pattern, the Chi-squared test was performed. Intraclass correlation coefficient (ICC) were calculated (model: two-way mixed; type: absolute agreement) to measure the inter-rater variability among the nine observers performing the quantitative-fit analysis of the 22 scapulae. The ICC was also calculated for fixability rating provided by the surgeons as a binary score (1- fixable; 0- not-fixable). The fracture was categorized as fixable when it was rated 1 by at least 80% of the surgeons. The classifications provided by the group of surgeons were also compared using ICC and Chi-square tests. We reported the ICC values according to the categories specified by Koo and Li[22]. The cut-off for statistical significance was kept at $p<0.05$. The statistical analyses were performed in IBM SPSS v.26 (IBM Co., Armonk, NY, USA).

Results:

Twenty seven percent of fractures were found to propagate through the lateral border, scapula body, and the medial border. Eighteen percent of the fractures involved the lateral border and the scapula body. Other fracture combinations can be seen in Figure 3. Seventy seven percent of the fractures involved the scapula body, followed by fifty four percent of the fractures involving the lateral border, forty five percent fractures involved the medial body and only thirty six percent fractures involved the glenoid.

The involvement of different anatomical regions of the scapula anatomy influenced the fixability potential of the available plates ($p\leq0.001$). Good inter-rater reliability (ICC: 0.844, 95%CI: 0.712 – 0.927; $p\leq0.001$) was found for the fixability categorization of the fractures. Overall, 11 out of the 22 fractured scapulae were found to be fixable using the pre-contoured plating system. None of the glenoid fractures were found fixable. Potential fixation could be achieved in 9 (out of 17) body fractures, 10 (out of 12) fractures involving the lateral border, and 9 (out of 12) fractures involving the medial border (*Figure 4*).

When a fracture was deemed fixable, a combination of long lateral plate and at least one of the medial plates was used for 6 (out of 11) fractures. The rest of the fractures could be fixed using only the long lateral plate (*Figure 5*).

Due to the consensus that the glenoid plate was unable to fit the fracture patterns included in this study (*Figure 5*), we excluded the observations for glenoid plates from the ICC calculations. For the remaining plates we observed good to excellent ($p \leq 0.001$) inter-observer reliability (*Table II*).

Inter-observer reliability was moderate (ICC = 0.842; 95%CI = 0.387 – 0.921; p=0.001) for the AO/OTA classification (*Table III*) and good (ICC = 0.883; 95%CI = 0.073 – 0.964; $p \leq 0.001$) for the Ideberg classification (*Table IV*). The Chi-square test suggested that the surgeon's ability to classify scapula fractures were dependent on the fracture classification being used ($p \leq 0.001$).

Discussion:

To our knowledge this is the first study done on three dimensional printed scapulae and scapula fracture fixation using an anatomical contoured plating system. Nguyen *et al.* conducted a similar study but used computerized 3D reconstructions of scapulae and digital templating, using the same plating system[23]. However, the authors used healthy cadaver scapulae and the templating was done by digitally superimposing the plates onto the scapulae[23]. In another study, the authors physically templated anatomical plates on healthy adult museum scapula specimens[17]. Despite the difference in methodologies, comparable results were obtained in our study and the aforementioned ones. The results from the studies showed that the long lateral plate achieved good fit along the fractures of the lateral border of the scapula. This can be attributed to the thicker geometry of the lateral border offering better screw purchase and the linear design pattern of the plate which makes it more congruent to the anatomy of the region.

Dugarte *et al.* conducted a 2D versus 3D scapula fracture mapping study using CT reconstructions and found the majority of fracture lines involved the base of the spine and lateral border, just inferior to the glenoid[24]. The fracture lines were least likely to involve the inferior lateral border. Armitage *et al.* reported similar results on 2D images of scapulae[25]. We found the long lateral plate successfully addressed all fractures exiting at the sub-glenoid, middle and distal thirds of the lateral border.

The medial border of the scapula, compared to the lateral border, is much thinner and offers poor to no screw purchase[10]. The short medial plate performed marginally better than the long medial plate. Of all four plates, the medial plates measured the greatest plate offset and overhang. This might have been due to the angle between its superior and inferior limbs not being acute enough and causing the plate to extend off the medial border. The medial plate, as with the lateral plate, offers no variable angle screw placement option[26,27] and no proximal or distal locking options for smaller diameter locking screws.

The glenoid plate had the worst score for anatomical fit compared to the other three plates. The short triangular shaped glenoid plate proved challenging to be placed into the spinoglenoid notch and posterior glenoid. The glenoid plate was not successful in addressing any glenoid fractures.

These observations are in line with our previous findings[17]. The Ideberg type 3, 4, and 6 fractures pose the greatest challenge to the treating surgeon and in our study, as we observed that the glenoid plate offered limited screw options to adequately fix these fractures. The glenoid plate offers the surgeon only one size, fixed angle screw fixation, with three screws proximal and one screw distal to the fracture line. When the fracture propagated, inferior to the spine, towards the medial border, the glenoid plate was found inadequate to address the fracture. When addressing the intra-articular glenoid fracture and the associated glenoid rim and/or neck fractures we prefer cannulated screws as first line treatment for these fractures, but a variety of fixation techniques, such as cannulated screws, buttressing plates, bone grafting (coracoid/iliac crest), cerclage wiring, suture anchors or a combination of these have been described in the literature[28,29].

The fixation of scapula fractures is not limited to the anatomical pre-contoured system. The use of alternative fixation is well described in the literature with good to excellent results[11,12,30]. Non-anatomical plates, with or without k-wire/screw fixation and even plates designed to address a completely different fracture pattern at different anatomical sites, have been used to fix scapula fractures. Utilizing different fixation techniques, as outlined in the literature, corroborates our observation that the current pre-contoured anatomical scapula plates might not be suitable to fit around all types of scapula fractures. Future developments should focus on introducing design changes to the existing designs to make them fit more fracture patterns.

The secondary aim of the study was to determine consensus on two available scapula fracture classifications. We used the AO/OTA and Ideberg classification systems to classify different types of fractures, non-glenoid fractures with AO/OTA and glenoid fractures with Ideberg and found that the consensus remains less than perfect. The AO/OTA and Ideberg classification systems are well described and often referred to in the literature. Although newer classification systems have been proposed, all the investigators unanimously decided on the AO/OTA and Ideberg classification systems.

In a previous study, Armitage *et al.* stated that many classification systems lack clinical correlation compared to actual fracture patterns[25]. Bartoníček *et al.* reported that the available classifications are purely descriptive and have neither therapeutic nor prognostic implications[21]. Recently, two new scapula fracture classifications systems were proposed which are yet to be adapted in our clinical facility[13,14].

1. The more comprehensive AO/OTA classification
2. The New International Classification for Scapula Fractures (NICSF)

Neuhaus *et al.* compared the validity of the AO/OTA and the (NICSF) and concluded that the NICSF system is validated and more reliable than the AO/OTA[15]. Another study by Harvey *et al*. confirmed that the inter-rater reliability increased when CT images were used in scapula fracture classifications[13,14]. In both the classification systems glenoid fractures were observed to have had the best agreement amongst the observers.

In our study, using 3D printed fractured scapula models, we observed better consensus amongst the surgeons describing glenoid fractures using the Ideberg classification compared to fracture classifications using the AO/OTA classification system.

Implementing 3D prototypes in practise has its limitations. The benefit of 3D printing is not limited to templating only as 3D printed scapula prototype has been used as an adjunct to radiographs in detailed pre-operative planning and teaching[31–33]. The authors would like to caution readers that the cost and time spent on the 3D prototyping process, may not be feasible in all orthopaedic institutions. With the machinery and expertise needed, institutions embarking on such research need to consider the volume of complicated fracture patterns encountered in an orthopaedic practice, in order to justify the cost-benefit.

The primary limitation of this study was the small sample size of the fractured scapulae used in the study. The secondary limitation of the study was that only one anatomical plating system was used in the study as it is also the only commercially available plating system in South Africa. The ability to address the fractures with non-anatomical plates has been well documented. The study did not use plate bending or other methods to improve plate shape to improve fit and fixation that would be possible in the clinical setting. For future studies, the authors would recommend that other available plating systems, including those not necessarily designed for scapula fractures, and different fracture fixation techniques be compared on a larger sample size of fractured scapulae.

Conclusion:

The long lateral plate had the best ability to fit scapula body fractures, followed by a combination of the long lateral plate and one of the medial plates, while the glenoid plate was found to be an unsatisfactory solution for addressing glenoid fractures. Improving the design of the anatomical contoured scapula plating system is recommended in order to improve the fixability of the plating system. Classifying scapula fractures using existing scapula fracture classification systems remain an underlying challenge globally, and the need a for a standardized and reproducible classification system is called for.

Classification	Definition	Ordinal Score
Fit	The plate fit around the fracture within surgical limits and there was no plate overhang observed.	1
No - Fit	The gap between the plate and the fracture line was above acceptable surgical limits and there was plate overhang.	0

Tables and figures:

Table I: *The scoring system used in this study.*

Plates	First Observations		Second Observations	
	ICC	95% CI	ICC	95% CI
Long Lateral	0.894	0.813 – 0.949	0.916	0.852 – 0.960
Long Medial	0.742	0.545 – 0.876	0.818	0.678 – 0.913
Short Medial	0.821	0.685 – 0.914	0.839	0.697 – 0.917

Table II: The intraclass correlation coefficient (ICC) and the corresponding 95% confidence interval (CI) calculated for the two observations sessions presented for each plate included in this study.

	AO/OTA					
	Surgeon 1	Surgeon 2	Surgeon 3	Surgeon 4	Surgeon 5	Surgeon 6
SCAPULA 1	14B2	14B2	14B2	14B1P1	14B2	14B2
SCAPULA 6	14B1P1	14B1P1	14B1	14BP1	14B1	14B1
SCAPULA 7	14B2	14B2	14B1	14B1	14B1	14B1
SCAPULA 9	14B2P1	14B2	14A3	14B2	14B2F	14B2
SCAPULA 10	14B1	14B2	14B1	14B1	14B2F	14B2
SCAPULA 12	14B1	14B2	14B2	14B2	14B1	14B1
SCAPULA 13	14B2	14B2	14B1	14B1	14B2	14B2
SCAPULA 14	14B1	14B1	14B2	14B2	14B2	14B2
SCAPULA 16	14B1	14B1	14B1	14B1	14B1	14B1
SCAPULA 20	14B2	14B2	14B2	14B2	14B2	14B2
SCAPULA 22	14B1	14B1	14B1	14B1	14B1	14B1

Table III: The scapula with isolated body fractures were classified using AO/OTA classification by the surgeons. Their observations are presented in this table.

	IDEBERG					
	Surgeon 1	**Surgeon 2**	**Surgeon 3**	**Surgeon 4**	**Surgeon 5**	**Surgeon 6**
SCAPULA 2	ID3	ID3	ID3	•	ID6	ID2
SCAPULA 3	ID2	ID2	ID4	ID2	ID3	ID2
SCAPULA 4	ID3	ID3	ID3	ID3	ID3	ID3
SCAPULA 5	ID3	ID3	ID3	ID3	ID3	ID2
SCAPULA 8	ID3	ID3	ID4	ID3	ID3	ID2
SCAPULA 11	ID5A	ID5B	ID5B	ID5A	ID4	ID3
SCAPULA 15	ID3	ID3	ID3	ID3	ID3	ID3
SCAPULA 17	*	*	*	*	ID3	*
SCAPULA 18	ID5A	ID5A	ID5A	ID5A	ID4	ID2
SCAPULA 19	*	ID3	ID2	ID5B	ID3	ID2
SCAPULA 21	ID3	*	ID3	ID3	ID3	ID3

(* = unclassified)

Table IV: Isolated glenoid fractures were classified by the surgeons using the Ideberg classification. The classification by each surgeon is shown in this table.

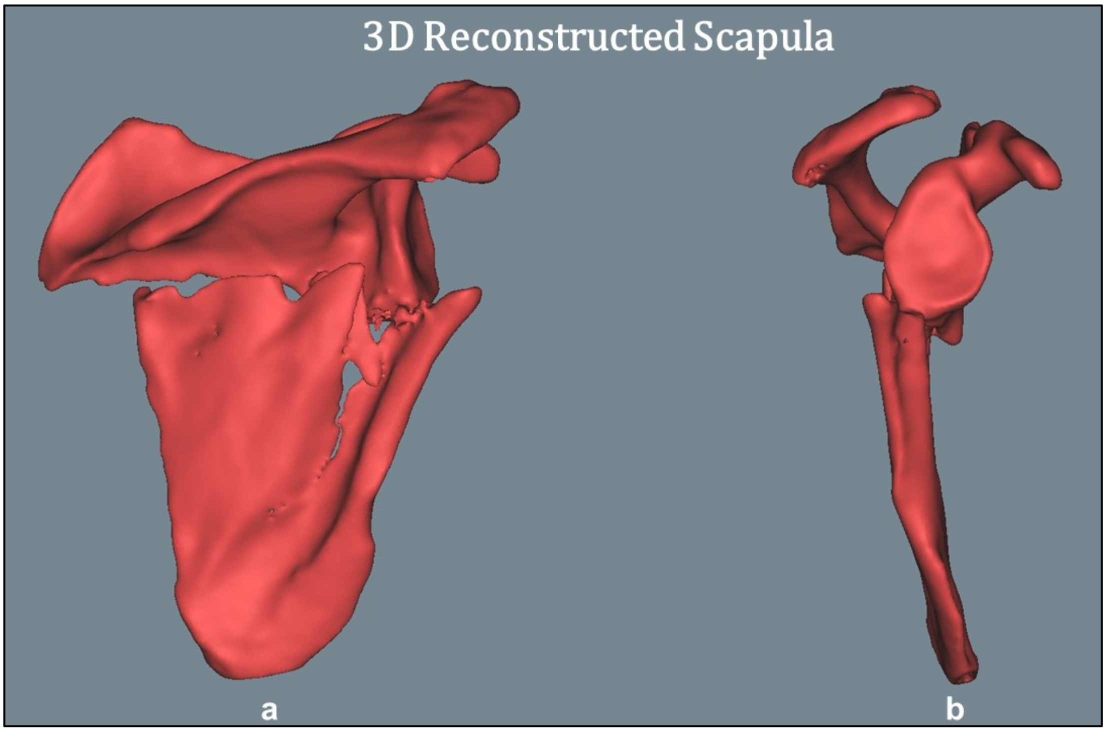

Figure 1: 3D reconstruction of the Scapula

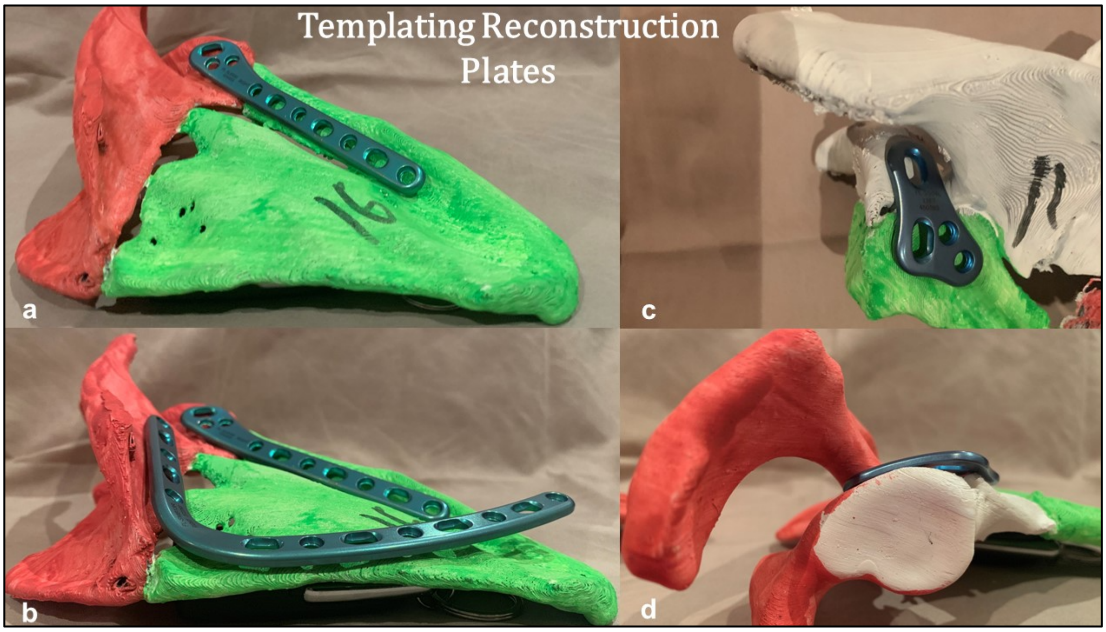

Figure 2: Scapula prototypes and surgical anatomical contoured plates

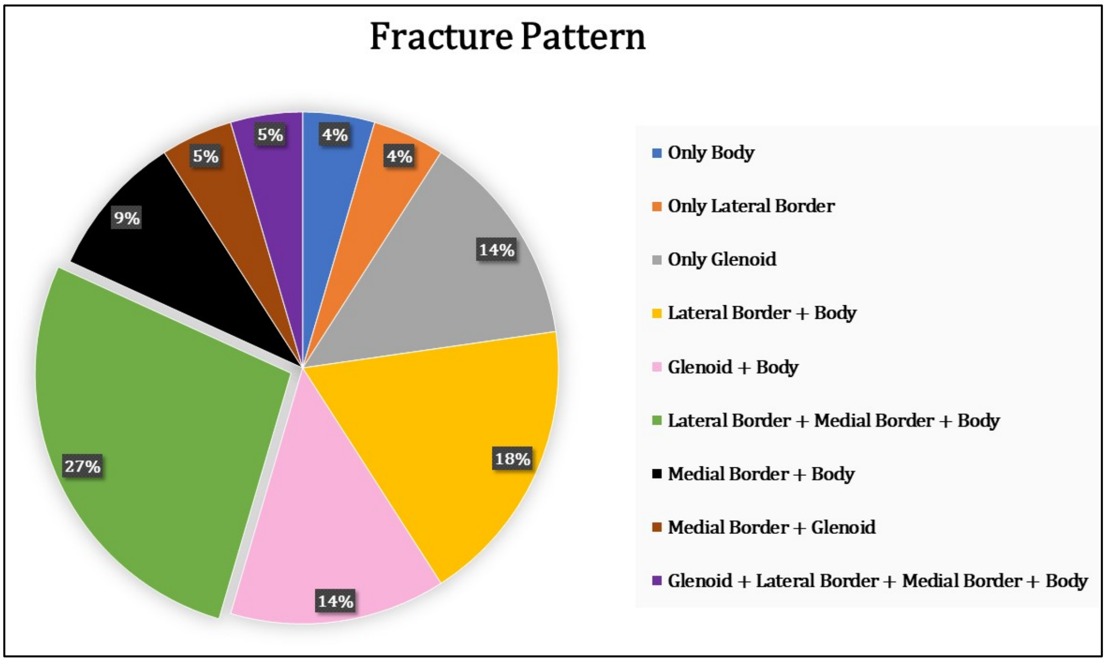

Figure 3: Fracture pattern graph

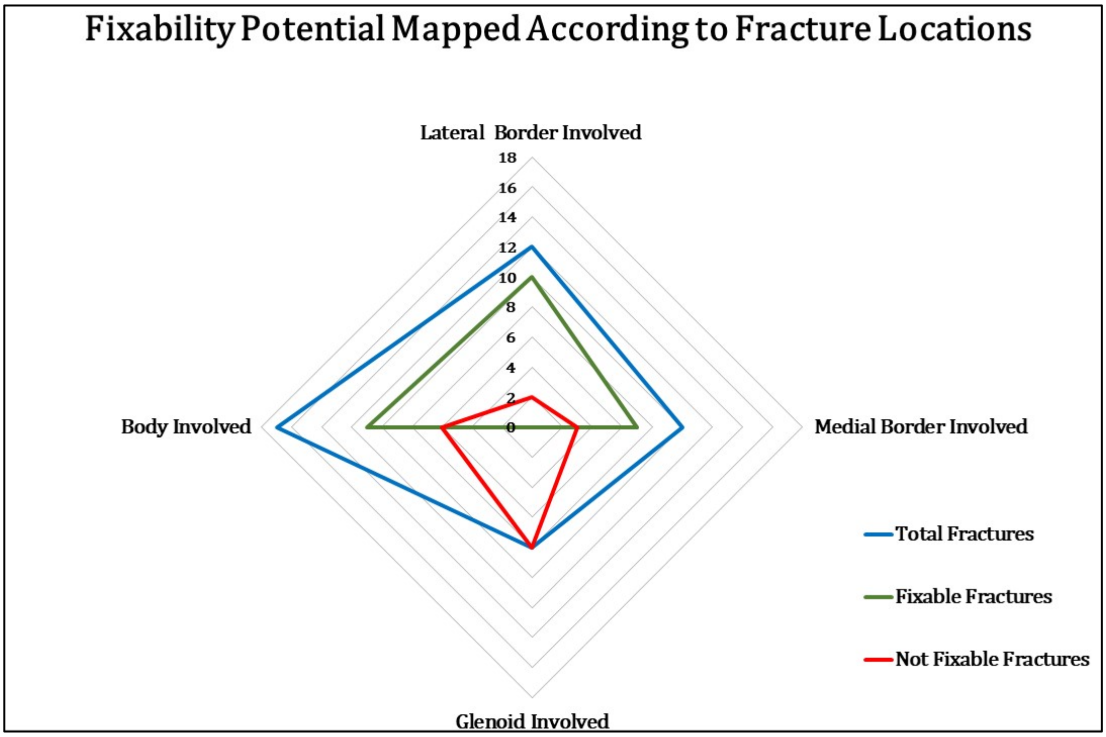

Figure 4: Fixability potential

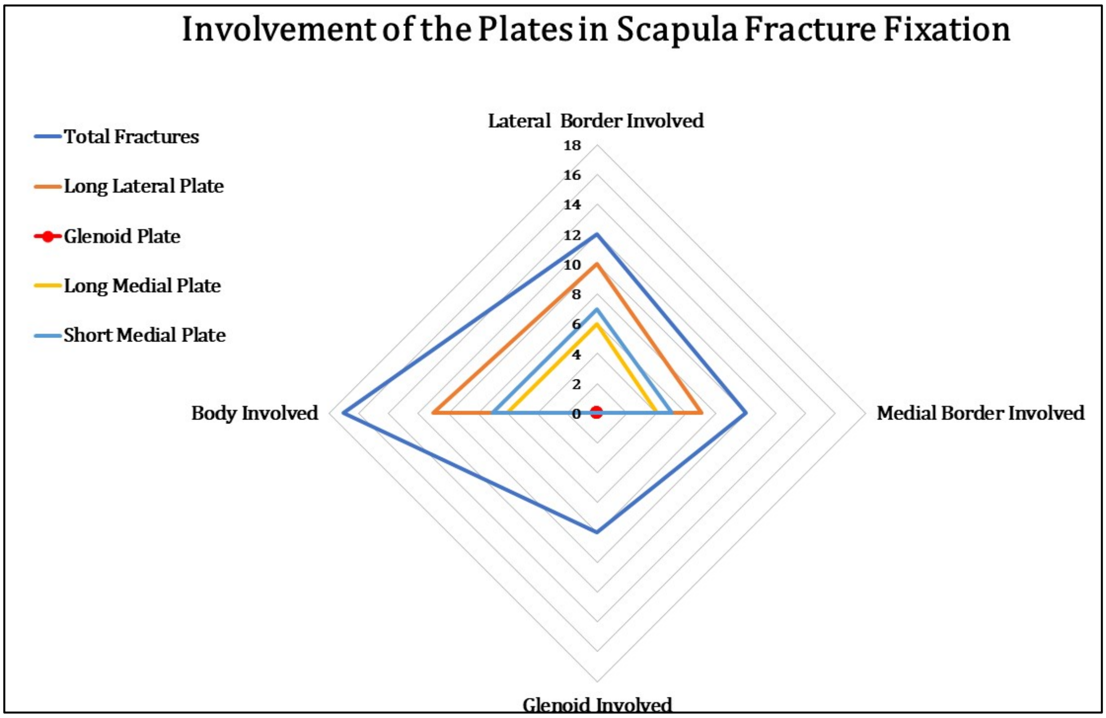

Figure 5: Involvement of the plates in Scapula Fixation

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PART B: ADDENDA

Reviewer A:

Review: Do anatomical contoured plates address scapula body, neck, and glenoid fractures?

In general I am happy with this submission as it is a problem for those of us that do have to treat scapula fractures. The article is very topical and does show the poor plate design of the system.

The general flow of the paper is good and I am happy with the layout for each section.

The article deals with scapula fractures and the plating system that is supposed to fit on the fractured scapula, this part is well defined and also covered in the title. I find the evaluation and the methods acceptable. The scoring system that is mentioned is not well described and is only referred to as similar to another scoring system with a reference. This will need to be clarified better. The score is not specifically given and the charts that are given are not self-explanatory. This will need to be clarified.

Although the results are a little unclear the discussion does a good job explaining the implications of the results.

The discussion also gives a literature review from line 200 to line 230 on the alternatives to the plates that have been shown not to fit. I don't know if this should be covered in this article other than referring the reader to the articles.

The secondary purpose of this article is relevant and well-structured being the evaluation and the inter observer accuracy of the two classification systems. I think this is important research but should be alluded to in the title as the prospective reader will not glean this from the current title. I think the research is well discribed and formulated with a good discussion and conclusion.

An issue in the Abstract is that the following (line 13) does not make sense and may be a typo: "**Results:** Eleven out of twenty-two fractures were found to be fixable using these **used** plates."

I could not find any gramatical or spelling mistakes

Document 1: Reviewer and acceptance letter from the South African Orthopaedic Journal (SAOJ)

Gmail **Roopam Dey <roopam.dey@gmail.com>**

[SAOJ] 432 Editor Decision

1 messages

Robyn Marais <robyn@jesser-point.co.za> 27 January 2021 at 12:28

To: Japie Jacobus de Wet <japie.dewet@gmail.com>, Roopam Dey <roopam.dey@gmail.com>, Basil Vrettos <basil@shoulderelbow.co.za>, Jean-Pierre du Plessis <jp@shoulderelbow.co.za>, Cameron Anley <drcameronanley@gmail.com>, Pududu Archie Rachuene <archie.pududu@gmail.com>, Leanne Claire Haworth <lee.haworth@gmail.com>, Habtamu Mamo Yimam <YMMHAB001@myuct.ac.za>, Sudesh Sivarasu <sudesh.sivarasu@uct.ac.za>, Stephen James Lawrence Roche <stephen.roche@uct.ac.za>

Japie Jacobus de Wet, Roopam Dey, Basil Vrettos, Jean-Pierre du Plessis, Cameron Anley, Pududu Archie Rachuene, Leanne Claire Haworth, Habtamu Mamo Yimam, Sudesh Sivarasu, Stephen James Lawrence Roche:

Thank you for submitting your manuscript entitled " Do anatomical contoured plates address scapula body, neck, and glenoid fractures?" to the South African Orthopaedic Journal.

It is a pleasure to inform you that the above-mentioned manuscript has been accepted, as is, for publication in the *South African Orthopaedic Journal*. The comments of the reviewers are attached.

You will be contacted by our Managing Editor if any further information is required. Any queries concerning your manuscript should be addressed to the Managing Editor at: pat@saoj.co.za

Thank you for your contribution to the *South African Orthopaedic Journal* and we look forward to receiving further contributions in the future.

Yours sincerely
Prof LC Marais
Editor-in-Chief: *SA Orthopaedic Journal*

Email: robyn@jesser-point.co.za

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South African Orthopaedic Journal

Document 2: SAOJ acceptance letter

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

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Assignment title:	For TurnItIn Submission
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Page count:	11
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24 May 2019

HREC REF: 311/2019

A/Prof S Roche
Department of Orthopaedic Surgery
H49
OMB

Dear A/Prof Roche

PROJECT TITLE: SCAPULA BODY AND NECK FRACTURES: PLANNING OSTEOSYNTHESIS USING 3D PRINTED ANATOMICAL MODEL. (SUB-STUDY LINKED TO 695/2016) (MMED CANDIDATE DR JJ DE WET)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 May 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Johannes de Wet will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

Document 4: HREC approval letter