Quantitative fit analysis of acromion fracture plating systems using three-dimensional anatomical modelling

by

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"Doctors are men who prescribe medicines of which they know little, to cure diseases of which they know less, in human beings of whom they know nothing"

- *Voltaire*

TABLE OF CONTENTS

DECLARATION

I, Johan Charilaou, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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ABSTRACT

Background

Displaced acromial fractures are challenging to treat. Complex bony anatomy, variable fracture morphology and limitations of available implants present challenges in achieving favourable surgical outcomes.

We determined to what extent currently available scapular and clavicular plating systems are able to provide adequate fixation options.

Methods

Patients presenting to an urban trauma centre with acromial fractures sustained from blunt trauma between 2012 and 2016 were identified (n = 15, 14M / 1F). The fracture patterns were categorized according to location (Type I = 13%, Type II = 27%, Type III = 60%). Computed Tomography (CT) scans were reconstructed to produce three-dimensional (3D) printed anatomical models on which a quantitative fit analysis was performed. Measurements were performed twice, by five separate observers, with fit graded as anatomical fit (< 2mm), intermediate fit (> 2mm) or no-fit.

Results

The anterior clavicle 6 hole plate fitted best in 45.7% of cases. Acromial plates only achieved 27.3%. The acromion short plate together with the lateral clavicle short plates performed the best in Type II fractures. An inter-observer intraclass correlation coefficient (ICC) agreement of 0.974 was obtained.

Conclusion

The available commercial acromial plating system fails to provide adequate congruency and fit for fixation. Clavicular plates were superior alternative implants. 3D printed anatomical models can be used effectively to assist in templating implants preoperatively.

Level of evidence

Level IV – Observational biomechanical basic sciences study.

Keywords

3D printing, additive manufacturing, scapula fracture, osteosynthesis, internal fixation, quantitative fit analysis, scapula plate, acromion fracture.

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LIST OF TABLES AND FIGURES

ABBREVIATIONS

3D: Three dimensional

ABS: Acrylonitrile butadiene styrene

CAD: Computer Aided Design

CNC: Computer numerical controlled

CO_2: Carbon dioxide

COI: Conflict of interest

CT: Computed tomogram

DICOM: Digital imaging and communications in medicine

FDM: Fused deposition modelling

FMRI: Functional magnetic resonance imaging

ICC: Intraclass correlation coefficient

LCP: Locking Compression Plate

MIMICS: Materialise interactive medical image control system software

MR / MRI: Magnetic resonance imaging

PET: Positron emission tomography

PJ: Polyjet

RP: Rapid prototyping

SLA: Stereolithography

SLS: Selective laser sintering

SPECT: Single-photon emission computed tomography

SSSC: Superior shoulder suspensory complex

STL: Stereolithography

US: Ultrasound scan

UV: Ultraviolet

PART A: LITERATURE REVIEW

OBJECTIVES

To discuss:

- Scapula fracture epidemiology, management and complications.
- Acromion fractures and its fixation options.
- Three-dimensional (3D) printing techniques and development.
- The use of 3D printing in orthopaedic and other surgical disciplines.
- Quantitative fit analysis of scapula plates.
- Gaps in current literature and possible future directives.

LITERATURE SEARCH STRATEGY

A literature review was conducted in the following databases: PubMed, PubMed Central, National Centre for Biotechnology Information (NCBI) and Google Scholar. Keywords used in this search were: 3D printing, additive manufacturing, scapula fracture, osteosynthesis, internal fixation, quantitative fit analysis, scapula plate, and acromion fracture. Peer-reviewed publications where the original article was available were included. Articles from the last 10 years were utilized. All articles were written in English or had an English translation. In articles that had references quoted which conveyed an integral concept applicable to this thesis, the original article was cross-referenced. Some cross-referenced articles were older than 10 years and these were also included to give a comprehensive overview of the topic.

SUMMARY AND INTERPRETATION OF LITERATURE

Scapula fractures

The surgical management of scapula fractures was first documented by the French.[5,12] In 1579 the first drawing of a scapula fracture was published by Ambroise Paré in his rendition of an injury during battle.[12,40] Jean-Louis Petit devised the first classification of scapula fractures. He divided the fractures into neck, body, and process with fractures of the scapular body being further divided into longitudinal, transverse and oblique.[12,42] Scapula fractures were specified by Monteggia as a fracture of the coracoid process, acromion process or the body of the scapula.[22,36] The first documentation of internal fixation of the scapula was in 1913, by Albin Lambotte of Belgium.[12,29] The index documentation of the surgical treatment for non-union of acromion fractures was performed by Darrach (1914), with two silk sutures.[12,22]

Associated injuries occur concomitantly with scapular fractures in almost 90% of patients. These are mainly localized to the same extremity (50%), thoracic injury (80%), head injuries (48%) and spinal fractures (26%).[12,49]

The lateral border of the scapula comprises of the acromion process. Fractures of this process represent 8% - 16% of scapula fractures and are thus infrequent.[11,30] It is recognized as an increasing complication of reverse shoulder arthroplasty.[11,13] Overuse and shoulder trauma are the main causes of acromion fractures. These fractures can be seen in combination with scapular body fractures, glenoid process fractures, distal clavicle fractures or disorders of superior shoulder suspensory complex.[11,38]

Acromion fracture pattern classifications comprise the following:

Ogawa & Naniwa (1997) subdivided it into Type 1 lateral to the spinoglenoid notch and Type 2 medial to the notch.[11,39]

Kuhn (1994): Type 1 marginally displaced. Type 2 displaced but subacromial space maintained. Type 3 subacromial space significantly reduced.[11,28]

AO/OTA classification grouped according to the amount of comminution and the measured displacement.[11,33]

Literature with regards to surgical management of these fractures is scarce, comprising mainly of case reports and small case series studies. This leaves a gap in some conclusive surgical indications and sufficient long term follow up to evaluate patient-reported outcomes.[3] The available data on decision making and management outcomes is mainly retrospective, with no distinction between surgical versus non-surgical treatment.[7] When dealing with an undisplaced, isolated acromion fracture, conservative treatment will produce excellent results because of the supporting anatomical structures. The fractured fragment is kept in place by thick periosteum on top and by the deltoid and trapezius muscles, which pull the fragment in opposite directions with the same force. With substantial downward displacement, open reduction and internal fixation is suggested in an attempt to reduce the resultant subacromial impingement and the risk of non-union.[14,39] Conservative treatment of displaced acromion fractures is associated with numerous complications. This spectrum ranges from intractable pain, partial or full rotator cuff tears secondary to subacromial impingement, reduced active and passive range of motion, acromioclavicular joint dislocation or subluxation, shoulder weakness, glenohumeral joint subluxation, damage to the brachial plexus and symptomatic non-union.[22,39]

Indications for surgical treatment for these process fractures include superior shoulder suspensory complex (SSSC) injuries with 2 or more disruptions, more than one centimeter of displacement, painful non-union and an associated ipsilateral fracture of other parts of the scapula.[3,19]

A multitude of complications is associated with operative management around scapula fractures. Infection rates of up to 4% are documented. Revision surgery for wound debridement, hardware removal, repeat open reduction and internal fixation in up to 17%.[7,15]

Various surgical options and techniques for internal fixation of acromion fractures have been tested and accepted. This includes plate fixation, tension band wiring or the use of Kirschner wires.[3,39] Interfragmentary screw fixation [3,35] and plate fixation supplemented with interfragmentary screws [3,16] has also been described. Plate osteosynthesis of far lateral fractures can cause implant prominence and skin irritation. Tension band wiring is better suited in this setting. This technique affords rotational stability of the lateral fragment as well as compression with a distraction force. Alternatively, a fixed angle locking plate on the superior surface may be considered. Care should be taken to avoid long screws penetrating the subacromial space with resultant rotator cuff impingement. The plate can also be used to buttress the lateral end of the acromion.[3]

More research is needed in this area to determine whether guidelines are too rigid or what the true outcomes of both surgical and non-surgical management are. Prospective studies are needed to prove that the benefit outweighs the risk of surgery.[7] As with any other fracture, the decision-making process is influenced by a number of factors, including the type of fracture, the degree of displacement and comminution, overall injury pattern as well as patient age and level of activity.

Once the surgical treatment is decided based on the patient and fracture features, the main objective of open reduction and internal fixation is to achieve anatomical reduction and secure fixation that will allow for early rehabilitation and bony union.[22]

3D printing

Three-dimensional (3D) printing technology and its applications in the realm of healthcare provision has evolved exponentially since its inception into the industrialized world. Subsequently, various uses for this technology have developed. This dramatic evolution is exponential and the Orthopaedic society has embraced the ability to turn computer data into a tangible physical model with materials such as plastic and metal.[21,50]

The predecessor of 3D printing as we know it today was developed in 1979 just before the advent of Computed Tomography (CT) scans. The model was created with a process of subtractive milling instead of additive layering as there were no 3D printers at the time. This technique starts with a block of material that is shaped under the control of a Computer Numerical Controlled (CNC) machine. This resembles sculpting a figure from a block of stone.[2,23]

Over the next 40 years, the 3D printing capabilities increased with the improvements in computer hardware and especially software programs and processing capabilities. More complex imaging modalities became available to generate detailed 2-dimensional reconstructions. The clinical applications and demands in 3D images became increasingly relevant.[18,51]

Commercially available prototypes gradually made inroads into the Orthopaedic market and medicine as a whole. This was still experimental and minimal clinical introduction of this interesting new development was documented.[17,21]

Further innovations were continually being developed, and it became apparent that the regulation of this field was imminent to adhere to strict governing policies. Quality control and economic policies were slow to keep up with the ever-changing advances.[37,51]

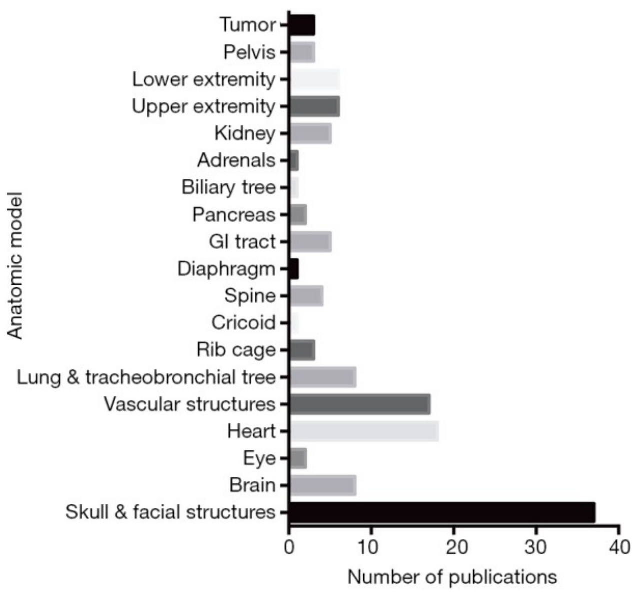

Figure I*: Articles published by anatomical location of the 3D printed model.*

Sourced from Hoang et al 2016.[23]

Advances in technology have made 3D modelling and 3D printing more affordable and readily available.[21,47] Various articles have been produced covering a wide spectrum of anatomical locations of interest with the most form the maxilla-facial area (Figure I).

Recent improvements in clinical image acquisition, user-friendly 3D software, as well as more affordable printing devices have now enabled 3D computer modelling and printing to become more accessible for use as an in-house technology.[21] The key benefit of 3D printing in medical applications is stereotaxis or tactile understanding of the anatomy.[21,25] By integrating 3D models into surgical practice, studies have shown the potential to reduce surgical time, decrease the time required under anesthesia, lower the risk of postoperative complications, and can possibly improve patient outcomes.[21]

This technology has also shown benefits for patients' education, and a 3D printed model of a patient's affected anatomy can greatly increase their understanding and acceptance of a planned procedure. In addition, it is easier to gain informed consent when patients are uncertain or have reservations regarding their treatment. Likewise, it provides benefits to a surgeon's education and training. When a surgeon is learning a new surgical technique, it can be beneficial to have increased visualization of topographical structures and the relationship between anatomic landmarks. This knowledge is usually gained through cadaver dissections during medical training; however, due to societal pressure, cost restrictions, health regulations, and the scarcity of desired abnormal cases, sufficient practical experience can be difficult to gain.[21]

Usage of individualized 3D printed models of bony anatomy will likely become standard practice in preoperative preparation, surgical replication, intraoperative assistance, and implant improvement.[17] Other applications of 3D printing models include the reconstruction of large bone defects. A mirror image created from the contralateral side of the pathology will adequately provide the required implant dimensions that would enable the specialist to contour the implant to the appropriate dimensions for an ideal fit preoperatively.[17]

Anatomic prototype production is the most common use of 3D printing in surgery. In a review by Hoang et al, the author report on 126 publications which reported the use of 3D printed anatomic models. Of these, only 18 publications reports on implants, prosthesis, splints, and external fixators, whilst 36 publications reported on surgical instrumentation and guides.[23]

A recent study in 2016 compared the benefit of 3D printed models compared to 3D images during preoperative planning. Participants planned surgery using 3D computer and physical models respectively. The residents reviewing the printed models achieved higher overall scores. The conclusion was made that 3D printed modelling improved the preoperative planning techniques of inexperienced surgeons.[23,53]

Kim et al defined an innovative technique by producing a real-size (3D) printed clavicle model. In this study, a CT scan of both clavicles was obtained, and a real-size clavicle 3D printed model produced. Utilizing a mirror image technique, the intact clavicle of the contralateral uninjured side is 3D printed inversely to produce a replica of the fractured side before the injury.[26] This technique could be used pre- and intraoperatively as an adjunct tool for minimally invasive plating of displaced comminuted midshaft clavicle fractures.

Distinguishing bone from adjacent soft tissue remains a big challenge when creating accurate 3D models from CT images of *in situ* scapulae. The glenoid in particular is a problematic anatomical area as the cancellous bones' radiodensity is almost indistinguishable from the surrounding soft tissue. Results from work by

Bryce et al validated the accuracy and reproducibility of creating 3D models from *in situ* scapulae by using efficient segmentation.[8]

There are 4 main stages involved in producing a 3D prototype model (Figure II) from Hoang *et al:*

Imaging

Image processing and segmentation

Creation of a reconstructed 3D computer model

Creation of the 3D printed model [23]

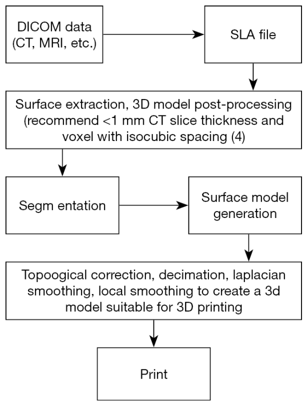

Figure II*: The 3D printing process from start to finish.*

Sourced from Hoang et al 2016.[23]

Imaging

3D medical imaging is the basis for all 3D models, and it is vital that the radiology department is involved and aware of the desire to create a 3D model before the imaging of the patient.[21,48] Considerations for the imaging should not only include the basic modality (CT), but also the imaging parameters such as the slice spacing and thickness, as well as the required resolution.[10,21]

The most appropriate choice of imaging modality is dependent on the tissue of interest and intended outcome. Bone is best captured with CT, whereas soft tissues such as the brain or heart are best viewed with MRI; both modalities are capable of producing images of sufficient quality for use in modelling.[21,54] Once an appropriate imaging modality has been chosen, the parameters of the scan also need to be considered. It is important that the imaging is set up to be 3D and in general the higher the resolution the better for creating 3D models or printing. Once created, the stack of DICOM (Digital Imaging and Communications in Medicine) images can be sent for model creation.[21,34]

Image processing

The image processing components of this pathway can be split into 3 main components:

Preprocessing of the images to improve quality.

Segmentation (selecting the regions of the image to be included in the model) and postprocessing.

Rendering (creation of a 3D interactive model).

The aim of preprocessing is to clean the raw image and improve quality, which most often calls for removing or minimizing noise from the image. Noise in an imaging sense is erroneous data or artifacts (visual static) created during the imaging process.[4,21]

Segmentation, using masking techniques, is the process by which the desired anatomy is separated from the surrounding unwanted tissue and any remaining noise.[21,52] The result is a binary mask, in which each voxel is labelled as either inside or outside the volume of interest. This is a vital step along the path to creation of a 3D model, and there are a number of issues affecting the final accuracy of the model that need to be considered, including the partial volume effect as well as a range of techniques for carrying out the segmentation process.[21]

After segmentation, the model is exported as a stereolithography (STL) file, and some further processing of the data is required before it is ready for use.[21,43] The software uses the STL file to generate a computer model of the object by representing the surface as a unique collection of small triangles, or tessellations, closely fitted together without gaps or overlapping. This tessellated surface then represents the objects virtual surface as an overlying mesh of triangles.[21]
Additional surplus noise and segmentation artifacts in the model must be identified and removed. Segmentation artifacts come in 2 basic types: surface irregularities, and unwanted bridges between sections that should not be connected.[21,46]

3D computer model

Smoothing of the model is the process by which the voxelated model from segmentation is turned into a smooth, more natural looking object. Caution must be taken when smoothing a model, however, as the tendency to “over smooth” can be strong. At this stage in the process, the 3D model can now be virtually manipulated to take measurements or test surgical procedures or virtual surgery can even be performed.[21]

3D printed model

The printer resolution or thickness of the printed layers is an important consideration. Thicker filament layers used in a model will result in a poorer quality appearance, and important features that have been carefully maintained throughout the modelling process can be lost. The process of printing a complex 3D shape generally requires the use of support material. This material is used by the printer to support the model during its creation and is then removed upon completion. Support material is particularly important when there are overhangs or delicate geometry associated with complex anatomy or pathology. Printing time is also an important factor to consider. The time to print a model after the segmentation and model development process is dependent on 3 factors: printer resolution, the volume of the model, and the orientation of the model.[21]

The most common 3D printing technologies used in the medical field are:

Fused deposition modelling (FDM)

Laminated object manufacturing

Stereolithography (SLA)

Polyjet (PJ) printing

Colourjet printing

Selective laser sintering (SLS)

FDM is a technique in which the 3D printer melts plastic and extrudes it out of a nozzle in a controlled path, gradually building the printed shape in layers, most commonly used by consumer or hobby printers. These printers are affordable and often have open-source software and technology.[9,21]

With laminated object manufacturing very thin layers of the build material (paper, polymer, or metal) are cut to precise shape, stacked, and bound together. This method was very popular for Orthopedic modelling and rapid prototyping and is cost effective because the raw materials are so readily available. However, this technique is now less commonly used as other technologies have been developed further and became more popular.

Both SLA and PJ printers use ultraviolet (UV) curable photopolymer resins to construct the model. Colourjet printing works by applying layers of powder or gypsum to a tray, then spraying directed bursts of glue onto each layer binding the powder together.

SLS uses a high-power carbon dioxide (CO_2) laser to fuse the powdered plastic together. The print bed is first covered in a layer of fine plastic polymer; once the layer has been deposited, each sequential layer is bound together by the CO_2 laser.

To calculate the filters and smoothing algorithms required to produce high-quality meshes, high-performance computers are recommended. There are Computer Aided Design (CAD) workstations that have been purposefully designed, optimizing the linear calculations used by the segmentation and modelling software. There are many commercial and freeware programs available that can be used to segment a region of interest out of a DICOM stack.[21]

Various materials can be used to print in 3 dimensions:

Sintered powdered metal

Stainless steel

Nitinol

Titanium

Ceramic

Bone-like (e.g., CT-bone [Xilloc, Geleen, Netherlands]

Plastics (e.g., PolyJet [Stratasys, Eden Prairie, Minnesota], polyether ether ketone, polyether ketone ketone, acrylonitrile butadiene styrene [ABS]).[17]

Quantitative fit analysis

Orthopaedic plate implants have been around since 1896. The design and applications have improved and are continuously expanded. Advances have been made with better materials used and the plates becoming more low profile and with a smaller footprint on bone. Various systems include Compression Plate, Dynamic Compression Plate, Limited Contact Dynamic Compression Plate, Point Contact Fixator, Less Invasive Stabilization System plate, Locking Compression Plate (LCP) and Pre-contoured LCP. The newer designs facilitate and promote a more bioactive healing process.[31,45]

From a structural point of view, while pre-contoured LCP's are made for a specific site, they cannot always fit the anatomy of all patients.[44,45] The variation in bone morphology, due to various factors including age, gender, race, and nutrition, is the main cause of a non-fit. Trying to provide plate shapes for all the possible anatomical variations, is impossible and would lead to an immense logistical challenge for hospitals and manufacturing companies. Plates are designed based on the average anatomical shapes of the bone morphology of the group evaluated.

Locked pre-contoured plates are a form of internal fixation implants. Stability is achieved without plate compression onto the bone. An anatomical fit between the plate-bone interface is not a prerequisite for a biomechanically stable fixation. Locking plate mechanics, however, demonstrate optimal load transfer when the interface from plate to screw is closest to the bone cortex it is applied to.[1,45] The greater this distance becomes, the less efficient it is for load transfer, due to the increased screw bending moment.[44,45] Therefore, to promote maximum fracture healing, there needs to be a balance in the distance between the plate and the bone. An anatomical plate, fitting securely without a gap will help achieve this balance.

Quantitative fit assessment involves measuring the distance between a plate and the underlying bone according to specific criteria. It is necessary to determine the suitable criteria and parameters for a clinically significant fit assessment. Traditional fit analyses of fixation plates were done by visual inspection of a plate fitted to cadaver or prototype bones. This process had its limitations. When using cadaver bones from a museum collection, it will include older bones. To use these in fit analyses the morphological changes through generations will be disregarded. Furthermore, the visual inspection of the plate fit produces results that are qualitative in nature.

In an effort to remedy these challenges, newer studies started to focus on using computerized or virtual methods to evaluate fit congruence. These methods will offer a mode of assessing fit in a standardized and objective way.

The availability of new technology in medical imaging opens up access to large data sets of bone morphology from present-day populations. This will improve the development of automated and semi-automated assessment methods. Virtual bone models can be reconstructed from CT or Magnetic Resonance Imaging (MRI). Virtual 3D plate models can also be created and digitally applied for fit assessment. New implant development and improvement of current systems can be derived from these data sets.

Previously used manual and semi-automated fit assessment methods are not ideal since both methods require a long processing time and are operator-dependent.

Computerized fit assessment methods integrating plate fit and positioning has become superior. This will make batch processing a possibility, which in turn will improve efficiency and result in an operator-independent outcome.[45]

Quantitative fit analysis was first described in the fit assessment for proximal tibia plates. Cadaver bones were used for the fit assessment.[20,45] Kozic *et al* proposed the first automated fit assessment on 93 tibias. With a proximal tibial plate being templated on models.[27,45]

In the upper limb, various studies have incorporated fit analysis to assess plates. Malhas *et al* used plates from four different manufacturers and applied it to 79 right human clavicles from cadaver specimens.[32] The most anatomical fitting plate from each manufacturer was clamped in place by two examiners with the fit then graded into, poor fit, good fit or anatomic fit. Intra-observer and inter-observer reliability was assessed by examiners repeating the process. A final score for each plate for each clavicle was obtained from the average scores. Resulting data indicate that systems with variable implant options are superior in smaller and usually female clavicles. No statistical difference was shown in larger clavicles. Plate contouring was needed in 73% of cases.[32]

In a different study, 100 clavicle pairs were analyzed by Huang *et al*.[24] A digitizer and modeling software were utilized to determine the position and size of the superior clavicular curve. Axial radiographs were produced of all clavicles and a pre-contoured LCP form Acumed was templated. Adobe Photoshop technology was used to freely translate and rotate the plates on the clavicle to assess the amount and location of the best fit. This was, however, a two-dimensional analysis of plate fit rather than a three-dimensional analysis and attributed as the main limitation of this study.[24]

Park *et al* conducted a study to evaluate the congruency of current scapular plate designs.[41] They used sophisticated 3D modeling techniques to virtually place fragment-specific locking plates on CT reconstructions of multiple cadaveric scapulae. All 4 plate designs from a single manufacturer were considered. To their knowledge, this was the first study to evaluate the congruency of fit for locking scapular plates. This study allowed for virtual, noninvasive analysis of several different measurement variables. This 3D image–analysis technique can be used to evaluate the congruency of any implant with any surface. Any number of implants may be studied in this manner.[41]

A new technique was proposed by Beliën *et al* by utilizing 3D models and distal clavicle reconstruction plates to treat acromion fractures and symptomatic os acromiale.[6] The authors suggested that this approach would be a valuable addition to traditional techniques. They printed a 3D model of the acromion whilst an osteosynthesis plate was pre-bent to fit the anatomical shape of the specific acromion. The technique was tested, and reports were presented on five patients, of which three had os acromiale and the other two presented with acromial fractures. These patients were followed-up during their rehabilitation and evaluated using the Constant–Murley and the Disabilities of the Arm, Shoulder and Hand scores. Making use of a preoperative patient-customized plate is a new technique with many potential uses.[6]

IDENTIFICATION OF GAPS OR NEEDS FOR FURTHER RESEARCH

Literature on the combined themes of modelling fracture specific plates around the acromion on 3D printed anatomical models is limited with available literature being of low evidence with confusing methodologies. Acromion fractures are uncommon and therefore optimum treatment is not well documented with no prospective patient outcome measured trials to support current practices. Additionally, guidelines are made but not always followed. Further adjuncts have become available to obtain a tactile understanding of the complex anatomy considering the need to identify the optimal plate for a specific fracture pattern. The advances in 3D printing are astronomical and the applications limitless. Specialists, therefore, need to embrace the new possibilities and engage in taking it forward to the advantage of all involved around providing quality healthcare, but more importantly, to the benefit of the patients.

REFERENCES

1. Ahmad M, Nanda R, Bajwa AS, Candal-Couto J, Green S, Hui AC. Biomechanical testing of the locking compression plate: when does the distance between bone and implant significantly reduce construct stability? Injury. 2007 Mar;38(3):358–64. doi:10.1016/j.injury.2006.08.058
2. Alberti C. Three-dimensional CT and structure models. Br. J. Radiol. 1980 Mar;53(627):261–2. doi:10.1259/0007-1285-53-627-261-b
3. Anavian J, Wijdicks CA, Schroder LK, Vang S, Cole PA. Surgery for scapula process fractures: good outcome in 26 patients. Acta Orthop. 2009 Jun;80(3):344–50. doi:10.3109/17453670903025394
4. Arezoomand S, Lee W-S, Rakhra KS, Beaulé PE. A 3D active model framework for segmentation of proximal femur in MR images. Int. J. Comput.

Assist. Radiol. Surg. 2015 Jan 5;10(1):55–66. doi:10.1007/s11548-014-1125-6

5. Bartonícek J, Cronier P. History of the treatment of scapula fractures. Arch. Orthop. Trauma Surg. 2010 Jan;130(1):83–92. doi:10.1007/s00402-009-0884-y

6. Beliën H, Biesmans H, Steenwerckx A, Bijnens E, Dierickx C. Prebending of osteosynthesis plate using 3D printed models to treat symptomatic os acromiale and acromial fracture. J. Exp. Orthop. 2017 Dec 24;4(1):34. doi:10.1186/s40634-017-0111-7

7. Brandsema B, Neuhaus V, Gradl G, Ring DC. Extra-articular scapular fractures: comparison of theoretical and actual treatment. Shoulder Elb. 2016 Jan;8(1):3–8. doi:10.1177/1758573215578587

8. Bryce CD, Pennypacker JL, Kulkarni N, Paul EM, Hollenbeak CS, Mosher TJ, et al. Validation of three-dimensional models of in situ scapulae. J. Shoulder Elb. Surg. 2008 Sep;17(5):825–832. doi:10.1016/j.jse.2008.01.141

9. Chae MP, Rozen WM, McMenamin PG, Findlay MW, Spychal RT, Hunter-Smith DJ. Emerging Applications of Bedside 3D Printing in Plastic Surgery. Front. Surg. 2015;2:25. doi:10.3389/fsurg.2015.00025

10. Choi JY, Choi JH, Kim NK, Kim Y, Lee JK, Kim MK, et al. Analysis of errors in medical rapid prototyping models. Int. J. Oral Maxillofac. Surg. 2002 Feb;31(1):23–32. doi:10.1054/ijom.2000.0135

11. Çiçekli Ö, Akar A, Topçu HN. Displaced acromion fracture: A rare injury, case report. Int. J. Surg. Case Rep. 2017;39:313–316. doi:10.1016/j.ijscr.2017.08.051

12. Cole PA, Gauger EM, Schroder LK. Management of scapular fractures. J. Am. Acad. Orthop. Surg. 2012 Mar;20(3):130–41. doi:10.5435/JAAOS-20-03-130

13. Crosby LA, Hamilton A, Twiss T. Scapula fractures after reverse total shoulder arthroplasty: classification and treatment. Clin. Orthop. Relat. Res. 2011 Sep;469(9):2544–9. doi:10.1007/s11999-011-1881-3

14. Darrach W. Fracture of the acromion process of the scapula. Ann. Surg. 1913;(59):455–456.

15. Dienstknecht T, Horst K, Pishnamaz M, Sellei RM, Kobbe P, Berner A. A meta-analysis of operative versus nonoperative treatment in 463 scapular neck fractures. Scand. J. Surg. 2013;102(2):69–76. doi:10.1177/1457496913482251

16. Dounchis JS, Pedowitz RA, Garfin SR. Symptomatic pseudarthrosis of the acromion: report of a case and review of the literature. J. Orthop. Trauma. 1999 Jan;13(1):63–6.

17. Eltorai AEM, Nguyen E, Daniels AH. Three-Dimensional Printing in Orthopedic Surgery. Orthopedics. 2015 Nov;38(11):684–7. doi:10.3928/01477447-20151016-05

18. Fadero PE, Shah M. Three dimensional (3D) modelling and surgical planning in trauma and orthopaedics. Surgeon. 2014 Dec;12(6):328–33. doi:10.1016/j.surge.2014.03.008

19. Goss TP. Double disruptions of the superior shoulder suspensory complex. J. Orthop. Trauma. 1993;7(2):99–106.

20. Goyal KS, Skalak AS, Marcus RE, Vallier HA, Cooperman DR. Analysis of anatomic periarticular tibial plate fit on normal adults. Clin. Orthop. Relat. Res. 2007 Aug;461:245–57. doi:10.1097/BLO.0b013e31809e6e45

21. Green N, Glatt V, Tetsworth K, Wilson LJ, Grant CA. A Practical Guide to Image Processing in the Creation of 3D Models for Orthopedics. Tech. Orthop. 2016 Sep;31(3):153–163. doi:10.1097/BTO.0000000000000181

22. Hill BW, Anavian J, Jacobson AR, Cole PA. Surgical management of isolated acromion fractures: technical tricks and clinical experience. J. Orthop. Trauma. 2014 May;28(5):e107-13. doi:10.1097/BOT.0000000000000040

23. Hoang D, Perrault D, Stevanovic M, Ghiassi A. Surgical applications of three-dimensional printing: a review of the current literature & how to get started. Ann. Transl. Med. 2016 Dec;4(23):456. doi:10.21037/atm.2016.12.18

24. Huang JI. Clavicular Anatomy and the Applicability of Precontoured Plates. J. Bone Jt. Surg. 2007 Oct 1;89(10):2260. doi:10.2106/JBJS.G.00111

25. Izatt MT, Thorpe PLPJ, Thompson RG, D'Urso PS, Adam CJ, Earwaker JWS, et al. The use of physical biomodelling in complex spinal surgery. Eur. Spine J. 2007 Sep;16(9):1507–18. doi:10.1007/s00586-006-0289-3

26. Kim HN, Liu XN, Noh KC. Use of a real-size 3D-printed model as a preoperative and intraoperative tool for minimally invasive plating of comminuted midshaft clavicle fractures. J. Orthop. Surg. Res. 2015 Dec 10;10(1):91. doi:10.1186/s13018-015-0233-5

27. Kozic N, Weber S, Büchler P, Lutz C, Reimers N, González Ballester MA, et al. Optimisation of orthopaedic implant design using statistical shape space analysis based on level sets. Med. Image Anal. 2010 Jun;14(3):265–75. doi:10.1016/j.media.2010.02.008

28. Kuhn JE, Blasier RB, Carpenter JE. Fractures of the acromion process: a proposed classification system. J. Orthop. Trauma. 1994;8(1):6–13.

29. Lambotte A. Chirurgie opératoire des fractures. Paris : Masson & Cie; 1913.

30. Lantry JM, Roberts CS, Giannoudis P V. Operative treatment of scapular fractures: a systematic review. Injury. 2008 Mar;39(3):271–83. doi:10.1016/j.injury.2007.06.018

31. Malekani J, Schmutz B, Gu Y, Schuetz M, K.D.V. Yarlagadda P. Orthopedic bone plates: Evolution in Structure, Implementation technique and biomaterial. GSTF J. Eng. Technol. 2012 Jun 1;1(1). doi:10.5176/2251-3701_1.1.23

32. Malhas AM, Skarparis YG, Sripada S, Soames RW, Jariwala AC. How well do contoured superior midshaft clavicle plates fit the clavicle? A cadaveric study. J. Shoulder Elb. Surg. 2016 Jun;25(6):954–959. doi:10.1016/j.jse.2015.10.020

33. Marsh JL, Slongo TF, Agel J, Broderick JS, Creevey W, DeCoster TA, et al. Fracture and dislocation classification compendium - 2007: Orthopaedic Trauma Association classification, database and outcomes committee. J. Orthop. Trauma. 2007;21(10 Suppl):S1-133.

34. McMenamin PG, Quayle MR, McHenry CR, Adams JW. The production of anatomical teaching resources using three-dimensional (3D) printing technology. Anat. Sci. Educ. 2014;7(6):479–86. doi:10.1002/ase.1475

35. Mick CA, Weiland AJ. Pseudoarthrosis of a fracture of the acromion. J. Trauma. 1983 Mar;23(3):248–9.

36. Monteggia G. Istituzioni Chirurgiche. Milan, Italy: Pirotta; 1803.

37. Morrison RJ, Kashlan KN, Flanangan CL, Wright JK, Green GE, Hollister SJ, et al. Regulatory Considerations in the Design and Manufacturing of Implantable 3D-Printed Medical Devices. Clin. Transl. Sci. 2015 Oct;8(5):594–600. doi:10.1111/cts.12315

38. Mulawka B, Jacobson AR, Schroder LK, Cole PA. Triple and quadruple disruptions of the superior shoulder suspensory complex. J. Orthop. Trauma. 2015 Jun;29(6):264–70. doi:10.1097/BOT.0000000000000275

39. Ogawa K, Naniwa T. Fractures of the acromion and the lateral scapular spine. J. shoulder Elb. Surg. 1997;6(6):544–8.

40. Paré A. Les oeuvres d'Ambroise Paré, conseiller, et premier chirurgien du Roy [dissertation]. Paris, France, Gabriel Buon; 1579.

41. Park AY, DiStefano JG, Nguyen T-Q, Buckley JM, Montgomery WH, Grimsrud CD. Congruency of scapula locking plates: implications for implant design. Am. J. Orthop. (Belle Mead. NJ). 2012 Apr;41(4):E53-6.

42. Petit J-L. Traité des Maladies des Os, tome second. Paris, France, Charles-Etienne Hochereau; 1723. p. 122–138.

43. Rengier F, Mehndiratta A, von Tengg-Kobligk H, Zechmann CM, Unterhinninghofen R, Kauczor H-U, et al. 3D printing based on imaging data: review of medical applications. Int. J. Comput. Assist. Radiol. Surg. 2010 Jul;5(4):335–41. doi:10.1007/s11548-010-0476-x

44. Schmutz B, Wullschleger ME, Kim H, Noser H, Schütz MA. Fit Assessment of Anatomic Plates for the Distal Medial Tibia. J. Orthop. Trauma. 2008 Apr;22(4):258–263. doi:10.1097/BOT.0b013e31816b10ba

45. Schuetz M, Yarlagadda PKDV , Harith H, MalekanI J SB. Quantitative fit analysis of orthopedic bone plates : methods, criteria and approach. J. Biomimetics Biomater. Tissue Eng. 2013;18(01):1–4. doi:10.4172/1662-100X.1000116

46. Shattuck DW, Leahy RM. Automated graph-based analysis and correction of cortical volume topology. IEEE Trans. Med. Imaging. 2001 Nov;20(11):1167–77. doi:10.1109/42.963819

47. Starosolski ZA, Kan JH, Rosenfeld SD, Krishnamurthy R, Annapragada A. Application of 3-D printing (rapid prototyping) for creating physical models

of pediatric orthopedic disorders. Pediatr. Radiol. 2014 Feb;44(2):216–21. doi:10.1007/s00247-013-2788-9

48. Sugar A, Bibb R, Morris C, Parkhouse J. The development of a collaborative medical modelling service: organisational and technical considerations. Br. J. Oral Maxillofac. Surg. 2004 Aug;42(4):323–330. doi:10.1016/j.bjoms.2004.02.025

49. Tadros AMA, Lunsjo K, Czechowski J, Abu-Zidan FM. Multiple-region scapular fractures had more severe chest injury than single-region fractures: a prospective study of 107 blunt trauma patients. J. Trauma. 2007 Oct;63(4):889–93. doi:10.1097/01.ta.0000235876.32569.db

50. Tetsworth K, Block S, Glatt V. Putting 3D modelling and 3D printing into practice: virtual surgery and preoperative planning to reconstruct complex post-traumatic skeletal deformities and defects. SICOT-J. 2017;3:16. doi:10.1051/sicotj/2016043

51. Tetsworth KD, Mettyas T. Overview of Emerging Technology in Orthopedic Surgery. Tech. Orthop. 2016 Sep;31(3):143–152. doi:10.1097/BTO.0000000000000187

52. Viceconti M, Zannoni C, Testi D, Cappello A. CT data sets surface extraction for biomechanical modeling of long bones. Comput. Methods Programs Biomed. 1999 Jun;59(3):159–66.

53. Zheng Y, Yu D, Zhao J, Wu Y, Zheng B. 3D Printout Models vs. 3D-Rendered Images: Which Is Better for Preoperative Planning? J. Surg. Educ. 2016;73(3):518–23. doi:10.1016/j.jsurg.2016.01.003

54. Zia S, Jaffar MA, Mirza AM, Choi T-S. Rician noise removal from MR images using novel adapted selective non-local means filter. Multimed. Tools

Appl. 2014 Sep 18;72(1):1–19. doi:10.1007/s11042-012-1253-3

PART B: MANUSCRIPT IN ARTICLE FORMAT

TITLE PAGE

Title

Quantitative fit analysis of acromion fracture plating systems using three-dimensional anatomical modelling

Running title

Plate fit analysis on 3D acromion

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Disclaimer

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MAIN TEXT OF ARTICLE

ABSTRACT

Background

Displaced acromial fractures are challenging to treat. Complex bony anatomy, variable fracture morphology and limitations of available implants present challenges in achieving favourable surgical outcomes.

We determined to what extent currently available scapular and clavicular plating systems are able to provide adequate fixation options.

Methods

Patients presenting to an urban trauma centre with acromial fractures sustained from blunt trauma between 2012 and 2016 were identified (n = 15, 14M / 1F). The fracture patterns were categorized according to location (Type I = 13%, Type II = 27%, Type III = 60%). Computed Tomography (CT) scans were reconstructed to produce three-dimensional (3D) printed anatomical models on which a quantitative fit analysis was performed. Measurements were performed twice, by five separate observers, with fit graded as anatomical fit (< 2mm), intermediate fit (> 2mm) or no-fit.

Results

The anterior clavicle 6 hole plate fitted best in 45.7% of overall cases. Acromial plates only achieved 27.3%. The acromion short plate together with the lateral clavicle short plates performed the best in type II fractures. An inter-observer intraclass correlation coefficient (ICC) agreement of 0.974 was obtained.

Conclusion

The available commercial acromial plating system fails to provide adequate congruency and fit for fixation. Clavicular plates were superior alternative implants. 3D printed anatomical models can be used effectively to assist in templating implants preoperatively.

Level of evidence

Level IV – Observational biomechanical basic sciences study.

Keywords

3D printing, additive manufacturing, scapula fracture, osteosynthesis, internal fixation, quantitative fit analysis, scapula plate, acromion fracture.

INTRODUCTION

Acromion fractures are uncommon and comprise 8% – 16% of scapula fractures.[2,6] With the advent of increasing reverse total shoulder arthroplasty, acromion fractures is an associated complication in 5% – 6.9% of cases.[5,6] Fractures of the scapula process are generally managed non-operatively with relatively good results.[1] Literature regarding surgical management is predominantly low-level evidence such as case reports and isolated case series and is therefore insufficient and circumstantial.[1]

Anecdotal experience suggests that pre-contoured plates assigned and developed for other anatomical sites sometimes fit better on alternative periarticular regions. Lateral end of clavicle plates are options when internal fixation of the acromion is performed.[2]

Quantitative fit assessment measures the distance between a plate used for internal fixation and the underlying fractured bone fragments.[13] This analysis was customarily performed by visual inspection of the templated implant on cadaver or prototype bones. The evolution in medical imaging technology allows access to morphological data of bone from modern populations. These datasets afford virtual methods for fit analysis and therefore enables enhancements in implant design.[13]

Additive manufacturing or three-dimensional (3D) printing encompass any technique used for creating a physical object from computer data through an additive process. A variety of materials can be laid down in successive layers.[9,14] 3D computer modelling and printing have become more accessible for everyday use in Orthopaedic practice since recent advances in clinical image acquisition, user-friendly software applications, and inexpensive printing devices.[9] A fundamental benefit of 3D printing in medical applications is the stereotaxis that provides a tactile understanding of the anatomy.[9,10] Beliën *et al* developed a novel method to treat acromion fractures and os acromiale by using a 3D model and a distal clavicle reconstruction plate.[2] The authors reported on the technique and outcomes in 5 patients. The models were printed, and the plates contoured to fit preoperatively. The fixation achieved was adequate for bone union. The conclusion was made that fashioning the plates according to patient-specific anatomy is possible and reduces surgical time.[2]

We conducted a pilot study on cadaver dry bone specimens, (unpublished data) which reported long acromion plates not to fit in 48% of specimens whilst the combined anatomical fit for acromion plates was only achieved in 51% of specimens (Table I).

Table I*: Plate fit assessment on cadaver specimens*

	Anatomical fit (%)	**Intermediate fit (%)**	**No fit (%)**
Acromion long (n=46)	15	37	48
Acromion short (n=47)	36	62	2
Lateral clavicle short (n=46)	28	67	4
Lateral clavicle long (n=46)	2	70	28

This highlights the need to critically evaluate acromion and clavicle plate congruence on acromion fractures. This observation served as a further need to investigate specialised fracture plates for the acromion.

However, limited theatre time and resource constraint environments make this difficult to test *in vivo*. The aim of this study is, therefore, to utilize actual size 3D printed models of acromion fractures to template and evaluate acromion and clavicle plate congruence. This can determine to what extent currently available plating systems are able to provide adequate fixation options for acromial fractures.

MATERIALS AND METHODS

Study design

This study followed an observational biomechanical basic science design. A multi-observer quantitative fit analysis of the scapular plates was performed. This was followed up with statistical analysis to investigate the extent to which these plates were successful in fitting to the fractured bone surface, within the surgical parameters.

Characteristics of the study and population

All patients with scapula fractures, who underwent a CT scan of the shoulder, presenting to Groote Schuur Hospital (Cape Town, South Africa) from 2012 to 2016 were identified using Phillips iSite Electronic Radiology System database. All fractures due to blunt trauma, irrespective of whether these fractures were surgically or conservatively managed, were considered for inclusion. Participants with Goss and Ideberg Type 1a and 1b fracture-dislocations of the glenoid rim were excluded. Malunited fractures undergoing delayed surgery and fractures due to gunshot wounds were also excluded. Gunshot wounds are typically difficult to segment due to scattered bullet fragments. These fracture patterns are also very comminuted and do not fit the usual fracture classifications or management paths. A total of 41 scapulae were examined and classified according to the anatomical location of the fracture on the scapula body, glenoid neck and -fossa, coracoid and acromion/scapula spine. Fifteen acromion fractures were finally identified for inclusion. The fractures were divided into 3 types according to the anatomical location of the fracture lines: (Figures III - V)

Type I – acromion process lateral to acromion angle. (n = 2, 13%)

Type II – acromion angle to spinoglenoid notch. (n = 4, 27%)

Type III – medial to the spinoglenoid notch or into scapular spine. (n = 9, 60%)

Figure III*: Type I fracture - acromion process lateral to acromion angle*

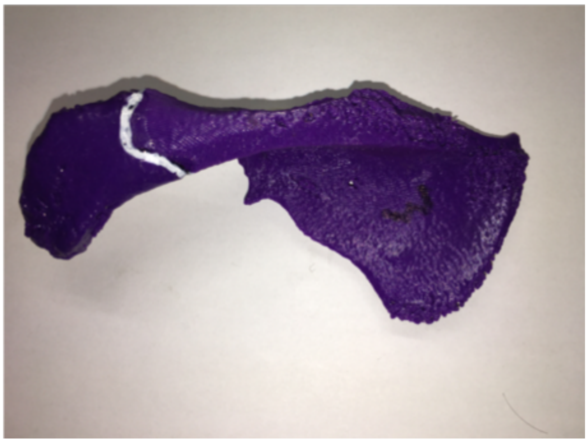

Figure IV*: Type II fracture - acromion angle to spinoglenoid notch*

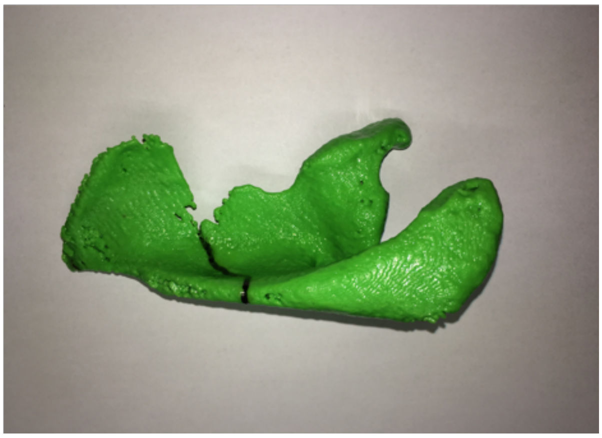

***Figure V**: Type III fracture - medial to the spinoglenoid notch or into scapular spine*

Research procedures

The Digital Imaging and Communication in Medicine (DICOM) files were obtained from the CT scans previously identified from the database. Multiplanar reconstruction (MPR; axial, sagittal, coronal) and 3D volume rendering of the fracture was obtained. Working on the 3D-reconstruction, the fractured bone was isolated with a digital cropping tool. The CT scans were reconstructed *in-silico* Materialise Mimics® (Leuven, Belgium). The Surface Rendering model of the fractured bone was created and exported to a Stereolithography (STL) file. The files were analyzed and prepared for printing with 3D dedicated Z-suite software. The Zortrax M200 printer system and acrylonitrile butadiene styrene (ABS), a common thermoplastic polymer plastic filament, was used to produce the prototypes. Areas of the fracture were identified, and care taken to treat each fractured fragment as a separate entity. The reconstructed model of each bone was synthesized into a physical 3D scapula using an additive manufacturing technique.

Plate fit analysis on 3D acromion

Fracture fragments were debrided, anatomically reduced and kept in position using ordinary glue. The only available plating system currently available in South-Africa is supplied by Acumed (Hillsboro, OR, USA).

Eight implants were used: (*i)* acromion short, (*ii)* acromion long, *(iii)* lateral clavicle short 4 hole, (*iv)* lateral clavicle short 8 hole, (*v)* lateral clavicle long 4 hole, (*vi)* lateral clavicle long 8 hole, (*vii)* anterior clavicle 6 hole, (*viii)* anterior clavicle 8 hole. We chose to include clavicle plates as we have been using these to stabilise acromial fractures for many years.

Conformity of fit and the potential degree of plate bending that might be required for an anatomic fit were assessed. The variables were a gap, alignment, and overhang. A digital Vernier caliper was used for measurements.

We devised the following grading system: (Figures VI to VIII)

<u>Anatomical fit</u>: if there was a 2mm or less gap between the plate and bone, no overhang and no bending needed to align the plate. Fracture fixation adequate with a minimum of 3 screws either side of the fracture line.

<u>Intermediate fit</u>: if more than a 2mm gap or if bending was required to narrow this gap or to correct the overhang to achieve the required fixation criteria.

<u>No fit</u>: if there was too much off ending and/or overhang to correct with plate manipulation, thus having screw holes not over the bone or if the plate was inadequate to obtain fixation, thus less than 3 screw holes on each side of the fracture.

Figure VI: *Anatomical fit < 2mm gap, no overhang*

Figure VII: *Intermediate fit > 2mm, but can bend to improve fit*

Figure VIII: *No fit > 2mm gap, can't fit with bending*

Five raters, comprising of a specialist Orthopaedic upper limb surgeon, a trainee Orthopaedic Surgery registrar, a medical student, a Bioengineer, and a

Biokineticist conducted the measurements on two separate occasions to determine the intraclass correlation coefficient (ICC). There was a two-week interval between measurements.

Data Analysis

All the data sets were collected and captured and patient details with demographics were identified. Stata 14 data analysis and statistical software were used. Data is described as a mean ± standard deviation if normally distributed.

Each observation was converted into a numerical score (no fit – 0; intermediate fit – 5; anatomical fit - 10) which were processed using IBM SPSS Statistics v.25 (Armonk, NY: IBM Corp).

Categorical data are presented as counts with frequencies indicated where appropriate. The best fitting plate per type of fracture was calculated as a frequency:

$$\frac{(Rater\ 1\ score + Rater\ 2\ score + Rater\ 3\ score + Rater\ 4\ score + Rater\ 5\ score)}{Total\ possible\ score\ per\ plate}\ x\ 100$$

RESULTS

Demographic data

The mean age of all participants, 14 male and 1 female, was 42.3 ± 13.8 years. In six patients, the left side was affected whilst nine patients were injured on the right-hand side. The majority of injuries (46.7%) occurred due to pedestrian-vehicle accidents (Table II).

Table II*: Mechanism of injury*

Mechanism of injury	n (%)
Pedestrian-vehicle accident	7 (46.7)
Motor vehicle accident	5 (33.3)
Motorbike accident	1 (6.7)
Blunt trauma	2 (13.3)

Data is presented as a count with the frequency indicated in parentheses

Fracture types

Two patients had a type I fracture (13.3%), four had a type II fracture (26.7%), and nine patients suffered from a type III fracture (60%).

Printing time

The mean printing time was 504.7 ± 123.3 minutes.

Inter-observer reliability

The overall intra-class correlation coefficient (ICC) agreement was 0.974.

Quantitative fit analysis

The Anterior clavicle 6 hole plate was the plate of choice in 45.7% of cases when all fractures were considered (Figure IX - A). Lateral clavicle short plates were the best fit in type I fractures (60.0% and 67.5% respectively) (Figure IX - B). The long acromion plate only fitted in 11% of fractures. The acromion short plate together with the two types of lateral clavicle short plates performed the best in type II fractures (Figure IX - C). In type III fractures the anterior clavicle 6 hole plate had the best fit (60%) followed by the anterior clavicle 8 hole plate (48.3%). The two lateral clavicle plates also had a 26.7% (lateral clavicle long 6 hole) and 27.8% (lateral clavicle long 8 hole) best fit in type III fractures (Figure IX - D).

The categorical data (Table III) is summarized as a consensus between the 5 rates for each plate per patient.

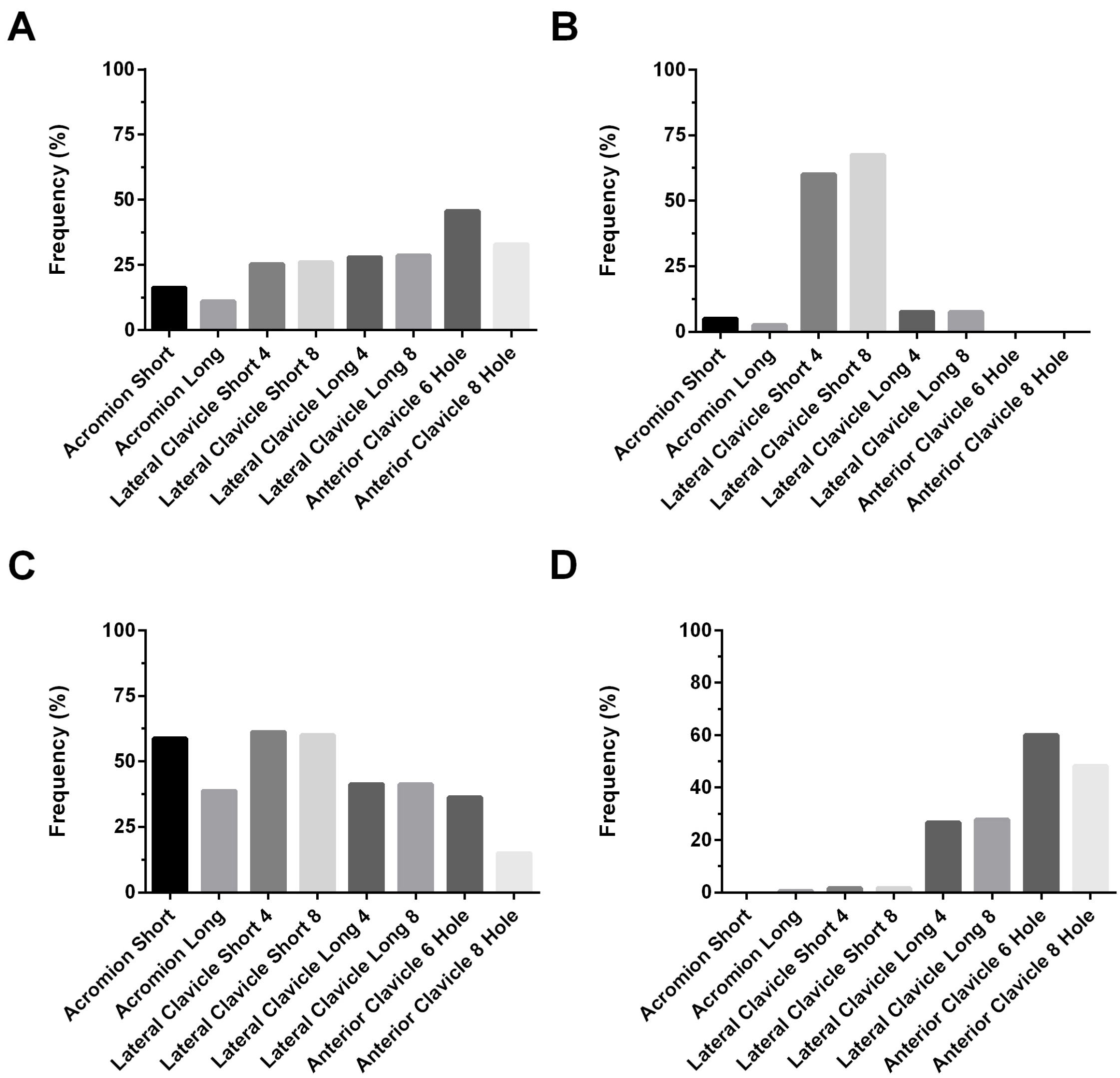

***Figure IX**: Frequencies with which specific plates were chosen as the 'best fit' amongst five independent specialists for (A) all fractures, (B) type I, (c) type II and (D) type III acromion fractures.*

***Table III**: Quantitative fit combined analysis per plate per patient*

Patient	Fracture type	Acromion Short	Acromion Long	Lateral Clavicle Short 4	Lateral Clavicle Short 8	Lateral Clavicle Long 4	Lateral Clavicle Long 8	Anterior Clavicle 6 Hole	Anterior Clavicle 8 Hole
1	3	n	n	n	n	n	n	f	i
2	1	n	n	f	f	n	n	n	n
3	3	n	n	n	n	i	i	i	i
4	3	n	n	n	n	n	i	i	i
5	2	i	n	i	i	n	n	n	n
6	2	f	f	f	f	i	i	f	i
7	2	i	i	i	i	i	i	n	n
8	3	n	n	n	n	n	n	f	i
9	3	n	n	n	n	n	n	n	n
10	2	i	i	i	i	i	i	n	n
11	3	n	n	n	n	n	n	i	i
12	3	n	n	n	n	n	n	f	i
13	3	n	n	n	n	i	i	f	i
14	1	n	n	n	i	n	n	n	n
15	3	n	n	n	n	i	i	i	i

n = no fit, i = intermediate fit, f = anatomical fit

DISCUSSION

The majority of acromion fractures in our cohort occurred as a result of high energy trauma sustained by a male predominance with a median age of 42.3 years (Table II).

A variety of fixation techniques have been described for the open reduction and internal fixation of acromion fractures, including tension band wiring for more distal fractures, plate fixation for fractures that are more proximal or through the acromial base and spine,[1,12] interfragmentary screw fixation,[1,11] plate fixation supplemented with interfragmentary screws,[1,7] and fixation with Kirschner wires.[1,12] However, published data about decision-making and treatment success of acromion fractures are mostly retrospective and do not compare operative versus non-operative treatment.[3]

The aim of this study was to determine to what extent a currently available scapular and clavicular plating system is able to provide adequate fixation options for acromial fractures (Figure IX: A - D).

The results from this study show that acromion plates, manufactured specifically for use in acromion fractures, were only deemed ‘somewhat suitable’ by a panel of five independent investigators, when fitted on 3D printed acromion fractures. Long and short acromial plates do not fit the fracture patterns identified at our level 1 trauma hospital in 80% of cases. The dedicated acromion plates were, however, more suitable for a subset of acromion fractures, termed type II (48.75%) fractures and less so for type I (3.75%) and III fractures (0.6%).

The majority (60%) of fracture types were categorised as type III extending into the scapular spine region (Figures III - V). This highlights the observation that the anatomically designed plates do not adequately address fracture patterns seen in our cohort.

A wide spectrum of heterogenicity of the acromion anatomy, infrequently used approaches, and limitations of available implants, together with variable fracture morphology present challenges in trying to achieve favourable fixation and resultant outcomes following surgery. Currently, surgeons incorporate the use of various fixed angle plate options intended for other periarticular areas in the fixation of scapula fractures. Plate systems for the lateral clavicle have been shown to be a good match for the acromion.[2] This trialling of implants is done intraoperatively and may add to the surgical time. This study confirms that the clavicular plating systems can be successfully used as alternative implants to the anatomical designed acromial plates. The location of the fracture lines determines the type of plate to be considered. The advantage of these lateral end of clavicle plates are that more screws with a smaller diameter are available for fixation to the lateral side of the acromion process in type I fractures (Figure IX - B) as compared to the dedicated acromion plates with larger diameter options in a straight line that will be more appropriate for a type II fracture (Figure IX - C). Plate congruence does not equal adequate biomechanical fixation and the fracture pattern needs to be adequately assessed.

The Intra class correlation ranges were observed to be between 0.89 to 0.99 for the first set of observations and between 0.81 and 0.99 for the second set of observations. The overall average ICC was found to be 0.965.

This supports the agreements between the 5 investigators relating to the overall fit assessment and shows excellent inter-observer reliability regarding whether the plates would adequately address the fracture patterns, supporting the fact that even though the orthopaedic knowledge was varied, the observations correlated well.

The intra-rater reliability was not formally processed in the analysis of the data and can be seen as a possible limitation.

By integrating 3D models into surgical practice, as done in this study, there is a potential to reduce the surgical and anaesthetic time and therefore reduce overall cost. This may also lower the risk of postoperative complications and improve patient outcomes. Better planning procedures improve plate selection for the fracture pattern and therefore optimal fixation. The literature has shown the added benefit of educating patients and empowering them to make informed decisions around accepting a proposed surgical plan when using 3D modelling.[9] Likewise, it provides benefits to surgeons' education and training.[9]

The use of custom 3D printed models of patient bone may become standard in preoperative planning, surgical simulation, intraoperative guidance, and implant development.[8]

Results from the work by Bryce *et al* verify that accurate and reproducible 3D models can be created from in situ scapulae by use of effective segmentation.[4] This validation of the accuracy of the prototype models that can be produced replicates the true nature of matching fracture fragments as done intra-operatively.

This study integrated three components, namely fracture fixation, 3D printing of anatomical acromion models and quantitative fit analysis of plates to come to the stated observations. The combination of these processes can assist surgeons preoperatively. One can apply these techniques to any anatomical site or implant system. 3D printing expertise is rapidly becoming more accessible to clinicians worldwide. The initial concerns of excessive costs and long production times are swiftly becoming negated. Clinicians need to be wary to still maintain high standards of quality control whilst complying to regulatory guidelines.

The production of 3D prototypes is an attainable skill not limited to surgeons or engineers. It is preferable to have basic anatomical knowledge to assure accuracy. The technique can initially take a novice a long time. This time shortened over the course of the study as investigators improved on their learning curve. The technical capabilities of the printer used also impacts the time needed to produce a 3D model. This, combined with the complexity of the fracture fragments itself, add up to the print time as shown with our mean printing time of 504.7 minutes per model. The print time was not subdivided and recorded for each stage of the process and also weakens the result. This was however only a secondary observation.

Another limitation of this study is that we believe this is the only anatomical scapula plating system available and therefore conclusions are limited to the sole supplier. The design is however inadequate especially for type I and III fractures (Figure IX: B and D). This is conceivably an avenue to pursue to develop customized patient-specific plates or to collaborate with the current developers to maximize the plate fit and design.

The sample size is also limited due to the rarity of these injuries. This is, however, the largest data set currently investigated.

The advances in 3D printing are progressive and the applications invariably will become limitless. We need to embrace these new possibilities with caution and engage in taking it forward to the advantage of all involved in providing improved quality of healthcare.

CONCLUSION

Currently, available dedicated acromial plating systems fail to provide adequate congruency and fit for fixation of the majority of acromial fractures in the present cohort. A more anatomical and versatile plating system is required. Clavicular plates were found to provide a better fit and potential better fixation, which should be borne in mind when planning operative fixation of acromial fractures.

Using 3D printed anatomical models can be used effectively to assist in templating implants preoperatively.

REFERENCES

1. Anavian J, Wijdicks CA, Schroder LK, Vang S, Cole PA. Surgery for scapula process fractures: good outcome in 26 patients. Acta Orthop. 2009 Jun;80(3):344–50. doi:10.3109/17453670903025394

2. Beliën H, Biesmans H, Steenwerckx A, Bijnens E, Dierickx C. Prebending of osteosynthesis plate using 3D printed models to treat symptomatic os acromiale and acromial fracture. J. Exp. Orthop. 2017 Dec 24;4(1):34. doi:10.1186/s40634-017-0111-7

3. Brandsema B, Neuhaus V, Gradl G, Ring DC. Extra-articular scapular fractures: comparison of theoretical and actual treatment. Shoulder Elb. 2016 Jan;8(1):3–8. doi:10.1177/1758573215578587

4. Bryce CD, Pennypacker JL, Kulkarni N, Paul EM, Hollenbeak CS, Mosher TJ, et al. Validation of three-dimensional models of in situ scapulae. J. Shoulder Elb. Surg. 2008 Sep;17(5):825–832. doi:10.1016/j.jse.2008.01.141

5. Çiçekli Ö, Akar A, Topçu HN. Displaced acromion fracture: A rare injury, case report. Int. J. Surg. Case Rep. 2017;39:313–316. doi:10.1016/j.ijscr.2017.08.051

6. Crosby LA, Hamilton A, Twiss T. Scapula fractures after reverse total shoulder arthroplasty: classification and treatment. Clin. Orthop. Relat. Res. 2011 Sep;469(9):2544–9. doi:10.1007/s11999-011-1881-3

7. Dounchis JS, Pedowitz RA, Garfin SR. Symptomatic pseudarthrosis of the acromion: report of a case and review of the literature. J. Orthop. Trauma. 1999 Jan;13(1):63–6.

8. Eltorai AEM, Nguyen E, Daniels AH. Three-Dimensional Printing in

Orthopedic Surgery. Orthopedics. 2015 Nov;38(11):684–7. doi:10.3928/01477447-20151016-05

9. Green N, Glatt V, Tetsworth K, Wilson LJ, Grant CA. A Practical Guide to Image Processing in the Creation of 3D Models for Orthopedics. Tech. Orthop. 2016 Sep;31(3):153–163. doi:10.1097/BTO.0000000000000181

10. Izatt MT, Thorpe PLPJ, Thompson RG, D'Urso PS, Adam CJ, Earwaker JWS, et al. The use of physical biomodelling in complex spinal surgery. Eur. Spine J. 2007 Sep;16(9):1507–18. doi:10.1007/s00586-006-0289-3

11. Mick CA, Weiland AJ. Pseudoarthrosis of a fracture of the acromion. J. Trauma. 1983 Mar;23(3):248–9.

12. Ogawa K, Naniwa T. Fractures of the acromion and the lateral scapular spine. J. shoulder Elb. Surg. 1997;6(6):544–8.

13. Schuetz M, Yarlagadda PKDV , Harith H, MalekanI J SB. Quantitative fit analysis of orthopedic bone plates : methods, criteria and approach. J. Biomimetics Biomater. Tissue Eng. 2013;18(01):1–4. doi:10.4172/1662-100X.1000116

14. Tetsworth K, Block S, Glatt V. Putting 3D modelling and 3D printing into practice: virtual surgery and preoperative planning to reconstruct complex post-traumatic skeletal deformities and defects. SICOT-J. 2017;3:16. doi:10.1051/sicotj/2016043

PART C: ADDENDA

CONTRIBUTIONS OF AUTHORS

Johan Charilaou: Primary author and principal investigator, data collection and processing. Final write up.

Steve Roche: Supervisor. Data collection and editing.

Roopam Dey, under the supervision of Sudesh Sivarasu: Technical support, processing and rendering of 3D models, editing and statistical analysis.

Frida Hansson: Data collection

Ruan van Staden: Data collection and rendering 3D models.

Sithombo Maqungo: Editing and review.

COMPETING INTERESTS AND FUNDING

There are no competing interests and no funding was received during this study.

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Plate fit analysis on 3D acromion

QUESTIONNAIRE / DATA CAPTURE INSTRUMENT

Microsoft Excel spreadsheet

box nr					
date					
researcher name					
patient name					
colour					
3d print model	fragements fit < 2mm				
	no fit > 2mm				
nibble	yes	no			
	plates				
acromion plate		Short	fit < 2mm	interm > 2mm	no fit
		Long	fit < 2mm	interm > 2mm	no fit
lat clav plate		short 4	fit < 2mm	interm > 2mm	no fit
		short 8	fit < 2mm	interm > 2mm	no fit
		long 4	fit < 2mm	interm > 2mm	no fit
		long 8	fit < 2mm	interm > 2mm	no fit
ant clav plate		6 hole	fit < 2mm	interm > 2mm	no fit
		8 hole	fit < 2mm	interm > 2mm	no fit

CONSENT FORMS AND ANY RELATED PARTICIPANT INFORMATION SHEETS

Not applicable as this was a retrospective review of a patient imaging with no clinical impact on management.

RESEARCH PROTOCOL

Title

Scapula fractures: Planning osteosynthesis using 3D printed anatomical models

Investigators

Principal: J. Charilaou

Supervisor: S. Roche

Co-authors: R. Dey, S. Sivarasu, F. Hansson, R. van Staden, S. Maqungo

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Table of contents

Title

Scapula fractures: Planning osteosynthesis using 3D printed anatomical models

Investigators

Principal: J. Charilaou

Supervisor: S. Roche

Plate fit analysis on 3D acromion

Co-authors: R. Dey, S. Sivarasu, F. Hansson, R. van Staden, S. Maqungo

Purpose of the study

The use of anatomical modelling of three-dimensionally (3D) printed scapula fracture fragments to assist in preoperative planning.

The secondary aim is to ascertain the anatomical congruence of an available pre-contoured plating system.

Background

Scapula fractures are notoriously difficult to manage operatively. Difficult surgical approaches, implant limitations, anatomical challenges, and morphological variance leads to hesitance from surgeons to perform osteosynthesis.

3D Printing, also known as additive manufacturing or rapid prototyping, is described frequently as a technical and industrial revolution that might significantly change the way we live. This manufacturing method is based on 3D computer models for the reconstruction of a 3D object by the addition of material layers, such as plaster, metal or plastic. Selective laser sintering (SLS), fused deposition modeling, and inkjet printing have emerged and almost overtaken stereolithography in terms of frequency of use.[3]

Imaging modalities have evolved exponentially, and we can obtain detailed reconstructions on electronic formats. Accurate and reproducible 3D models can be created from in situ scapulae by the use of effective segmentation. The sources of digital multidimensional images are, computerized tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), single photon emission computed tomography (SPECT), ultrasound (US), functional MR (fMRI), magnetic source imaging, and surface light scanning.[5]

However, the in vivo milieu poses challenges to safely and adequately reduce and fixate complex fractures. Anatomically pre-contoured implants invariably need some adjustment and bending around the scapula. This leads to added surgical time and with it the associated risks. Intraoperative fluoroscopy is also difficult to accurately obtain due to the anatomic orientation of the shoulder girdle.

3D Models can help with a better understanding of indirect manipulation of fragments required to achieve anatomical congruence. It also improves the understanding of anatomy and pathology by means of tactile and visual experience to complement images displayed on a computer monitor.

Increased accessibility and lower costs make this field an exciting prospect for future medical applications. A wide variety of surgical subspecialties already implementing this valuable adjunct include tumour resections, craniomaxillofacial reconstruction, and cardiothoracic surgery.

Benefits include intraoperative guidance, preoperative planning, teaching, and training. The model can be shown to the patient, drastically improving their education and refining the consent.[2] Accurate plate selection, screw lengths, and orientation can be determined.

Disadvantages are the costs of specialized machinery[4], and the time needed to produce a model. The segmentation can take hours and the printing time itself is proportional to the size and desired quality of the model. The average printing time is approximately 7 hours. Complexity of the fracture is directly proportional to time consumed to produce the final model.

The field of bioengineering is also rapidly acquiring the skills and understanding to accurately collaborate with radiologists and surgeons to produce high-quality models. The accuracy of the 3D print is dependent on the contrast in the parent image, and also on the technical capabilities of the printer. Contemporary 3D printers have a filament thickness of about 0.1 mm. In practice, because of the vibrations originating in the motion of the heads themselves, the achievable spatial resolution rarely reaches this limit, and it is usually about 0.5 mm.[2]

These advantages and disadvantages need to be extensively evaluated and explored in the field of Orthopaedic Surgery.

Methodology

Study design

Observational biomechanical basic sciences study

Characteristics of study and population

We will conduct a pilot project to ascertain the anatomical congruence of a pre-contoured plating system. This will be done on intact dry museum specimens. The specimens are denuded of soft tissues and displayed no evidence of previous fractures or callus formation. We will obtain these from the University of Cape Town, Department of Anatomy in the Faculty of Health Sciences. The specimens are skeletally mature. No demographic details are available on the origin, gender or age of the specimens.

We want to confirm that the plating system does not supply enough options to adequately fixate all fracture types. The glenoid plate, in particular, is difficult to fit according to anecdotal experience.

The main study will be conducted in conjunction with the Department of Human Biology's division of Biomechanics. We will identify patients with scapula fractures who underwent a shoulder CT scan following blunt trauma presenting to Groote Schuur Hospital from 2012 to 2016. We will evaluate 41 scapulae and classify the fracture patterns according to anatomical location of the scapula body, glenoid neck and -fossa, coracoid and acromion/spine.

The first fracture pattern to be used is the acromion/spine component. The other fracture patterns will be used as a separate study.

<u>Recruitment and enrollment</u>

The Phillips Electronics iSite Electronic Radiology System will be used to search for all shoulder CT scans performed during the study period. This data is not public domain and access is password protected for appropriate healthcare providers. We did not obtain consent for the use of these CT scans as we are doing the study retrospectively and no intervention was affected or altered. A power analysis was done using the formula:

$n = [Z \text{ star} \times P (1 - P)] / E^2$

Z star = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI), P is expected proportion, E is desired precision (half desired CI width). For small populations n is adjusted so that n(adj) = (Nxn)/(N+n). Analysis (done using R). Assuming a power of 95%, we need to test 36 scapulae. We also calculated the total for a CI of 75% to be 24 scapulae. We will continually reassess the feasibility of the project to try and obtain as many 3D models, so we can improve the statistical significance. The sample size will be subdivided into the different fracture classifications and each subgroup will be proportionally represented by random selection.

Inclusion criteria:

- All scapula fractures due to blunt trauma will be included irrespective if they were surgically or conservatively managed.

Exclusion criteria:

- Goss and Ideberg Type 1a and b fracture-dislocations of the glenoid rim. These fractures seldom need open reduction and fixation as the fragments are small knock off or avulsed entities.
- Malunited fractures undergoing delayed surgery were also excluded.
- Gunshot wounds were excluded as they are difficult to segment due to scattering from bullet fragments. These fracture patterns are also very comminuted and do not fit the usual fracture classifications.

Research procedures

- Pilot study

Each scapula will be templated with the 6 different anatomically contoured plates available for the various fracture patterns. These are a glenoid, an acromial, two medial border and two lateral border plates. The plates will be aligned to the intended anatomical site.

Conformity of fit and the potential degree of plate bending that might be required for an anatomic fit will be assessed. The variables are gap, alignment and overhang. A digital Vernier caliper will be used to do the measurements. We will use this devised grading system: Anatomical fit will be if there was a 2mm or less gap between the plate and bone, no overhang and no bending needed to align the plate. Intermediate fit is a more than 2mm gap or if bending is required to narrow this gap or to correct the overhang. No fit is if there is too much offending and/or overhang to correct with plate manipulation, thus having screw holes not over bone.

This will be performed by two Orthopaedic surgery registrars on a single occasion to limit the inter-observer variability. The exact morphology and dimensions of each clavicle were not measured.

- Main study

The Digital Imaging and Communication in Medicine (DICOM) file will be uploaded. Multiplanar reconstruction (MPR; axial, sagittal, coronal) and 3D volume rendering of the fracture will be obtained. Working on the 3D-reconstruction, the fractured bone can be isolated with a digital scissor tool.

The CT scans will be reconstructed in-silico using Materialise Interactive Medical Image Control System Software (Mimics®). This is image processing software for 3D design and modelling, developed by Materialise NV, a Belgian company specialized in additive manufacturing software and technology for medical, dental and additive manufacturing industries.

Then the Surface Rendering model of the fractured bone can be created and exported to a Stereolithography (STL) file. The file can be analyzed and prepared for printing with 3D dedicated Z-suite software. The Zortrax M200 printer system and acrylonitrile butadiene styrene (ABS), a common thermoplastic polymer plastic filament will be used to produce the prototype.

Areas of the fracture will be identified, and care will be taken to treat each fractured part as a separate entity. The reconstructed model of each bone will be synthesized into a physical three-dimensional scapula using additive manufacturing technique.

The same measurements will be conducted as for the pilot study to determine plate congruence. The digital Vernier caliper will also be utilized.

A Specialist Orthopaedic Surgeon, a Trainee Orthopaedic Surgery Registrar and a Medical student will conduct the measurements on two separate occasions to limit inter- and intra-observer variability.

Data Analysis

The primary objective is to evaluate the use of 3D reconstruction in preoperative planning. This includes anatomical reduction, implant selection, plate congruence and selection of an appropriate surgical approach.

Fracture fragments will be printed in different colours. These will be reduced and kept in position using ordinary glue. The only locally available plating system is from Acumed (Hillsboro, OR, USA). This system will be used, and the best plate identified to address the fracture configuration. Any adjustments to the anatomically pre-contoured plates can be made and templated. Other alternatives like a lateral end clavicle plate for acromial fracture fixation will also be templated. The best surgical approach can be identified once the above were considered.

All recorded data will be recorded on an Excel/Numbers spreadsheet. All data will be collected by the investigators and stored on password protected computers to ensure confidentiality. No names will be used once the data has been collected and patients will be identified by a random number held separately from the demographic data. Statistical analysis can be performed once the data has been collected.

Risks and benefits to the trial participants

This will benefit patients undergoing open reduction and internal fixation for these difficult fractures in future. There is no risk to the patients we used to obtain the CT scan files.

Difficulties and complications

Validation of accuracy of printed models needs to be considered.

The cost to produce a model needs to be kept low to make it viable.

The total time to complete a single model will initially be long. As the investigators improve and practice the technique this will become shorter.

The power analysis demonstrates a large number of scapulae needed to gain sufficient and relevant statistical data. This could be a limiting factor taking time and cost into account.

Declarations

The investigators have no conflict of interest to declare.

Appendices

Appendix 1 - Data capture form

References

1.Bryce CD, Pennypacker JL, Kulkarni N, Paul EM, Hollenbeak CS, Mosher TJ, Armstrong AD. Validation of three-dimensional models of in situ scapulae. *Journal of Shoulder and Elbow Surgery* 2008;17(5):825-832.

2.Bizzotto N, Sandri A, Regis D, Romani D, Tami I, Magnan B. Three-Dimensional Printing of Bone Fractures: A New Tangible Realistic Way for Preoperative Planning and Education. *Surgical Innovation* 2015;22(5):548-551.

3.Martelli N, Serrano C, van den Brink H, Pineau J, Prognon P, Borget I, El Batti S. Advantages and disadvantages of 3-dimensional printing in surgery: A systematic review**.** *Surgery* 2016;159(6):1485-1500.

4.Rengier F, Mehndiratta A, von Tengg-Kobligk H, Zechmann CM, Unterhinninghofen R, Kauczor HU, Giesel FL. 3D Printing based on imaging data: review of medical applications. *International journal of computer assisted radiology and surgery* 2010;5(4):335-341.

5.Udupa JK, Herman GT. *3D imaging in medicine*. 2nd ed. CRC Press; 2000.

HREC APPROVAL LETTER

HUMAN RESEARCH ETHICS COMMITTEE
18 JAN 2019
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

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FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signature Removed	Date Signed	19/1/2019

Comments to PI from the HREC
Thank you for the deviation doc

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	16/1/2019		
HREC REF Number	695/2016	Current Ethics Approval was granted until	30/10/2017
Protocol title	Quantitative fit analysis of acromion fracture plating systems using three-dimensional anatomical modelling		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study			
Principal Investigator	Prof. S. Roche		
Department / Office Internal Mail Address	Orthopaedic Surgery	stephen.roche@uct.ac.za	

1.1 Does this protocol receive US Federal funding?	☐ Yes	X No

12 March 2018 • Page 1 of 5 • FHS016

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

COVER LETTER 1

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Approval

This manuscript has been read and approved by all authors.

Each author believes that the manuscript represents honest work.

Declaration

This manuscript was accepted as a podium presentation at the following:

- International Society of Orthopaedic Surgery and Traumatology's (SICOT) 38th Orthopaedic World Congress, Cape Town, South Africa, 30 November - 2 December 2017.
- 63rd Congress of the South African Orthopaedic Association (SAOA), Port Elizabeth, South Africa, 4 – 7 September 2017.
- 8th World Congress of Biomechanics (WCB), Dublin, Ireland, July 2018.

COVER LETTER 2

Conflict of interest statement

None of the authors, their immediate families or any research foundations with which they are affiliated received any financial payments or other benefits from any commercial entity related to the subject of this article.

Ethical committee approval

University of Cape Town, Faculty of Health Science, Human Research Ethics Committee HREC REF 695/2016

AIMS, OBJECTIVES, AND HYPOTHESES

Aim

To determine to what extent currently available plating systems are able to provide adequate fixation options for acromial fractures.

Objective

To print three-dimensional (3D) anatomical models of acromion fractures.

To ascertain if 3D models can assist templating clavicle and acromion plates on acromion and scapular spine fracture models and assessing quantitative fit of plates.

Hypothesis

Available acromion plates used in open reduction and internal fixation do not fit the anatomy adequately. The use of 3D printing anatomical scale models can assist in templating these fractures to assist in quantitative fit analysis of acromion and other alternative plates.

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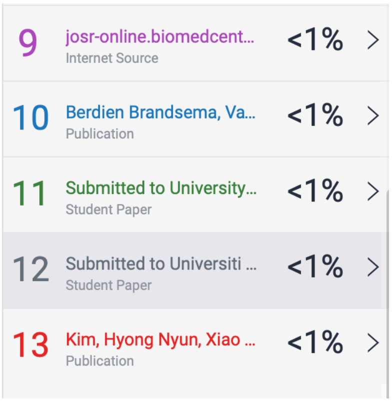
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TABLES AND FIGURES

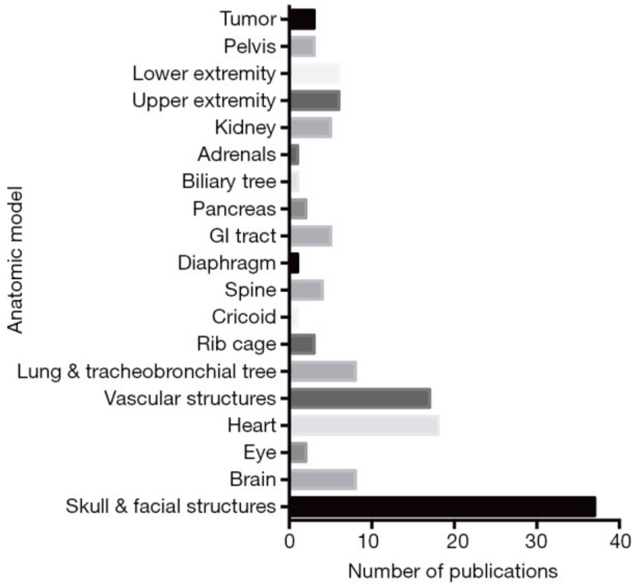

Figure I*: Articles published by anatomical location of the 3D printed model.*

Sourced from Hoang et al 2016.[23]

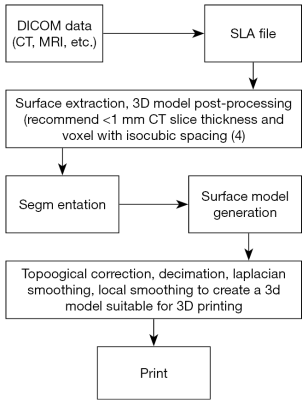

***Figure II**: The 3D printing process from start to finish.*

Sourced from Hoang et al 2016.[23]

***Figure III**: Type I fracture - acromion process lateral to acromion angle*

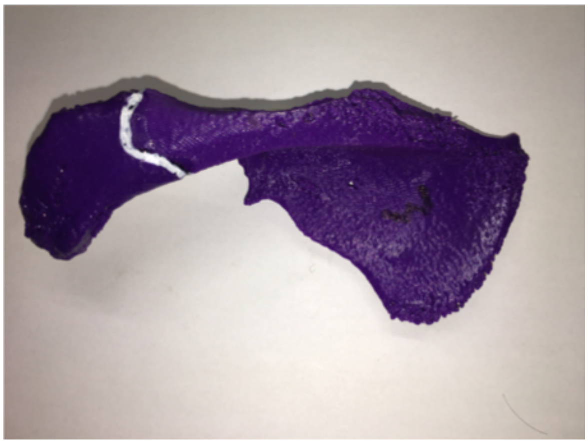

Figure IV*: Type II fracture - acromion angle to spinoglenoid notch*

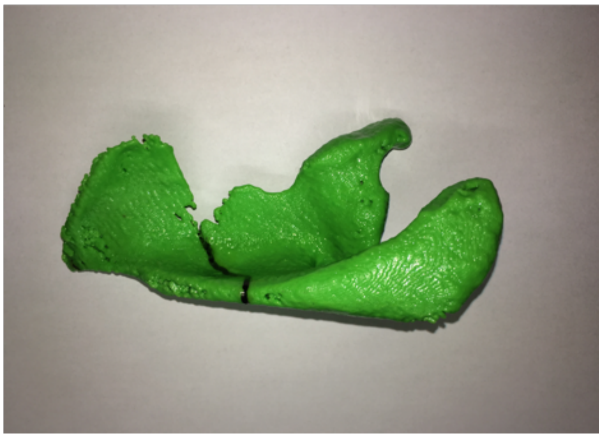

Figure V*: Type III fracture - medial to the spinoglenoid notch or into scapular spine*

Plate fit analysis on 3D acromion

Figure VI: *Anatomical fit < 2mm gap, no overhang*

Figure VII: *Intermediate fit > 2mm, but can bend to improve fit*

Figure VIII: *No fit > 2mm gap, can't fit with bending*

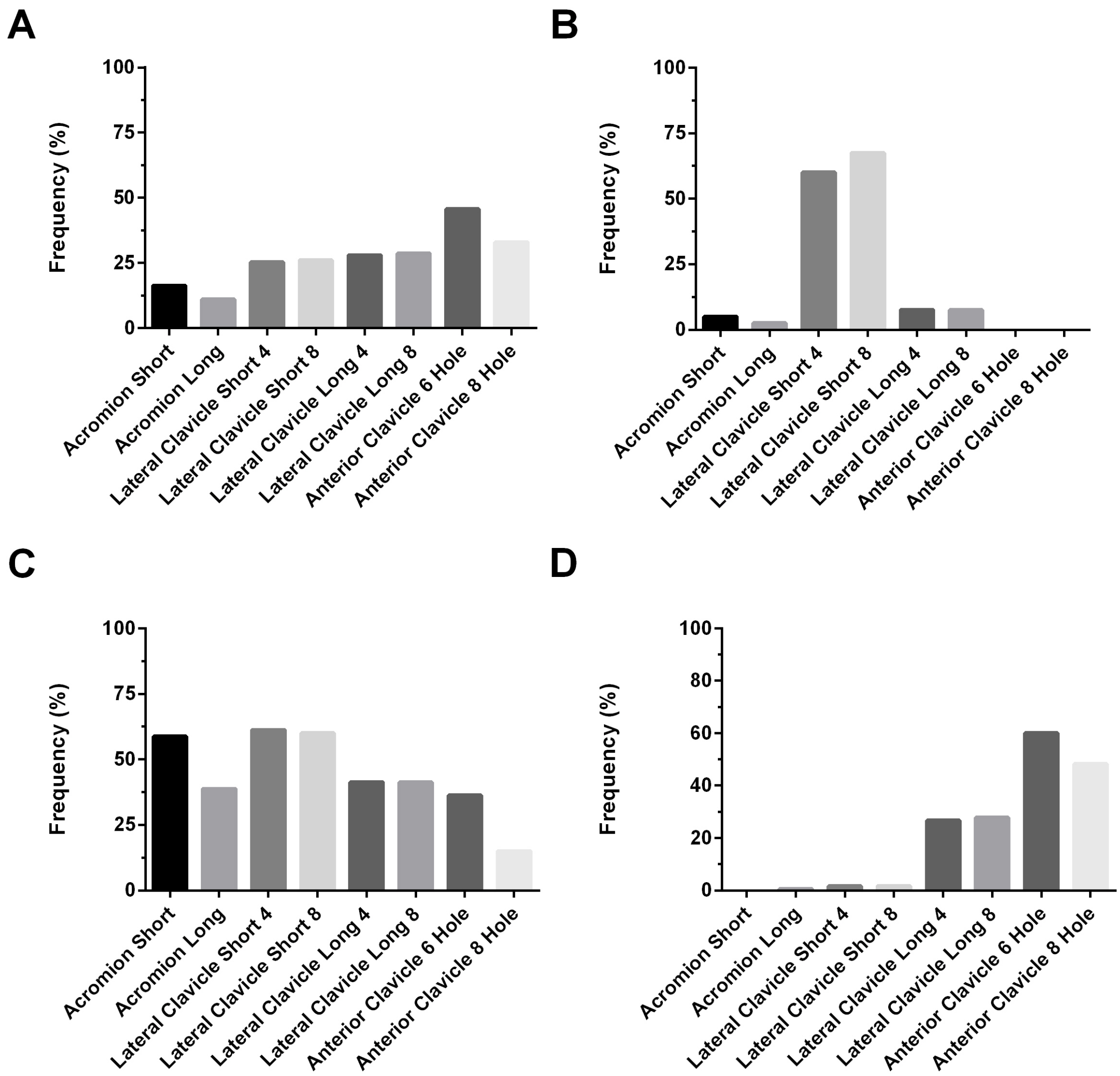

Figure IX*: Frequencies with which specific plates were chosen as the 'best fit' amongst five independent specialists for (A) all fractures, (B) type I, (c) type II and (D) type III acromion fractures.*

***Table I**: Plate fit assessment on cadaver specimens*

	Anatomical fit (%)	**Intermediate fit (%)**	**No fit (%)**
Acromion long (n=46)	15	37	48
Acromion short (n=47)	36	62	2
Lateral clavicle short (n=46)	28	67	4
Lateral clavicle long (n=46)	2	70	28

***Table II**: Mechanism of injury*

Mechanism of injury	n (%)
Pedestrian vehicle accident	7 (46.7)
Motor vehicle accident	5 (33.3)
Motorbike accident	1 (6.7)
Blunt trauma	2 (13.3)

Data is presented as a count with the frequency indicated in parentheses

***Table III**: Quantitative fit combined analysis per plate per patient*

Patient	Fracture type	Acromion Short	Acromion Long	Lateral Clavicle Short 4	Lateral Clavicle Short 8	Lateral Clavicle Long 4	Lateral Clavicle Long 8	Anterior Clavicle 6 Hole	Anterior Clavicle 8 Hole
1	3	n	n	n	n	n	n	f	i
2	1	n	n	f	f	n	n	n	n
3	3	n	n	n	n	i	i	i	i
4	3	n	n	n	n	n	i	i	i
5	2	i	n	i	i	n	n	n	n
6	2	f	f	f	f	i	i	f	i
7	2	i	i	i	i	i	i	n	n
8	3	n	n	n	n	n	n	f	i
9	3	n	n	n	n	n	n	n	n
10	2	i	i	i	i	i	i	n	n
11	3	n	n	n	n	n	n	i	i
12	3	n	n	n	n	n	n	f	i
13	3	n	n	n	n	i	i	f	i
14	1	n	n	n	i	n	n	n	n
15	3	n	n	n	n	i	i	i	i

n = no fit, i = intermediate fit, f = anatomical fit