Development of New Locking Mechanism for Mini-Fragment Hand Plates for Small Bone Fracture Fixation

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ENGR 8772 MASTER OF ENGINEERING THESIS

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I, *Jesvin Varghese,* hereby declare that all work presented in this document was solely completed by myself. Any material used from external sources have been acknowledged and referenced to the best of my knowledge.

Jesvin Varghese *02/11/2020*

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Executive Summary

Hand anatomy comprises of intricate and complex features which could be affected by various disorders and traumatic injuries. Some of these injuries are mild and some can be very serious. Fracture that are less severe are treated using splints or cast which stabilises the fracture over a few days or weeks depending on the degree of severity. However, there are more severe fractures that would not be treated by solely using cast and splints. These fractures that may have serious dislocations require surgical treatment that involves using plates, screws and pins to stabilise the fractures. The patients are assessed using various recognised ways such as Disabilities of Arm, Shoulder and Hand (DASH) score to assess the performance of implant as well as to identify any potential complications. This project was completed under the requirements of Austofix Pty Ltd, an Australian recognised manufacturer and supplier of orthopaedic devices. The primary clients of the products are hand surgeons of Macquarie University Hospital, based in Sydney. The aim of this project is to develop a locking mechanism for mini-fragment plates that can be used across metacarpals and phalanges of hand.

Based on the clinical literature review conducted, it was identified that the current state of art for hand fractures is hand plates and screws with variable angle screw technology. Based on this research, it was decided that three types of Variable Angle Screw Technology (VAST) buttons and one 1.5 mm locking screw with M2.3x0.45 locking head were designed with necessary jigs needed for testing. The three types of buttons designed are threaded parallel button, threaded tapered button and spline button. All parts were designed and analysed using Solidworks.

Changes were made to the design based on the analysis completed in Solidworks that assessed the interaction between the VAST buttons and the locking screw. After the final designs were finalised, all technical drawings were completed in Solidworks with adequate tolerancing. The drawings have been approved by the technical design coordinator at Austofix and sent to the manufacturer expected to arrive in late October/ early November for mechanical testing.

There have been limitations in this project with the Covid-19 pandemic that has occurred as well as technical limitations due to lack of experience in technical file management as well as manufacturer limitations. After the testing the parts and achieving satisfactory results, this project has a great scope for future work. The future work of this project will involve implementing this developed locking system in mini-fragment hand plates which alone will require a significant amount of research and concept designs.

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1 Introduction

Hand anatomy comprises of intricate and complex features which could be affected by various disorders and traumatic injuries. A total of 27 bones constitute the hand anatomy including the wrist and hand which are innervated by 3 different types of nerves – median, ulnar and radial nerves. The bones of hands are classified into carpals, metacarpal and phalanges (Figure 1). The carpal bones constitute for wrist bones comprising scaphoid, lunate, triquetrum and pisiform bones. The five metacarpal (11) bones are the long bones in the fingers each having base, shaft and a neck. The thumb metacarpal bone is the shortest and is considered to be the most mobile. All metacarpals distally connect with the phalanges of their respective digits. Phalanges occur in 14 numbers, each finger containing 3 phalanges each. The thumb, however, has 2 phalanges.

Removed due to copyright ownership.

Figure 1 Hand Anatomy (Bones in hand): Shows all bones within the hand which are specific to this project which are carpal bones, metacarpal bones and phalanges. (ASSH, 2020)

Hand fractures are classified into different types based on the location and severity of the fracture. The most common type of hand fracture is the carpal fracture which usually occurs from an axial compressive force and hyperextension due to a fall. When a person's wrist is exposed to hyperextension, their volar ligaments are put under pressure with the shear forces. Depending on what bone of the hand is fractured and the degree of fracture, treatment varies from patient to patient. While most small fractures are dealt with splints or casts as mentioned earlier, severe fractures cannot be dealt in the same manner. Serious fractures and dislocations are treated using pins, plates and screws.

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Figure 2 Metacarpal fracture treated with plate and screws. The figure on the left shows the fractured metacarpal and on the right, the fractured bone is treated with a metacarpal plate which stabilises the injury site thereby healing it.

Within the carpal bones, the most common carpal fracture occurs in Scaphoids and Triquetrum which constitutes to 68.2% and 18.3% respectively. Carpal bone fractures are predominantly dealt with volar wrist plates. As looking at all areas of hand fractures could demand a vast range of research and design variation, the focus for this project is solely on metacarpal and phalangeal fractures.

Metacarpal fractures can occur in metacarpal base, shaft and neck all requiring different treatment approaches (Figure 2). Impaction fractures that occur in the metacarpal bases with minimal displacement can be treated with minimal measures such as splinting. However, more severe fractures such as carpometacarpal dislocations and unstable injuries are managed by closed reduction and external immobilisation for a significant period of time. This usually can lead to grip weakness and residual pain. K-wire pin fixation was considered one of the most effective measures to stabilise the carpometacarpal fractures. Within the metacarpal base, fracture dislocations in the fourth and fifth metacarpals require open reduction and internal fixation. Fractures in metacarpal neck hardly require surgery as it is said that about 50-60° of angulation is acceptable with very minimal or no functional deficit.

There are many companies currently manufacturing and supplying hand plates around the globe including Synthes, Medartis, Acumed, Biomet etc. Austofix is an Australian based company that designs and manufactures orthopaedic trauma devices such the Femoral nails, humeral nails/plates, Tectona hip plates, spine cage and various other systems are used in orthopaedic surgeries. Austofix is currently one of the many suppliers of hand plates in Australia. Hand fracture treatment technology is evolving rapidly in the market with new devices designed and designed by surgeons all over the globe.

This project was proposed to Austofix by the primary clients, Dr Damian Ryan and Assistant Professor Graham Gumley, who are two of the leading hand surgeons in Macquarie University Hospital in New South Wales. The aim of this project was to release an Australian made, Australian owned product in the market. Dr Damian and Assistant Professor Graham had several requirements that had to be met in the project goals. All concept designs were consulted with them for approval before progressing further into the next stage. The main requirement from the clients was to provide a fully functionally and clinically tested and approved hand plate system with a range of hand plates with the instruments required. However, this will be a long-term goal of this hand project as this requires a significant amount of research, design work and testing to be conducted. Hence, for practical reasons, the hand project will be divided into manageable goals and stages.

The ENGR7700 Engineering Thesis Project will be focussing on the first stage of this project. The first stage of the hand project focusses on developing and testing a locking mechanism using buttons and screws. The locking mechanism design will be developed, analysed and tested thoroughly until satisfactory results are achieved. The project will be progressing into its next stage once the locking mechanism is finalised is the first stage. Clinical literature review has been conducted to identify the current state of art and results from the clinical studies conducted.

2 Clinical Literature Review

2.1 Key Functions of Literature Review

The key functions of this clinical literature review are:

- Define the purpose and scope of the review.
- Briefly describe the devices covered by the review.
- Identify the individuals performing the literature review.
- Identify the sources: journal articles, internal sources, clinical and regulatory databases.
- Define the selection criteria of the literature articles used.
- Define any filters or limitations for information used.
- Define any classification system be used to define the relevance or weight applying to each reference.
- List the articles used in the review, including reasons why some data may be excluded.
- Analyse the data with regard to how it applies to the relevant Austofix devices.
- Draw conclusions based on original purpose of the review.

2.2 Purpose and Scope of Literature Search and Review

- Summarise any key clinical research and new knowledge published regarding mini fragment hand plate since 2010.
- Summarise the findings of any published clinical studies with a focus on any meta-analyses that may have been published since 2010.
- Review any findings regarding possible new contraindications for the device.
- Any other data that may be pertinent to the safety and performance of the devices for their intended purpose.

2.3 Device Description in Brief

The Austofix Mini Fragment locking, and compression plate range comprises of a range of plates from which a suitable plate is determined depending on the location and type of fracture. The plates are used in conjunction with locking screws and cortex screws. All implants are manufactured from Titanium and contoured for better anatomical fit.

2.3.1 Indications and Contraindications

Austofix Mini Fragment Hand plates are indicated for the following use:

- Temporary fixation, correction of small fragments.
- Avulsion fractures and proximal, middle and distal phalange fractures.

- Distal radius and metacarpal fractures.
- Arthrodesis and osteotomies.

The device is contraindicated in following cases:

- Existing or suspected infections at or close to the site of the implantation.
- Any allergies or sensitivity to foreign bodies; appropriate tests must be conducted where hypersensitivity or allergy to material is suspected.
- Reduced bone quality insufficient to support the device implant.

2.4 Literature Review Sources

Personnel

Personnel undertaking and/or reviewing this literature search:

Table 1 Document preparation undertaken by Jesvin Varghese and Reviewed by Josh Balfour and Associate Professor John Costi

Prepared By:	Reviewed By:
Jesvin Varghese Bachelor of Engineering (Biomedical)/Master of Engineering (Biomedical)	**Josh Balfour, PhD.** *Regulatory Associate, Austofix* **Associate Professor John Costi, PhD, FIEAust, FIOR** Course Coordinator (Mechanical engineering)

Time Frame

This literature review will focus on the period between 2010 and 2020.

Literature Sources used to identify data.

A literature review was conducted on both internal and public databases:

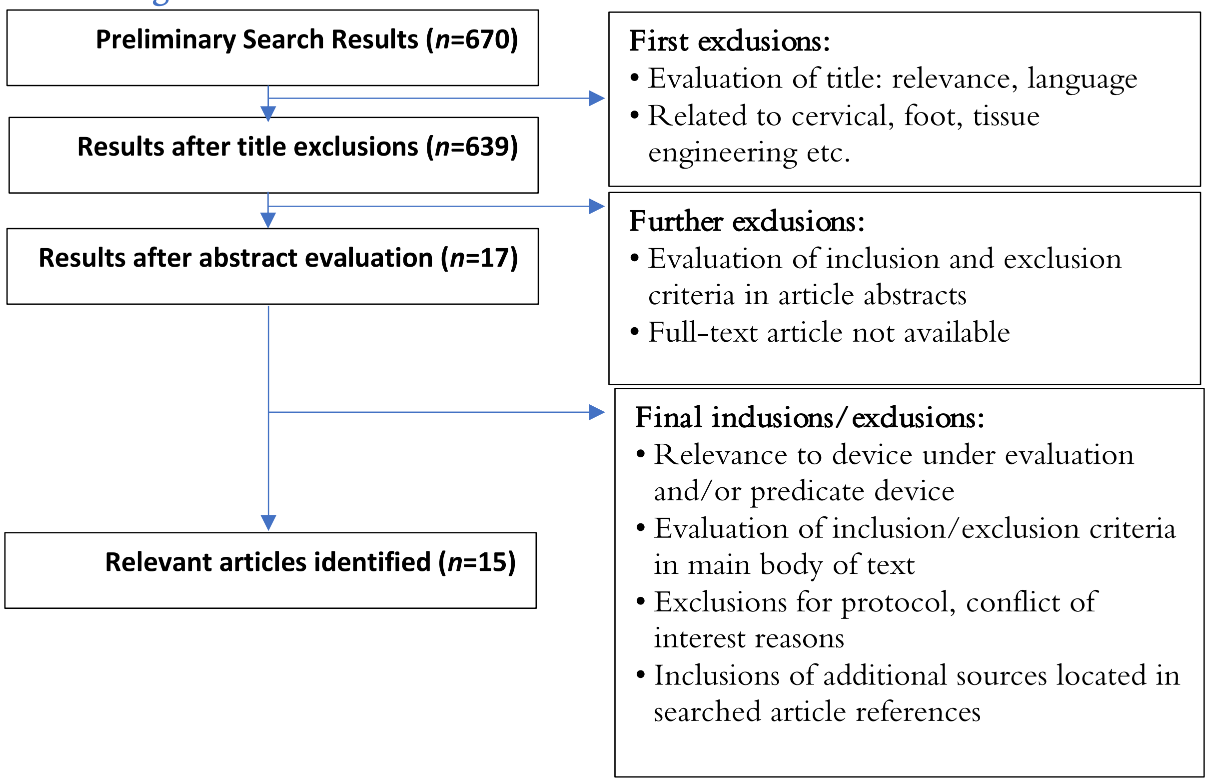
- FDA Medical & Radiation Emitting Device Recalls (RMRED database includes all the recorded instrument recalls by the FDA).
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
- FDA Manufacturer and User Facility Device Experience (MAUDE database includes adverse events and notifications to the FDA).
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- TGA Database of Adverse Event Notifications (DAEN database records adverse events related to medical devices in Australia).
  http://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx
- PubMed/Medline (www.pubmed.com).
- Any other sources.

2.5 Data Search and Results

Table 2 Data Search Results for clinical review search done using databases such as RMRED/MAUDE, PubMed to research and analyse the recalls, adverse event notifications and journal articles related to hand fractures.

Search	Types of Documents	Keywords and Synonyms	Outcome: Papers chosen etc
RMRED/MAUDE	Recalls, notifications	Hand plate	No results returned
	Recalls, notifications	Synthes hand	No results returned
PubMed	Journal Articles	(Synthes) AND (interphalangeal OR Phalange OR metarcarpal) AND (meta-analysis OR systematic review)	16 results returned - 13 removed for title relevance (tissue engineering, screws, prosthetic hand, knees fractures, guidelines) - 2 removed for abstract relevance (Distal radius 3 remaining deemed relevant
	Journal Articles	(hand plate) AND (interphalangeal OR Phalange OR metarcarpal) AND (meta-analysis OR systematic review)	168 results returned - 162 removed for title relevance (tissue engineering, screws, prosthetic hand, knees fractures) - 2 removed for abstract relevance - 1 eliminated for full test (no clinical results) 3 remaining relevant
	Journal Articles	(Hand plate) AND (arthrodesis OR arthrodeses) AND (meta-analysis OR systematic review)	486 results returned - 464 removed for title relevance (tissue engineering, cervical fractures, foot related) - 13 removed for abstract relevance 9 remaining relevant

2.6 Findings


Preliminary Search Results (*n*=670)
Results after title exclusions (*n*=639)
Results after abstract evaluation (*n*=17)
Relevant articles identified (*n*=15)
First exclusions:
• Evaluation of title: relevance, language
• Related to cervical, foot, tissue engineering etc.
Further exclusions:
• Evaluation of inclusion and exclusion criteria in article abstracts
• Full-text article not available
Final inclusions/exclusions:
• Relevance to device under evaluation and/or predicate device
• Evaluation of inclusion/exclusion criteria in main body of text
• Exclusions for protocol, conflict of interest reasons
• Inclusions of additional sources located in searched article references

2.7 Review of Clinical Literature

2.7.1 Current State of Art

Table 3 Current state of art table to compare studies conducted for hand fractures with regards to their key content, publishing date, devices included, number of patients and overview of results

<table>
<tr><th>Author</th><th>Title</th><th>Date published</th><th>Devices included</th><th>Number of patients</th><th>Summary of results/complications</th></tr>
<tr><td>D.Dreyfuss et al.</td><td>Comparison of locking plates and intramedullary pinning for fixation of metacarpal shaft fractures</td><td>Jan 2019</td><td>Kirschner wire pinning, Depuy Synthes & Hand fracture system, Acumed</td><td>59
30 (K-wire)
29(Plates)
Mean Age: 27.5(k-wire); 29.4 (plates)</td><td>Operative time: 41 min (K-wire); 58 min (Plates)
Grip strength: 83% (K-wire); 93% (plates)
Rotational deformity: 6° (K-wire), 1° (Plates)</td></tr>
<tr><td colspan="6">The study was conducted to compare the outcomes of two different fixation methods for metacarpal fractures- intramedullary pins and locking plates. The study included patients that were treated with pins between years 2013 to 2015 and those who were treated using plates and screw between years 2016 and 2017. The outcome measurements used for analysis included grip strength, finger alignment/rotation, Disabilities of the Arm, Shoulder and Hand (DASH) score ad radiographic measurements. No cases of infection, hardware migration and failure were observed in both groups. The study observed number of advantages with using plates in terms of grip strength, range of motion, rotational deformity although operative time was higher. Better stability and reduced tissue irritation were observed with the low-profile plates used in the patients. As the study involves plates and its benefits compared to other fixation methods, the study will be highly weighted in the clinical review (Dreyfuss, 2019).</td></tr>
<tr><td>B. Zhang et al.</td><td>Comparison of AO Titanium locking plate and screw fixation versus anterograde intramedullary fixation for isolated unstable metacarpal and phalangeal fractures</td><td>Sep 2016</td><td>Intramedullary nails, AO titanium locking plate</td><td>147
76 (Intramedullary pin);
71(AO plate)
Mean Age: 34(Pin); 33(AO plate)</td><td></td></tr>
<tr><td colspan="6">The aim of this study was to compare the outcomes between AO titanium locking plate and screw and anterograde intramedullary fixation in fixation of metacarpal and phalangeal fractures. Patients were divided into their respective groups based on the treatment they were receiving. Follow-ups were conducted at week 1 and 1, 3 and 6 months. Outcome measurements for analysis included visual analogue scale (VAS) score, range of motion DASH score and grip strength. At a 3-month follow-up significantly positive and better results were observed in Intramedullary group compared to locking plate. However, over the time, these difference in the results were similar to the locking plate result at 6-month follow-up. Likewise, it was noted that the patients in the intramedullary group showed more signs of complications with time. This study suggests the importance and need for developing a device that is stable over a longer period of time than a device which outperforms in the first few weeks to fail later (Zhang et al, 2016).</td></tr>
</table>

2.8 Demonstration of equivalence to current devices

Table 4 Competitor analysis table to compare four key competitors in the market that deals with hand fractures. The key competitors identified were DePuy Synthes, Medartis, Acumed, and Biomet from which many similarities and different between the technology were observed.

		Removed due to copyright ownership.		
	Depuy Synthes LCP compact hand. Modular hand system	**Medartis** APTUS Hand	**Acumed** Hand Fracture System	**Biomet** A.L.P.S Hand Fracture
Material	Titanium	Pure titanium or titanium alloy (ISO 5832-3)	Titanium	Titanium (TiMAX)
Thickness		0.8 mm for 1.5 TriLock	0.8, 1.3mm	1.0, 1.1 mm (for 1.5mm plate) 1.65 mm (for 2.5 mm plate)
Phalanges	yes	yes	Yes	n/a
Metacarpals	yes	yes	yes	n/a
Carpals	yes	yes	n/a	n/a
Screw angulation	n/a	30°	30°	20°
Screw options	1.0, 1.3, 1.5, 2.0 and 2.4mm	1.5/2.0 TriLock screws (locking) 1.2/1.5/2.0/2.3 cortical screws (fixation)	1.5, 2.3mm hexalobe lag screw and hexalobe MultiScrews	1.3 mm non-locking 1.5 mm non-locking 2.5 mm locking
Plate range	*	*	*	*
*Refer to below details for range of plates and instruments used in competitors				

Depuy Synthes LCP Compact Hand *(Note: All figures shown below are retrieved from the respective competitors' surgical techniques)*

Plate Range:

1. Straight Plate 2.0/2.4
2. Adaption Plate 1.3/2.0/2.4
3. Condylar Plate 2.0/2.4
4. Rotation Correction Plate 2.0
5. T-Plate 2.0/2.4
6. Adaption plate
7. T-Adaption Plate 1.3/2.0/2.4
8. Y-Adaption Plate 1.3/2.0/2.4
9. Mini Condylar Plate 2.0
10. Mini-H Plate 2.0
11. Strut Plate 1.3

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Figure 3 Stress distribution with torsional load (yellow = increased stress) (Medartis Surgical Technique)

LCP combi-hole **Locking Hole** **Compression Hole**

Medartis TriLock 1.5 APTUS Hand

1. Straight Plate
2. T-Plate
3. Rotation plate
4. Double row T-Plate
5. Grid Rectangular Plate
6. Grid Trapezoid (6,8,10 holes)
7. Scaphoid Plate

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Figure 4 Stress distribution with torsional load (yellow = increased stress) (Medartis Surgical Technique)

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Figure 5 TriLock screw can be locked up to 3 times

Acumed Hand Fracture System

1. Compression Plate 0.8/1.3
2. Straight Plate 0.8/1.3
3. T-Plate 0.8/1,3
4. Offset Plate 0.8
5. Curved Medial/Lateral Plate 0.8
6. Avulsion Fracture Hook Plate 0.8
7. Metacarpal Neck plate 1.3
8. Rolando fracture hook plate 1.3
9. Rotational correction plate 1.3

Removed due to copyright ownership.

Figure 6 1.5mm (pink) and 2.3mm (Yellow) Hexalobe MultiScrews

Biomet A.L.P.S Hand Fracture

1. Straight Plate
2. T-Plate
3. Y-Plate
4. Web Plate
5. T/Y Plate

2.9 Clinical Studies

Articular fractures of fifth metacarpal fractures are very common among hand fractures which likely occurs from extra force applied on metacarpal head. The ideal treatment for the metacarpal intra-articular fractures is anatomic reduction and immobilisation depending on the severity of the fracture. These fractures are likely to result in posttraumatic osteoarthritis, pain and reduced grip strength. K-wires have been commonly used over the past years for fusions. However, they have been associated with complications such as pin migration and pin-tract infections. Likewise, K-wires require removal later down the years. These reasons lead to design of low-profile plates that were made to mitigate the adverse effects of K-wires. A study conducted by Yoshida et al. investigates both techniques-K wires and low-profile locking plate to compare the biomechanical stability of either (Yoshida, Obopilwe and Rodner, 2018). The study involved testing of 12 fresh frozen hand cadavers from six different subjects whose fifth metacarpal and hamate were dissected (Figure 6). Six hands were used in the K-wire group and their respective contralateral hands were included in the plate group. Two 1.6 mm K-wires were placed in a cross-pin configuration from metacarpal into hamate. A 2 mm mini locking plate by APTUS, Medartis with 2 unicortical screws and 3 biocortical screws was used in the plate group. The metacarpals were secured in the polyvinyl chloride pipe. The hamate was then loaded on the volar surface a rate of 0.01mm/s to failure Yoshida, Obopilwe and Rodner, 2018).

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Figure 7 Plate fixation in articular fracture. The images show the metacarpal fracture that causes an unstable bone and second image shows the fixation of the bone achieved using hand plate. (R.Yoshida, 2017)

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Figure 8 Stiffness of plate vs k-wire. It was observed that the stiffness was higher in the K-wire when compared to the plate mechanism (R.Yoshida, 2017)

The stiffness results of both devices after the biomechanical test was recorded (Figure 7). Similar results were observed in both techniques in terms of stiffness, peak force and energy to peak force. It was concluded from the study that low-profile plates are capable to providing of adequate biomechanical stability similar to K-wires. In addition to that, use of low profile mitigates the adverse effects of K-wires such as pin migration, site infection and need for removal. As removal is not needed for plates, it be advantageous to those patients who have a slower bone reunion due to lifestyle e.g. smoking, diabetes. The result cannot be completely used to assess the functionality of the implants. The results only provide the biomechanical response of the implants; the biological/clinical response of the implants needed to be tested to understand a wholistic behaviour. Likewise, the stability of the plate and K-wire was only tested in one mode of failure(Yoshida, Obopilwe and Rodner, 2018)..

D. Dreyfuss et al. conducted a study comparing the outcomes of locking plates and intramedullary pinning for fixation of metacarpal shaft fractures. Thirty patients included in the study were treated using Kirschner wire pinning and twenty-nine patients were treated using plates and screws by Depuy Synthes and Acumed hand system (Dreyfuss et al., 2019). The patients assessed one-year post-surgery where optimum extension and flexion were tested in each digit were examined and compared with the same in opposite hand. A hydraulic hand dynamometer was used to calculate the mean grip strength. The rotational deformity for the fingers were measured by observing the angle of rotation of the distal phalanx in a straight fist position relative to adjacent health finger. Disabilities of the Arm, Shoulder and Hand (DASH) score and radiographic images were used during the follow up to assess the outcome. It was observed that 82.1% of digits in the wire pin group and 91.4% in locking plate group has excellent range of motion. No infection, device migration or failure was recorded in both groups. Although, one patient in the wire pin group reported development of lasting stiffness in all fingers and as well as increased pain sensitivity (Dreyfuss et al., 2019).

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Figure 9 (b) shows the fifth metacarpal fracture treated using K-wire fixation (d) fifth metacarpal fracture treated using locking plate(D.Dreyfuss, 2018)

Results from the study suggests the advantages of using locking plates for fixation of metacarpal fractures compared to using pins for the same (Figure 8). While fracture reduction was observed in the groups equally, locking plates required a significantly longer operative time. As shown in results, locking plates were inferior to pins in terms of range of motion achieved. Using plate for fixing in the metacarpal region allows it to be positioned by extensor tendon retraction instead of tendon split. This also avoids disruption of joint capsule and screw penetration through the head of the bone. The low-profile locking plates which were used in the study were found to provide more mobilisation during fixation. Patients that were treated with the pins were found to have rotational deformity, some of which might be due to the fact that the pins were fixed with no locking device. It was also noted that, those with rotation in the middle or fourth metacarpal had a slightly higher mean DASH score. The study concluded that, based on the results collected, locking plates and screws are better in fixing metacarpal fractures when compared to wire pins. The technology provides better stability, early rehabilitation, reduced risk of malrotation and reduced tendon irritation (Dreyfuss et al., 2019).

While the success rate of using locking plates for fixation of small bone fractures is high, there are complications that need to be considered when designing the plates. The length of the plate used at the fracture site has a significant role in allowing flexions and extensions. In a study with a 35-year old man who fractured his third and fourth metacarpal. The third metacarpal was treated using 0.8 mm thick, 1.7 mm nine-hole plate with 5 self-tapping screws and the fourth metacarpal was treated using a 0.8 mm thick 1.7 mm six-hole plated with 4 self-tapping screws(Dreyfuss et al., 2019).

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Figure 10 Plate Fixation in metacarpal bone. Different length plates were used in different metacarpal bones results in different outcomes and has a different rate of healing (D.Dreyfuss, 2018)

While the fourth metacarpal was fully healed, the third metacarpal showed a 30% loss in flexion. This deficit in the movement was likely due to the how close the fracture site was to the capsular insertion as well the length of plate (Figure 9). While the long plate was efficient in achieving reduction, it led to limiting flexion which resulted in limiting the range of stretch for extensor tendon. Another factor that needs to be considered is the metacarpal shortening. A 7° loss in extension was observed with every 2 mm of shortening. The loss of extension tolerance is 20° indicating that the maximum acceptable shortening of metacarpal is 5-6mm (Dreyfuss et al., 2019).

The insertion of the extensor carpi radialis longus and brevis must be taken into consideration during the procedure. These are connected to the bases of second and third metacarpals while the fourth metacarpal does not have these attachments. Deforming forces in the tendons can result in dorsal shaft angulation and misplacement at the site of injury. The tolerance for dorsal angulation is 15° for fourth and fifth metacarpal and 10° or less for second and third metacarpal. Studies show that dorsal angulation of 30° or more can result in low grip strength. The extension of the proximal interphalangeal joint (PIP) must not be overlooked when the metacarpal phalangeal joint (MCP) is fully flexed/extended.

Four-corner fusion is a commonly used procedure used in fixing fractures in the wrist (Figure 10). The procedure is intended to provide grip strength, preserve motion while reducing the pain present (Gonzalez del Pino et al, 2012). J.G Pino et al developed a novel system that improved precision in positioning and fixation of the midcarpal joint using four corner fusion- Variable angle locking intercarpal fusion system. The system targeted the main complications revolving the midcarpal fixation plates which include non-union, hardware failure and wrist impingement. Similar plate has been designed and manufactured by Synthes- Variable Angle Locking Compression Intercarpal Fusion Plate (VA LCP ICF Plate). A study conducted by C.Eder et al. investigated the radiological clinical outcomes as a result of using the Synthes VA LCP ICF Plate. 11 patients (6 male; 5 females; mean age: 53.27 years) who had undergone the

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Figure 11 Synthes VA LCP ICF Plate Four-corner fusion plate was used to treat carpal bone fracture stabilisation manufactured by Synthes(J.G Pino, 2012).

treatment with Synthes plate were studied out of which 6 patients agreed for further studies (Gonzalez del Pino et al, 2012).

In short-term evaluation after three months, five out of six patients did not show any complications. However, one case of broken screw was observed which is assumed to likely be due to incompliance with postoperative treatment. Seven patients agreed to taking further data using the Case Documentation Form (CDF). The form was used to produce more detailed explanation of (i) dorsiflexion deformity of the lunate (ii)carpal height and (iii) Ulnar wrist translation. The form also assisted in assessing subitems of a procedure such as the reaming guide in Synthes procedure which adequate fit of plate, holding strength, ease of reaming, reaming depth and ease of handling all of which were rate good on a scale of excellent to poor (excellent-good-satisfactory-poor). The results for final stability assessment was rated excellent in four cases and good in three. In long-term evaluation, it was seen that four patients encountered carpal collapse in their dominant hand and two cases with the same in non-dominant hand. The study also compared Synthes locking plate with other types of similar fixation. The two main procedures for stage II carpal collapse are proximal row carpectomy (PRC) and midcarpal arthrodesis (MCA). Studies have shown favourable results for PCR in terms of ease of procedure. It was noted that, one of the studies indicated higher rate of secondary operation for four corner fusion compared to PRC mainly due to high rate of non-unions and hardware failures. The result for Manchester-Modified DASH score showed an average of 41.5 points. In the operated hand, the average dorsal extension was 54.17°, flexion of 45.83 °, ulnar abduction of 26.67 ° and radial abduction of 24.17 °. The study also indicates that non-locking plates, when compared to locking plates have a higher rate of complications such as plate migrations, implant failure etc (Figure 12) (Gonzalez del Pino et al, 2012).

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Figure 12 Grip strength results of operated versus non-operated hand in 6-month follow up. Results showed varying numbers between the patients contralateral and operated hand with a higher strength in operated hand for two patients and for others, non-operated hand showed higher sterngth (J.G Pino, 2012)

The scapholunate ligament which a scaphoid plays an important role in maintaining the normal functions of the wrist and allowing full range of motion with no pain. Tear in this ligament needs to be fixed with immediate response to prevent adverse effects due to degenerative changes in midcarpal articular surface. S.Odella investigated the effectiveness of four-bone arthrodesis using a dorsal locking plate for fixation of stage III scapholunate collapse/ scaphoid non-union. The study included twenty patients with a mean age of 53.1 years who were treated by dorsal locking plate (Odella, 2018). The following deliverables were tested: grip strength, range of motion, pain, Disability of the Arm, Shoulder, Hand (DASH) score. The study included three different types of dorsal locking plates- Medartis arthrodesis plate 2.0 (5 patients), Acumed Hub-cap TM (10 patients) and KLS Martin Flower plate (5 patients). The average follow-up was 6 years and the average DASH score was 16.6±11 points. The Mayo wrist score was measured among the 20 patients where it was good for two patients, fair for sixteen patients and bad for two patients. The 2 patients with a bad Mayo wrist score showed a reduced range of motion after surgery. The average range of motion in flexion and extension was respectively 42°

±18.5° and 37°±12.7°. The results did not show notable differences between the different plates used. The plates used in the study showed satisfactory clinical results in terms of DASH score, low rate of complications and need for revision surgeries. It was noted that, for the range of motion in a four-bone arthrodesis to improve, a good lunate reduction is recommended(Odella, 2018).

2.9.1 Biomechanical Studies

Various biomechanical tests have been conducted to test the stability of locking plates in comparison to many other fixation methods for hand fractures. E.Melamed et al. in 2016 conducted a biomechanical study that investigated the stability of intramedullary headless screw (IMHS) and plating technique in fixation of unstable metacarpal shaft fractures (Melamed et al. 2016). The hypothesis of the study was that the intramedullary screw will provide inferior stability over plate implantation. The specimens were grouped into five groups based on the treatment they received- 1.5 mm non-locking plate, 1.5 mm locking plate, 2.0 mm non-locking plate, 2.0 mm locking plate and 2.4 mm short cannulated IMHS. Forty-four metacarpal (second to fourth digits) cadavers harvested from 8 human cadavers were used for biomechanical analysis. Specimens were prepared with 3 mm volar gapping mid-shaft osteotomy (Figure 13). Groups 1-4 were plated with DePuy Synthes plates with specifications mentioned above. All treatment instruments were manufactured from stainless steel (Melamed et al. 2016).

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Figure 13 2.0mm locking plate test set up. The biomechanical test was conducted in 8 cadavers which were prepared with 3mm volar gapping mid-shaft osteotomy(E.Melamed, 2016)

All specimens were tested to failure in 4-point bending test apparatus which fixed in a servohydraulic test machine. The apparatus was set up in a manner that will keep the dorsal cortex facing down always.

All IHMS implants failed at the screw-bone interface while one specimen was noted to have failed in the 1.5 mm and 2.0 mm non-locking plate group. Three specimens in the 1.5 mm and

2.0 mm locking plate groups too failed at the screw-bone interface. The highest mean load to failure was for 1.5 mm non-locking plate with 364 ± 130N and the lowest load to failure (LTF) of 75±20N occurred in the IMHS group. The mean LTF for other groups are shown below (Figure 14).

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Figure 14 Average Load to Failure data. Results showed a higher LTF in non-locking plates and lower LTF in locking plate and Intramedullary nails. (E. Melamed, 2016)

The table below shows the stiffness data among the 5 groups (Figure 15). 2.0 mm Locking plates had the highest stiffness of 135±16 N/mm and lowest stiffness of 55±15 N/mm was observed among the IMHS constructs. It was also noted that 1.5mm and 2.0mm non-locking plates had a lower stiffness compared to the 2.0 mm locking plate group. The study concluded that the IHMS offers significantly lesser stability compared to plate fixation (Melamed et al, 2016).

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Figure 15 Average Stiffness Data. The highest stiffness was shown in 2.0mm locking plate as expected and lowest stiffness was observed in intramedullary nails. (E, Melamed, 2016)

In 2012, Stephanie D. et al. conducted a study to analyse and compare biomechanical characteristics locking plates with TriLock system and non-locking plate for fixation of diaphyseal metacarpal fracture. Freshly frozen pig metacarpals which were prepared from hooves stored at -20°C were used for the study (Figure 16) (Doht, S et al. 2012). The pig metacarpals have similar biomechanical qualities to human metacarpals and minimal difference in inter-specimen structure. Majority of metacarpal fractures occurs in adults from 15-34 years. Human cadaver bones were not used in this study as most bones from donors are osteoporotic and hence not ideal for biomechanical tests. All tests were conducted using Zwick Roell Z020 testing machine. In metacarpal bones, the bending forces are greater than extension forces. Therefore, to replicate this, a physical bending stress was simulated using a three-point bending test model and load was applied on dorsal apex at 100mm/min. The maximum load and stiffness in a load to failure was tested for all samples. The fracture pattern was reproduced using a biomechanical fracture model, where the oblique shaft fracture was produced by bending a metacarpal bone over an edge by dorsal force application.

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Figure 16 Different Plate design for testing products (Stephanie D, 2012)

The test comprised one non-locking linear plate and three locking plates using TriLock interlocking mechanism where each group had ten bones. In the first four groups with a non-locking linear and locking linear plates of 22 mm length and 1mm diameter were tested. The results for seven groups in terms of maximum load and stiffness(Doht, S et al. 2012).

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Table 5 Results of maximum load and stiffness for seven groups. Maximum load was observed in locking double-row eight hole plate fixed with eight monocortical screws with a low stiffness. Highest stiffness was observed in locking linear plate with four bicortical screws (Stephanie D, 2012)

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Figure 17 Maximum load and stiffness for 7 groups- non-locking linear with monocortical, non-locking linear with bicortical, locking linear with monocortical and bicortical screws as well as locking double plate with different holes(Stephanie D, 2012).

A significant difference was seen in maximum load results when comparing the two linear plates with bicortical fixation (group 2 and group 4). The maximum load in group 2 was also higher relative to group 5, locking double-row plate with six holes (Figure 17). The highest maximum load was recorded in group 6, locking double-row plate with eight holes fixed with four screws. No significant difference was observed between the seven groups in terms of stiffness (Doht, S et al. 2012).

2.9.2 Conclusion: Risk/Benefit Analysis

A review of literature shows that mini-fragment hand plates are a state of art treatment for small bone fractures. The most common alternative to hand plates is Kirschner wire, however plates are considered superior to K-wires as they provide better stability, early rehabilitation and reduced tendon irritation. K-Wires have been associated with complications such as pin migration and pin-tract infections with need for pin removal in later years. The low-profile feature in plates mitigates the need for plate removal.

A prospective study conducted compared the outcomes of locking plates and intramedullary pins. The results showed excellent range of motion for digits in both groups (82.1% digits in wire pin; 91.4% in plate). Although no infections or migrations were recorded, one case in the pin group reported development of lasting stiffness in the fingers with increased pain sensitivity. It was also noted that despite the advantages of plates over wire pins, locking plates require a significantly longer operative time. Patients who were treated using pins were found to have rotational deformity, some of which might be due to absence of locking device.

The length of the plate used in fixation of fractures have a significant effect in allowing flexions and extensions. A study compared the differences in outcome between two different lengths-nine hole plate for third metacarpal and six-hole plate for fourth metacarpal both 0.8 mm thick. Results showed a 30% loss in flexion for 9-hole plate used in third metacarpal although it was efficient in achieving reduction. The dorsal shaft angulation which occurs due to deforming forces in tendons was 15° and 10° in the fourth and third metacarpal respectively. Studies have shown that a dorsal angulation of 30° or more can result in low grip strength.

Another type of plate identified in this clinical review is a four-corner fusion plate used for midcarpal/wrist fracture fixation. One of the prospective studies conducted showed higher complications such as plate migration, implant failure etc. in non-locking plates when compared to locking plates. Out of the two main procedure for stage II carpal collapse (proximal row carpectomy (PRC) and midcarpal arthrodesis), studies showed favourable results for PCR in terms of ease of procedure. Likewise, in another study of similar plate design, the Mayo wrist score measured was good for 2 patients, fair for 16 patients and bad for 2 patients. All plates tested (Medartis arthrodesis plate, Acumed Hub-cap TM and KLS Martin Flower plate) showed satisfactory clinical results in terms DASH score, low rate of complications and need for revision surgeries. A good lunate reduction is recommended for an improved range of motion in a four-bone arthrodesis.

Biomechanical tests have been conducted across various plates and fixation devices. A biomechanical study which compared the effects of intramedullary headless screw (IMHS) and plating technique showed significant difference between the two. All IMHS implant failed at the screw-bone interface and one implant in the non-locking plate group. Highest load to failure (LTF) was observed in 1.5 mm non-locking plate (364 ± 130N) and lowest LTF in IHMS (75±20N). Highest stiffness was observed in 2.0 mm locking plates (135±16 N/mm) and lowest in IMHS (55±15 N/mm). In real world, target values for stiffness and load to failure can be different varying from person to person and physiology. Therefore, although results showed a superiority of plate fixation over IHMS, biomechanical test on cadavers alone cannot be used to derive a reliable conclusion.

2.9.3 Identification of Gaps and Key focus

Design of implant technology is a progressive field that has a potential for adapting new designs or even improving current systems to optimise clinical results. Literature review conducted for this project indicated improvements in the following areas:

i) Low profile plates are a preferred method of fracture treatment by surgeons. They have been clinically proven to be better performing when compared to other methods such as K-wires.

ii) Angulation of plate: studies have shown that angulation of 30^{o} or more can result in a lower grip strength. Hence the maximum value of angulation targeted should be 30^{o}.

iii) Lengths: Length of plate is an area that needs to be looked at further as there are studies which suggest longer plates being more reliable in fracture reduction, however they limit flexion. Hence, more technical study is required for length of plates.

iv) Different locking mechanisms: Although various sizes, angles and materials of the plates have been tested, very little has been explored in different types of locking mechanisms. Different types of locking mechanisms could be tested against each other to identify the most suitable mechanism.

The project will incorporate modifying and optimising the above areas as well as designing as per client specifications.

3 Aim & Methodology

Aim

The aim of this project is to design and develop a locking mechanism for hand plates for fracture fixation adhering to the 2.9.3 Indications for gaps and key focus. As indicated, investigating different types of locking mechanism-tapered threaded, parallel threaded and spline, will be a key focus as this has not been investigated thoroughly according to the clinical studies conducted. As this is an industrial project, the requirements and preferences of the client will be prioritised for the benefit of company. The angle, thickness and length of the plates, when the project progress, will be recommended to the client based on the literature review. Final design will be based on testing results and client feedback.

The mini-fragment hand project was undertaken in collaboration with Austofix Pty Ltd, a company specialised in design, development, manufacturing, and distribution of orthopaedic devices. Development of locking mechanism for hand plates was specifically initiated by Dr Damian and Graham, a leading surgeon practising in New South Wales. All design requirements were firstly consulted with the primary stakeholders, Dr Damian and Graham. and meetings conducted were based in Sydney and Adelaide. The design developed was discussed with the team technical design coordinator Nirmal Menon prior to sending it off to the manufacturer.

All designs were modelled in Solidworks which is a computer-aided software that assists with mechanical modelling. Prior to commencing the project, a basic knowledge in Solidworks was acquired with regards to basic modelling and drawing features which required to model the prototypes. The design specifications were based on the information from surgeon as well as clinical literature reviews.

3.1 1.5 mm Locking Screws

Locking screw technology is an integral feature in medical implants which has grown and been used significantly. Using a locking screw instead of conventional screws has shown many advantages over the use of the conventional screw types. Firstly, conventional screws demand a precise adaptation with the contacting implant. Imprecise contact of the screw with the plate will result in alteration of the osseous segments and draws the bone segments toward the plate. Locking screws, on the other hand, does not require the plate to contact the underlying bone precisely. Rather, when the locking screw is tightened, they automatically lock into the plate stabilising the bone segments with minimal compression. Thus, the locking screws do not cause disruption to the cortical bone perfusion as there is less compression. Locking screws also have an advantage of being unlikely to loosen from the implant. This is an extremely useful feature across fracture sites especially with the use of bone grafts where loosening will not occur during the graft implantation and healing. For the same reasons, there is a very minimal chance of inflammatory complication. When inserting the locking screw into the plate, the threaded locking head of the screw engages and locks into the hole of the plate securing the plate in position. The use of conventional screws applies pressure on the plate against the bone which generates friction that is needed for stabilising the plates (Figure 18). The Locking head screw, however, does not have an intimate contact with the plate (Figure 19). In this case, the loading forces are transmitted are transmitted to the plate from the screws. Using locking technology allows the screws to lock into the plate as well as the bone at the same time providing high mechanical stability (Homsi et al 2020).

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Figure 18 Conventional Screw Locking Method. The conventional screw applies pressure on the plate against the bone which generates friction needed for stabilising plates (Homsi et al, 2020)

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Figure 19 Locking Screw locking method. The loading forces are transmitted from plate to the bone. This technology helps lock the plate into the bone firmly (Homsi et al, 2020)

From the clinical literature review, it was seen that locking plates had the most preference over other methods for the highly positive result it had shown over clinical tests conducted. Given the advantages of locking screws and as well as the requirements from the primary client, this project has initially focussed on developing a locking screw. The locking screw designed is only for initial testing purposes after which, depending on the test results, more variations will be designed. The locking screw designed in the first stage is a 1.5 mm Locking Screw using Solidworks. The screw designed was modelled to have a twin start locking shaft and a triple start locking head. Multiple start threads are widely used medical implants for various reasons. A multi-start thread comprises two or more intertwined threads which run parallel to each other. This intertwined pattern increases the lead distance of the thread while maintain the pitch.

Multiple start thread will allow more contact surface engagement with the plate in a single rotation (Figure 20).

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Figure 20 Multi-start thread example. The lead of the thread is equal to the pitch multiplied by the number of threads. Therefore, in a single revolution, there will be multiple threads.

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Figure 21 Multiple Start Thread

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Figure 22 Step 1: Base Dimensions were created in Solidworks. All height dimensions were halved as the first step was a base revolve to achieve the full size.

The first and the most important step to modelling a locking screw was to create and identify the base dimensions (Figure 22). The screw part name was defined by the shaft diameter i.e. the shaft diameter of the modelled is 1.5mm, which means the part name is 1.5 mm Locking screw. The first step involved using a revolve base feature along the centreline. Hence, all dimensions referring to the height were half the size because, when using the revolve feature, these dimensions will double up. For instance, the 1.15 mm (circled in red) dimension will equate to 2.3 mm after the revolve base which makes the locking head diameter. There is an 8° taper in the locking head, which is an essential design feature that allows rigid locking of the screw into the plate. The 1.02 mm length defines the length of the drill point. A 45° angle was provided to later incorporate the hex feature onto the screw.

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Figure 23 Screw Blank Model: created from base dimension using Base Revolve feature. The main dimensions such as length, major diameter of shaft and head were defined using these base dimensions

The blank model of the screw (without the threads) after the base revolve feature applied is shown above (Figure 23). This configuration is used in drawings to define overall length and width dimensions. The screw modelled was of 18 mm length and is subject to vary according to customer preference after design testing and release.

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Figure 24 Cortical Thread Start Plane: Used as a point of reference to start the helix of the shaft to cut threads out.

After the blank screw was modelled, a plane was created to start the cortical thread from the end of the shaft (figure 24). This plane is used as a starting point for the helix of the 1.5 mm shaft.

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Figure 25 Shaft helix from cortical thread plane. The helix was created using a 1.5 mm major diameter and 0.8 mm pitch.

Using the previously added cortical thread start plane as reference, a helix was created as shown to just finish slightly before the edge of screw head(Figure 25). The desired pitch of the shaft thread is 0.4 mm with a twin start thread. This means that the lead of pitch must be twice the pitch i.e. 0.4*2=0.8 mm.

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Figure 26 Thread Profile for Shaft: Defines the minor and major diameter as well as the thread profile which is used to cut through

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Figure 27 After thread profile is cut through. The cut-sweep feature was used to cut out the thread profile around helix in previous steps. This image reflects the single start with the given helix pitch and lead.

Followed by the helix feature, the helix thread profile (Figure 26) was cut out using the cut-sweep feature in Solidworks. The helix in the previous step was used as the profile to cut out the shape. It can be seen that the threads are far apart from each other. This is because, by far, the helix has a lead that is double the pitch, however, it is single start. In order to apply a twin-start thread, a circular pattern feature was applied to the shaft which resulted in a twin-start shaft thread.

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Figure 28 After twin start is applied: This was achieved by the using a circular pattern of the cut-sweep before which creates another start for the thread.

Once the shaft threads were finalised, a similar method was used to create the locking head thread. The helix however had to be constructed slightly differently. As mentioned earlier, the locking head of the screw has a flat surface till about 0.3mm and then later tapers down at an angle of 8°.For this reason, a straight helix cannot be used to model the threads in the locking head. The parameters shown in the below image was used to create the helix shape. As mentioned earlier, the locking head has a triple start which means that the lead will be three times the pitch i.e. for a desired pitch of 0.4mm, the lead will be 0.4*3=1.2mm. While the pitch was kept constant throughout, the height at which the diameter changes was specified in the table (Figure 29).

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Figure 29 Helix Parameters. A variable pitch was used in this part as a smooth running out of the thread is required.

The profile used for the locking head is different to that used for locking shaft (Figure 30). The screw major is 2.3 mm and the minor was based off from the thread chart standard. A tolerance of the thread minor for the M2.3 x 0.4 mm was provided in the thread chart from which 1.98 mm minor was used. Other dimensions for the thread profile was calculated based on the thread minor and thread major used. The profile create was used in the cut-sweep feature using the helix as a profile to cut out the desired thread.

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Figure 30 Locking head thread profile. This profile is different to the shaft profile. The profile used is a standard profile for the screw.

The thread form created using the first cut-sweep feature had only provided a single start thread (Figure 31)with an increased lead. The three thread starts are created using the circular pattern as in previous step.

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Figure 31 Single start thread: The helix lead was triple the pitch as the head is a triple start head.

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Figure 32 Triple start thread. A circular pattern was used to create 3 starts for the thread cut out.

The thread forms modelled were rechecked using Solidworks features which will be discussed in *4.0 Results and Analysis* section. Once the thread forms were finalised, the hexalobe feature was incorporated into the model. A T4 hexalobe (Figure 33), was modelled as per ISO standard at the face of the screw head. A cut-extrude feature was used to cut the hexalobe to depth of 0.8mm.

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Figure 33 Hexalobe Feature. The dimensions for hexalobe were derived from the ISO Standard that defines the radii, minor and major dimensions. This feature was then cut in the thread to fit the T4 screwdriver.

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3.2 Variable Angle Screw Technology (VAST) Button

Variable Angle Screw Technology (VAST) Buttons were the first part designed in this project. VAST buttons usually represent the anatomic plates which are used in the fracture reduction process in hand fractures. The locking technology is firstly designed within the button which undergoes several rounds of testing which is then incorporated into the plate design. In this way, the design will be more accurate and precise. The button interacts with the locking screw in a fixed and variable angle, where the locking screw is expected to cut into the test buttons. From the competitor analysis that was conducted in clinical literature review, it was found that the average plate thickness ranged from 0.8 mm to 1.65 mm. In order to provide design that is highly competitive in the market, the button was first made to 0.8 mm thickness. Three different types of buttons were decided on for the initial testing stage to determine optimum features and dimensions the plate. The three types decided on were – (i)Threaded parallel button, (ii) Threaded Tapered Button and (iii) Spline Button.

3.2.1 Threaded parallel button

The threaded parallel button provides the most commonly used locking system between the competitors. It is a parallel threaded hole designed to accommodate the locking screw. This part was achieved by using a range of Solidworks features. The first step for modelling the threaded parallel button was to extrude a circular surface with the thickness of 0.8 mm, which is the desired thickness of the button. The diameter used for this button was 7.5 mm which is the correct size suitable for the testing gigs as well as large enough to handle by hand (Figure 34).

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Figure 34 Step 1- Extrude a surface

Followed by the extrusion, four external flutes were created using cut extrude feature. These cut-outs do not significantly affect the functionality of the button. However, the flutes around the button reduces the material required in the manufacturing stage which in turn reduces the cost involved (Figure 35).

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Figure 35 Step 2: external flutes were creates to aid visually better and well as to minimise maximum possible material without compromising on the mechanical strength.

Followed by the external cut-outs, the pilot hole for the threaded hole was created. A 1.80 mm hole was created to cut out the minor pilot hole. A smaller hole with a diameter of 0.9 mm was created for testing purposes (Figure 36). This hole functions as a test point at which a testing jig is placed.

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Figure 36 Step 3: Pilot hole and test hole. The pilot hole is for the threads that are to be cut out in next steps and the test hole is design to act as a reference of direction and position.

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Figure 37 Pilot Hole Profile which define the minor diameter for the threads and a chamfer to ensure smooth insertion of screw. A cut revolve was used to cut the feature

The profile was later modified to have a chamfer of 1mm height and 35°(Figure 37). The reasoning behind this will be discussed in *3.4 Results and Discussion* section. This profile was then cut-out using cut-revolve feature in Solidworks. The profile was revolved along the centre axis.

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Figure 38 Helix profile with a pitch of 0.4 and lead of 0.8mm was used to achieve a twin start thread

The helix profile (Figure 38) was created with a pitch of 0.4 and a lead of 0.8 mm. The lead was double the value of the pitch as the desired thread type is a twin start thread. It is notable that the locking feature in the VAST button is a twin start thread and the locking head has a triple start thread. This was designed in such way that these distinct featured of the parts allow them to lock the screw more securely into plate as it will cut more into the plate.

Below image (Figure 37) shows the thread profile used to cut the thread in the plates. This profile was designed to match the thread profile of the locking head M2.3x0.4. The thread dimensions were derived from the ISO thread form standard. The profile was pierced into the helix which was created in the previous step. A cut-sweep feature in Solidworks was used to cut the thread form using the helix as a profile. Similar to the screw model, the cut-extrude feature was patterned twice using circular pattern feature to create the twin thread form. The second image shows a section view through the central axis to show the thread forms (Figure 39).

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Figure 39 Locking plate thread profile

3.2.2 Threaded Tapered Button

The outer profile of the tapered button is very similar to that of the threaded button. Therefore, most of the steps until the inner thread profile is exactly the same (Figure 40).

Removed due to copyright ownership.

Figure 40 Outer profile of tapered button similar to parallel button

Removed due to copyright ownership.

Figure 41 Tapered pilot hole- a 10º taper was added in the pilot hole to create a taperd helix and thread feature

The difference between the parallel and tapered button primarily differs in the step shown above (Figure 41). A 5º outward draft was added to the pilot hole to add a taper. There is no significant difference visually between both the buttons as the angle is very small. However, it is assumed that there will be a significant difference between the test results of both types of buttons. The helix and thread profile used for the tapered button is exactly the same as the parallel threaded button.

3.2.3 VAST Spline Button

The spline button uses a different locking technology to securely lock the M2.3x0.4. The outer profile of the spline button is the same as the threaded buttons. The outer profile of the button was created by extruding a 7.5 mm circular sketch (Figure 42).

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Figure 42 Step 1- Sketch outer profile

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Figure 43 Step 2- Extrude circular profile using boss extrude feature

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Figure 44 Step 3- External cutting flutes

The below image shows the profile used to define the spline hole dimensions (Figure 45). These dimensions are extremely critical to the functionality of the spline and its interaction with the locking screw. The profile was then cut using cut-revolve feature along centre axis. Point 1 and 35° in the image below defines the chamfer within the button that allows the screw to insert smoothly into the button especially when inserting at 15° angle. Dimension 2, 1.04mm, is the point at which the screw starts cutting into the button. Dimension 3, 6.28°, which tapers down ensures adequate locking of the screw as the screws cuts the button more along the taper. Dimension 4 (0.96mm) ensures that the screw does not penetrate through the button. Dimension 5, 16.5°, provides enough clearance for the screw when it is inserted at its maximum angle of 15°. For instance, if the 16.5 is 10°, the screw will hit the bottom surface before 15° angulation. The section view of plate below (Figure 46) shows the spline hole after the cut-revolve feature is applied.

Figure 45 Spline Profile

Figure 46 After cut revolve of spline profile

Removed due to copyright ownership.

Figure 47 First Spline of the spline hole was create to act as reference for the other splines

The first spline in the spline hole is created by using the revolve cut feature on a rectangular sketch on the same plane as the sketch of the spline hole (Figure 47). This rectangle sketch was angled at approximately 10° to create a recess at an angle. This recess was then mirrored and patterned around spline hole to create 5 splines of equal dimensions (Figure 48).

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Figure 48 After all splines are created: within the structure, there are splines which are pointing features and recesses. Depending on the direction at which the screw is inserted it can go into the spline or the recess.

4 Results and Analysis of Designs

Prior to finalising prototype drawings, the parts modelled were assembled together in Solidworks. Solidworks assembly clearly depicted the interaction between the VAST buttons and locking screw and they well they locked in with each other. There were many potential collisions that were observed between the parts in the assembly that will be discussed in this section.

The below image shows the assembly of locking screw in threaded parallel button (Figure 49). One of the first issues detected while inspecting the assembly was the screw thread failing to run out smoothly as shown with the two marked positions. Thread runout in a screw creates a smooth transition within the screw and mitigates any issues in manufacturing. Thereby, the smooth runout of the thread was achieved by changing the helix diameter of the locking head. In the table helix table, the diameter at the edge of the screw head was increased which resulted in smooth runout.

Removed due to copyright ownership.

Figure 49 Screw helix not running out smoothly. Failure to run out smoothly will result in sharp edges and manufacturing inaccuracy.

The crest width of a screw is the surface of the screw that interacts with the major diameter of the screw and minor diameter of the button. While analysing the locking screw, it was noted that, the crest width of the locking screw was inconsistent throughout the thread (Figure 50). Although this may not seem like a significant difference, in screw as small as 2.3mm, any minor difference can affect the screw optimal functionality. Intersection curve is a feature in Solidworks that was used to convert the lines where threads meet to analyse the inconsistency in crest width. This inconsistency mainly occurs due to the helix shape and diameter throughout the thread. Hence, altering the helix diameter was the solution to achieving the consistency.

Removed due to copyright ownership.

Figure 50 Crest width using interference curve. Inconsistent crest will result in inconsistent locking with the button. Some points will be tighter than others in the button.

The helix parameters of the screw were changed in Solidworks as shown below without changing the pitch using a trial and error method (Figure 51). Consequently, the crest width across the thread was made consistent.

Removed due to copyright ownership.

Figure 51 Consistent crest width achieved by changing helix

Having the option of 15° variable angle either way was one of the requirements proposed by the proposed by the client. For this reason, whenever a screw was placed in all different types of buttons, the interaction of screw with the button is analysed at both 0° and 15°. The first image shown below shows the screw placed at a 0° angle straight through (Figure 52). No significant issues are visible at this point. However, as soon as the screw was placed in a 15° angle (Figure 53), the screw minor had started colliding with the thread minor of the button. The solution to this was to either decrease the thread minor of the screw or increase the thread minor of the pilot hole. Based on earlier issues that had occurred regarding the screw crest width, changing the minor of the screw can affect the crest width of the screw. Therefore, a safer and easier option was to increase the pilot hole diameter by 0.1mm from 1.80 to 1.90 mm.

Removed due to copyright ownership.

Figure 52 Screw at 0 º

Removed due to copyright ownership.

Figure 53 Screw at 15 º angulation. At 15º the minor diameter of screw and button and clashes with each other. Therefore, one of the two needs to be reduced to mitigate the clash.

When analysing the screw, another issue that came up was the thin wall section that was visible between the hexalobe feature and the screw wall. The below image shows the section view of screw cut along the front plane. When measured using Solidworks evaluation tools, it was noted that the wall thickness at the specified point was only 0.8 mm, which is too thin (Figure 54). This meant that there is a high chance of the screw breaking at that point when load is applied for a constant time. A wall section of 0.3 mm at least is needed for that wall thickness to be stable under pressure. This could have been only achieved by reducing the depth of the hexalobe which was initially 1.01mm.

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Figure 54 Thin wall section of the hex feature. This will cause the screw to easily break under pressure/force

A research on competitors with hexalobe screws was conducted to find the minimum depth needed for the hexalobe. A competitor with a T10 hexalobe was identified to have a depth of as low as 0.07mm. Therefore, it was deduced that the depth could be reduced enough to have a satisfactory wall thickness. However, the shallower the depth, the higher the chance the screwdriver slipping off the screw. Hence, the thickness was reduced to 0.7 mm which gave a wall thickness of 0.41 mm which is within the satisfactory range as shown below (Figure 55).

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Figure 55 Wall thickness increased by reducing hex depth to 0.7mm

Initially, the button thickness was made to 0.8 mm to replicate the thinnest plate in the competitor range. However, the button thickness had to be increased to fit a test gig. All buttons used for locking systems in different parts of the body are tested using the same jig shown below. For the button to be held firmly in the jig, it was needed that the button needs to be slightly thicker than gap shown using the red line. The gap in the testing jig is 1.05 mm (Figure 56). Therefore, the button in later stages was modified to be 1.3 mm instead of 0.8 mm. All threads and helix diameters were adjusted accordingly. The button thickness, however, had to be modified again to suit manufacturer needs. It was advised by the manufacturer that the material available for manufacturing is only available in 2 mm thickness.

Removed due to copyright ownership.

Figure 56 Testing jig for button set up

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Removed due to copyright ownership.

Figure 57 Direction of screw insertion. There is a good chance that the surgeon will insert at different positions depending on which the insertion of the screw is smooth or hard.

The image above comprises the angulation of screw at 15° and different coloured lines that depict the centre axis of the button (red), angled centre axis of button (green) and centre axis of screw (blue) (Figure 57). It is very critical to understand the possibilities of direction at which the surgeon may insert the screw into the plate. The ideal position for inserting the screw is via the green axis. However, if the surgeon inserts the screw via the blue axis, it is clear from the image that the screw head will collide with the surface of the button while inserted. If inserted with more force, it can potentially damage the plate. As this situation is a scenario that potentially arise, in order to minimise the risk associated with the angled insertion, a larger chamfer was added to the threaded button (modified designs are shown in methodology section).

4.1 Limitations and Challenges

There were a number of challenges and limitations that were encountered throughout the project that has slightly affected the output of the project in the given timeline. One of the key limitations in this project was the challenges that were brought forth by Covid-19 pandemic. The initial design stage was delayed by a few weeks due to the other project delays in the company. The delay in the design stage was compensated by focussing more on clinical literature review prior to the design stage. For the same reasons, there has been delays in manufacturing and arrival of testing samples. Hence, the testing has not happened yet. The feasibility of the designs henceforth is only theoretically assessed and not yet tested fully.

Another challenge that was faced during the project was the lack of experience in designing hand implants. Anatomy of hand and hand fractures needed to be fully understood prior to designing the buttons and screws. Each part of the human body has different requirements in terms of implant size and anatomic fit. Therefore, when modelling the screw and button, thorough research is needed about the muscles and bone structure to determine the implant thickness, length etc. One of the other limitations noticed was the degree of the analysis that can be done in Solidworks prior to sending to the manufacturers. There is a very limited number of analysis technique that allows to accurately assess the parts interacting with each other. This leaves an ambiguity to a certain level for the results. A significant amount of time was spent on drawings of the parts. The tolerancing requirements in drawing is different for each manufacturer. Since, very small parts are dealt with, tolerancing in the drawings are extremely critical. The smallest change (even of 0.02mm) can result in significant changes.

There have been limitations from the manufacturer that had demanded changes in the part details. One of the limitations was the availability of material. It was advised by the manufacturer that the material available for buttons is only available in 2 mm thickness. The buttons were originally made in 1.3 mm thickness. However, due to this request, there thickness had to be changed 2 mm. Consequently, extra time was taken to adjust dimensions in the thread, helix, and splines accordingly.

5 Current Status and Future Work

Currently, all parts which include Threaded Parallel Button, Threaded Tapered Button, Spline Button and Locking screw has been modelled. The parts have been assembled in Solidworks and analysed to the maximum capability with the available resources. The drawings for all parts were revised multiple times, checked by the technical design coordinator, and signed off to send to manufacturer (refer to appendix). Manufacturer feedback has been received for the drawings and necessary changes have been made. A final quote for the 15 buttons of each type, 50 screws and 30 testing jigs has been finalised with the manufacturer. All parts due in for testing in late October/early November. Currently, all testing methodologies for an initial stage of testing has been discussed and planned. These methodologies are discussed in the following section 5.1 Biomechanical testing. While waiting for the parts to arrive, meanwhile, the testing jigs have been in design process.

5.1 Biomechanical testing

5.1.1 Screw Torque Testing

The aim of this testing is to measure and analyse the maximum torque at which a screw fails. The test will be conducted as per ISO 6475-1989 Implants for surgery. According to the clinical literature review, studies show that the ideal torque level is 0.4 Nm. A constant force/torque is applied in order to rotate the head of the screw at a uniform angular velocity of 1 rpm to 5 rpm until failure occurs. Once the screw reaches a certain torque value, the screw will fail which is noted as the breaking torque. This maximum breaking torque as well as the angle of rotation during the failure of the screw is recorded. If the maximum torque recorded is less than 20% of the full-scale reading of the machine, this result is disregarded, and the test is repeated using a lower range. The locking screw is fixed for testing using a three-jaw self-centering chuck aligned using a locating pin.

5.1.2 VA Locking Mechanism Testing and Verification

The aim of this test is to analyse the effectiveness of the variable angle locking mechanism. To start with, a fresh sample of screw will be taken, and the head diameter of the screw is recorded. The screw is inserted at 15° until it feels fully locked and the maximum torque at the specific locking position is recorded. If the screw goes through the button, the maximum torque value reached is recorded. Once the screw fails at any given position, the diameter of the screw after failure is recorded. The distance of the head that sits above the surface of the button is measured. If the screw is sitting below the surface of the button, it is stated 'sub-flush'. It should be ensured that the maximum height above the top surface of the button must not exceed 0.7mm. The screw will be then removed with the maximum torque value and head diameter measured again. The same screw is inserted again at a lower angle aiming for a torque just above 0.4Nm based on the clinical evaluation results. The same steps are repeated for the lower angle.

5.1.3 VAST Strengthening Test

This test is conducted to analyse the variable angle feature in the spline button which is to optimise the locking feature. The 1.5 mm Locking Screw designed will be placed in the button projected at 15° angle towards the relief cut at a torque of about 0.4Nm to 0.6Nm. The load is introduced to the screw and recorded to the tip of the screw to shear it in the direction of the spline opposite to the relief cut. A load-displacement curve will be plotted based on the results.

5.1.4 Testing Device

One of the testing devices designed and sent off to manufacture is threaded and non-threaded plug gauge for the threaded buttons and spline button respectively. The design for the gauges was based off the device (Figure 58).

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Figure 58 Sample for plug gauges

Three gauges were designed for the three buttons each gauge having a GO gauge end and a NOGO gauge end. The GO gauge and NOGO gauge are designed to have a pitch diameter dimensioned in bottom tolerance and top tolerance relative to the nominal pitch diameter of the button. The nominal Pitch Diameter (refer to Appendix 7.6) of the threaded buttons (parallel and tapered) is 2.05 mm (Figure 59).

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Figure 59 Nominal pitch diameter of threaded button

The tolerance in the drawing (refer to Appendix 7.3) for the button is +/- 0.03. Therefore, the GO gauge and NOGO gauge were designed to have a pitch diameter of 2.02 mm and 2.08 mm respectively.

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Figure 60 GO gauge and NOGO gauge for threaded button and spline button

The Gauges were designed for testing (Figure 60). When manufactured, these gauges will have laser marking on them to distinguish between the different tolerances. The buttons were designed in their top and bottom tolerances to test with the NOGO gauge (Figure 62) and GO gauge (Figure 61) respectively. Using these gauges, the buttons manufactured can be checked whether they are in the acceptable tolerance range as there can be issues in manufacturing that may result in a part being made out of the specification.

Figure 61 GO Gauge assembled with a bottom tolerance button

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Figure 62 NOGO Gauge assembled with a top tolerance button

5.2 Design Scope

Once the parts for testing arrives, all parts will be tested as per the standards and recognised methods. Based on the test results, currently, it is expected that a fair amount of modifications will be required based on the test results for the current parts. There will be one or two types of buttons that will be preferred over one another and screw thread design modifications will be required as well. The first design stage post testing will be modifying the screw and buttons based on the test results. The prototypes of these samples will be made for stage 2 of testing and verification which is expected tot provide more precise and closer to desired results.

As mentioned earlier, the VAST buttons are made only to finalise on the locking system/technology of the hand system. When the test results of the locking system are satisfactory, this locking system will be incorporated into a locking plate which will be the next big design stage. Design of locking plate will consume a time frame of at least 6 months as the range of hand plates is vast. Competitors in the market currently offer a wide range of plates in various sizes and changes suitable for different bones within the hand as shown from the Acumed range of hand plates (Figure 63). The shapes vary from straight plates to t-plates, u-plates, y-plates etc.

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Figure 63 Acumed Range of Plates

The design of these plates will require careful detailing in terms of anatomic fit and contour. The plates are designed, the drawings will be completed and discussed with manufacturers to make samples for testing. The plate samples will have a set of testing standards that are different to the screw and button testing. Depending on the test results and testing methodologies, a few rounds of testing will be conducted from which necessary modifications will be made to the plates. The next stage of design will be design and modelling of surgical instruments for the hand plate system which will undergo the same procedures before finalising on the design. The current interest of market for the surgeon is Australia only. All testing conducted will be conducted as per ISO and ASTM standards for not limiting the scope of release just to Australia.

6 Condusion

To conclude with, this project has been truly rewarding in terms of getting an overview of hand fractures, the current state of art, the advantages and disadvantages of current market predictors etc. By far, three different types of locking mechanism have been developed – threaded parallel button, threaded tapered button and spline button, all modelled using Solidworks. Once, the parts arrive in November, all three mechanisms will be tested under the same testing conditions with the 1.5 mm Locking Screw that has been designed. Depending on the test results, necessary modifications will be made in the design will undergo another round of testing. Testing methodologies have been planned and discussed as per the ISO standards. This project has a significant space for more research and work to be done with hand plate designs that will be have the currently developed locking mechanism. A full hand surgery system can be release when the both the plate and instruments have been designed and tested successfully.

7 Appendix

1.1 The Disabilities of the Arm, Shoulder and Hand (DASH) Score Sheet

The Disabilities of the Arm, Shoulder and Hand (DASH) Score

Clinician's name (or ref) ______________________ **Patient's name (or ref** ______________________

INSTRUCTIONS: This questionnaire asks about your symptoms as well as your ability to perform certain activities. Please answer *every question* , based on your condition in the **last week**. If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on you ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week.

1. Open a tight or new jar	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
2. Write	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
3. Turn a key	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
4. Prepare a meal	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
5. Push open a heavy door	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
6. Place an object on a shelf above your head	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
7. Do heavy household chores (eg wash walls, wash floors)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
8. Garden or do yard work	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
9. Make a bed	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
10. Carry a shopping bag or briefcase	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
11. Carry a heavy object (over 10 lbs)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
12. Change a lightbulb overhead	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
13. Wash or blow dry your hair	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
14. Wash your back	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
15. Put on a pullover sweater	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
16. Use a knife to cut food	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
17. Recreational activities which require little effort (eg cardplaying, knitting, etc)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (eg golf, hammering, tennis, etc)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
19. Recreational activities in which you move your arm freely (eg playing frisbee, badminton, etc)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
20. Manage transportation needs (getting from one place to another)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
21. Sexual activities	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal	Not at all	Slightly	Moderately	Quite a bit	Extremely

social activities with family, friends, neighbours or groups?

23.	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable
	Please rate the severity of the following symptoms in the last week					
24.	Arm, shoulder or hand pain	None	Mild	Moderate	Severe	Extreme
25.	Arm, shoulder or hand pain when you performed any specific activity	None	Mild	Moderate	Severe	Extreme
26.	Tingling (pins and needles) in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
27.	Weakness in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
28.	Stiffness in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
29.	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much I can't sleep
30.	I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Thank you very much for completing all the questions in this questionnaire.

Print page | Close Window | Reset

The Disabilies of the Arm, Shoulder and Hand (DASH) Score is 0

To save this data please print or Save As CSV

Nb: This page cannot be saved due to patient data protection so please print the filled in form before closing the window.

(**NB.** A DASH score may not be calculated if there are greater than 3 missing items.)

There are two further small sections to this score. They are both optional. Just click below to select

WORK MODULE **SPORTS/PERFORMING ARTS MODULE**

Reference for Score: Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG)
Am J Ind Med. 1996 Jun;29(6):602-8. Erratum in: Am J Ind Med 1996 Sep;30(3):372.

1.2 Drawing of Locking Screw (Confidential)

All drawings were completed using Solidworks, in ASTM drawing draft and units in millimetres.

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Removed due to copyright ownership.

1.3 Drawing of Threaded Parallel Button (Confidential)

Removed due to copyright ownership.

1.4 Drawing of Threaded Tapered Button (Confidential)

Removed due to copyright ownership.

1.5 Drawing of Spline Button (Confidential)

Removed due to copyright ownership.

7.6 Screw Profile Parameters

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Major Diameter: Largest diameter of the thread of the screw or nut

Minor Diameter: The smallest diameter of the thread of the screw which refers to the core diameter

Pitch Diameter: For a parallel straight thread, when an imaginary line is passed through the middle of each thread surface, pitch diameter is the length between the imaginary lines on either side as shown in the image

Pitch: The distance from a point of thread to corresponding point on the next thread

Angle: Angle between sides of the thread which is measured in an axial plane

Helix angle: the angle that define the helix of the thread

Crest: Defines the major diameter of the screw that interacts with the minor diameter of the mating part

Lead: The distance a screw thread progresses in one single turn

7.7 Tool Used to Cut the Screw Details

Figure 64 Tool used to cut the screw threads

7.8 Standard for hexalobe feature (ASTM F543-13)

The following standard dimension from the standard ASTM F543-13 were used to design the hexalobe feature in the screw.

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Figure 65 Schematic of screw with hexalobe drive connection

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Figure 66 Hexalobe drive connection dimensions

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