# Mechanical Testing of Variable Angle Locking Screws for a New Proximal Humeral Plate

Submitted to Flinders University,

School of Computer Science, Engineering, and Mathematics.

In fulfilment of,

Bachelor of Engineering (Mechanical)(Honours),
Master of Engineering (Biomedical)

By

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Declaration

'I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.'

Ryan Spry

Date: 22/08/2017

Acknowledgments

I would like to express my gratitude to Associate Professor John Costi, Academic Supervisor, for support and guidance throughout this project.

I am grateful for the time and assistance that the members of the engineering services group, at Flinders University, have provided over this project. Specifically, with use and training on testing machines as well as input into equipment design.

Lastly, I would like to thank Byron Trump, Industry Supervisor, for his support, guidance, and encouragement with all aspects of this project.

# Abstract

This project was performed in conjunction with a local company, Austofix, in the development of their new proximal humeral plate design. This project was designed to test the performance of the Variable Angle Screw Technology (VAST) that the company has designed to incorporate Variable Angle (VA) locking screws into their proximal humeral plate design.

In this project, relevant literature has been explored, from looking at potential risks of proximal humeral fractures and anatomy, to surgical techniques and proximal humeral plate design. This will provide an appropriate background and understanding on the intricacies of proximal humeral plate development. Throughout the literature review, discussions have been incorporated on how aspects of the fixation plates use can affect the design and development of the plate. The review also observes trends in the biomechanical testing of these plates.

The literature was used to observe the current style and types of proximal humeral plate testing, in relation to biomechanical testing and review studies. This provided great insight into the trends of these types of testing techniques as well as showing why different tests have been performed. It was key to observe the common methods of testing, as well as the differences between testing techniques.

This project has used the information gained by the literature and standards to help develop and test the new proximal humeral plate design. The testing that has been designed has incorporated information gained by the literature and standards, as well as being based on the requests given by Austofix and restrictions based on testing equipment. This has resulted in the design of three testing methods and the investigation into two other potential methods of testing.

The focus of testing for this project was to evaluate the performance of the VAST feature Austofix has designed, which allows the use of VA screws. The use of VA screws is a recent development in the field, providing flexibility during surgery. This is due to VA screws being able to be inserted over a range of angles.

This VA technology provides significant advantages over fixed angle screws and has shown to have a better performance. As this technology is still new, there needs to be significant testing to ensure that performance has not been compromised with the VA design. This has been performed during this project by observing the performance of a single VAST hole feature and VA screw interface. These constructs underwent a torque and ramp loading test, to observe the designs performance and the effect of differing tolerances and angles of insertion. This involved the screws being inserted into the button constructs in accordance with standard torque, to observe screw locking and head protrusion. Those specimens that passed the torque test were then ramp loaded at 5 mm/min, using a testing jig based on reviewed literature. This shear loading was used to observe the maximum force achieved before failure of the specimen occurred. Full results and discussion, are outlined in this report. The information obtained will help determine the direction of the project and also address any design changes. Additionally, a cyclic fatigue loading test was designed. This testing method has currently not been utilised, but may potential be performed by the end of the project.

Due to some constraints of the project not all testing was performed. In the report, we will discuss some of the limitations and how some of these limitations were overcome. For those testing methods that have not been finalised, a future works discussion has been performed outlining the importance of these testing methods.

# Contents

# Table of Figures

# Table of Tables

# Executive Summary

Proximal humeral plates are one of the most common methods of surgical fixation for proximal humeral fractures. The fixation and stability of these constructs will often determine the outcome of the procedure, with this being a key function for allowing the union of the bone fragments. This task however can be hard to accomplish as there are many factors that may affect the outcome of these surgeries and the performance of fixation plates. Additionally, there is a lack of knowledge on how these factors affect fracture generation and therefore make testing very difficult. The outcome of each patient also varies largely dependent on the individual, as outcomes are also affected by the biology of the patient and their lifestyle.

Largely proximal humeral fractures are seen in the elderly, as this is a common form of fragility fractures due to low bone mineral density (BMD). Typically bone density deteriorates with age, where woman are the most affected due to their biology. Although men are less likely to have lower BMD, due to the aging population and extended lifetimes, men are becoming more likely to suffer from this condition. Currently the ratio for women to men is 3:1, this is based on each genders susceptibility to low BMD and conditions such as osteoporosis. Therefore, women over the age of 65 years are the main population that suffer from proximal humeral fractures. Although this is the general population, fixation plates are made to be generic, with one design. This is due to the cost of making custom plates and the time constraint to make a custom plate on short notice. Therefore, these plates must not only perform appropriately for elderly women, but also males and patients of younger age groups and different ethnic backgrounds.

To prove a fixation plate's ability, it must be tested biomechanically. There are available standards that provide methods of testing bone fixation plates, however, these are generic and vague. These standards provide a generic testing method for all bone fixation plates, but do not provide a margin of acceptable performance. This is due to the general lack of knowledge and ability to predict clinical performance using biomechanical testing. These standards for testing fixation plates, state that they cannot be used to directly compare to clinical performance. Explaining that testing must be performed against a currently used design, which has had significant success in a clinical setting. This sets up how testing of orthopaedic devices is conducted, where testing must be performed against predicate devices to show that a new design has an equal or better performance.

When reviewing literature, it is also hard to determine what the appropriate methods of testing are. There is often contradiction between the standards (ISO/ASTM) and biomechanical testing studies in terms of methods of testing and the constructs used. Therefore, to make an appropriate test method, it must have significant evidence to support the parameters and method. This is obtained using information from the standards, as well as relevant biomechanical studies and appropriate modelling to justify the test.

The original aim of this project was to assist Austofix to develop a new proximal humeral plate. Throughout the project this aim was refined to focus on the variable angle locking technology. This was mainly due to the limitations on the time of the project as well as the developmental process in place.

The Information that was gained from the literature review and from development of the design was used in the aid of developing testing methods for the project. These testing methods were based off the requirements of Austofix, to justify and prove the performance of their new proximal humeral plate design. The information gained from these justified

testing methods, would help in the development of this design. The focus of testing was to determine the appropriate dimensioning of the VA locking screw and the VAST hole feature designs. This was performed using single VAST hole plates, “buttons”, to observe the performance of a single VA screw/VAST hole feature construct.

This resulted in five testing methods being designed and two being performed over the period of this project. These testing methods included testing of single screw/hole constructs, including aspects of insertion torque, screw head protrusion, ramp loading tests, cyclic loading tests and investigation into the need of fret testing. The investigation into a total construct fatigue test was also performed, where testing using this method was outside the scope of this project. The testing outlined in this report describes the preliminary testing performed on this design and for the project. As such there is a lot of information to be gained from these testing methods on the properties of this design, where each test focuses on specific properties.

# 1 Literature Review

## 1.1 Introduction

Proximal humeral fracture fixation plates are a common and useful method in acquiring reduction and fixation of proximal humeral fractures. The use of such fixation plates often promotes more stability of the fracture and a better outcome for patients. The design of these fixation plates is ever evolving due to the increasing risk of proximal humeral fractures, as well as an increase in knowledge gained from biomechanical and clinical testing studies. The design of these fixation plates heavily involves testing, to provide information about the plate and its performance. These tests are based on relevant anatomy and biomechanical properties of the proximal humerus, to provide the closest comparison possible to in vivo properties. An overview of the process of designing a proximal humeral plate was researched, from the need of the product, to the design and testing of the plate to prove its performance. This has been a key step in understanding many aspects of the design and testing of proximal humeral plates. This information will provide a background for what will be required to help Austofix develop and test their new design. Ultimately, aiming to develop a better performing proximal humeral plate that uses variable angle screw technology (VAST).

Proximal humeral fractures account for around 5 % of all fractures in the human population (1,2), which increases to 10 % in patients over the age of 65 (3). This makes proximal humeral fractures the seventh most common type of fracture (Figure 1)(3). These fractures become increasingly common with age where 75 % of the patients are over the age of 60 (4,5). A study in the USA found an incident rate of 253 per 100,000 (0.253%) population in patients over 65 years of age (6), placing proximal humeral fractures at the third most common fracture type in this age group.

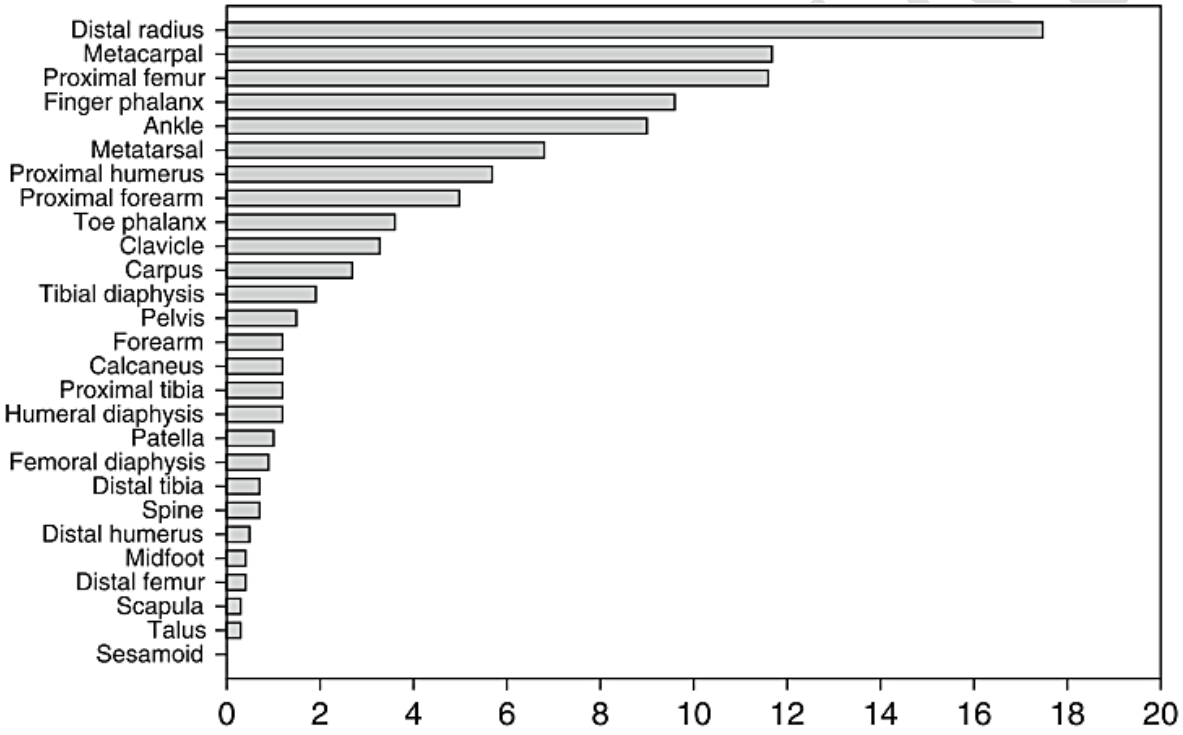


*Figure 1 Fractures arranged in order of decreasing frequency in % (3)*

The occurrence of these fractures has been increasing over the years due to a growing and aging population (3,7). Due to the occurrence of proximal humeral fractures and often unfavourable outcomes after treatment, new designs and studies are continually being performed to obtain more knowledge and better treatment outcomes.

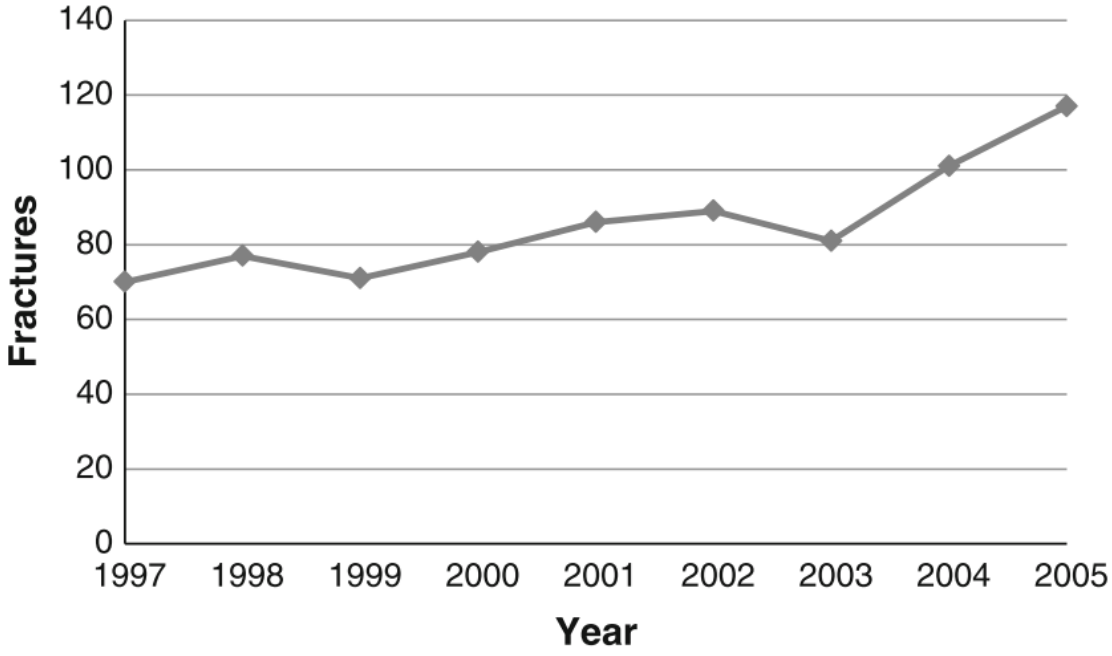


*Figure 2 Proximal humeral fractures between 1997 and 2005 for a town in the USA* (7)

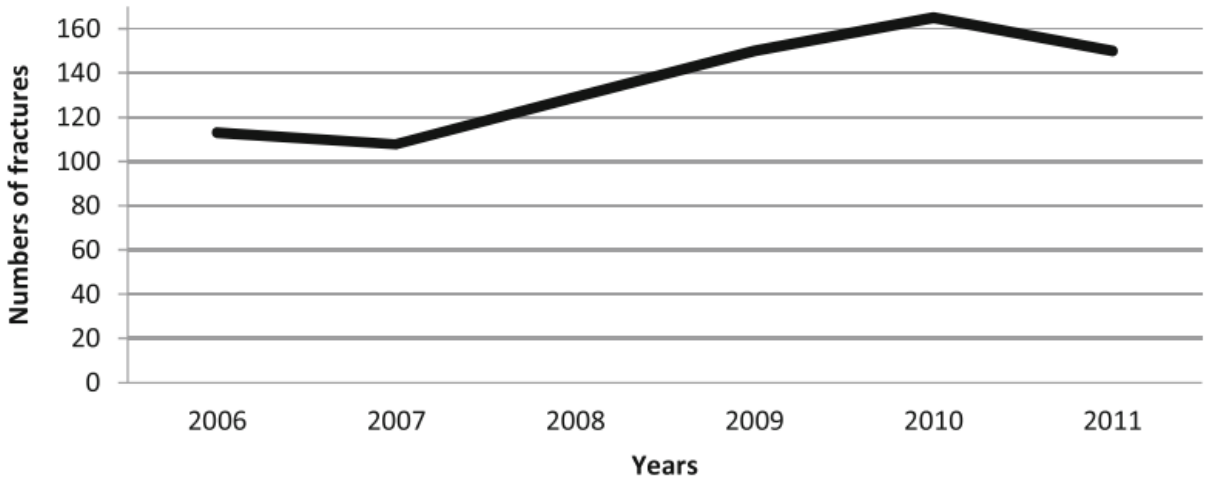


*Figure 3 Proximal humeral fractures between 2006 and 2011 for a town in the USA* (8)

As an example of the progression of proximal humeral fractures two studies by Bahrs et al. over fourteen years produced the graphs in Figures 2 and 3. These studies observed the trends of proximal humeral fractures in a town in the USA, observing the increase of proximal humeral fractures since 1997. These graphs support the idea that proximal humeral fractures are occurring more frequently.

There is no ideal method of treatment for these fractures, as treatment is often subjective and based heavily on the classification of the fracture and patient information. Treatment can utilize either non-operative or operative methods of treatment, where several versions of operative techniques are available with different advantages and disadvantages. Due to multiple treatment methods and a lack of knowledge on outcome after treatment, there is still debate about which method is the best (9). Proximal humeral locking plates are a potential solution to overcome many of the issues with treatment and have shown to provide favourable biomechanical performance in both laboratory and clinical settings (10). Proximal humeral plates are currently one of the most popular methods of treatment, which utilize a bone plate that attaches to the bone to stabilise the fracture. The plate is held slightly off the bone by bone screws with threaded heads, locking the plate in place while allowing for blood flow under the plate. When designing a new fixation plate there are many factors to consider in the design and the testing, which will help ensure that the implanted plate performs properly. Some of the common factors that have been seen in the literature and standards have been: who is most at risk, what factors increase the risk, the anatomy and implications of tissue damage, how are these fractures classified, what are the surgical methods, and what are their advantages and disadvantages. As these factors have been commonly seen, it was important to get a better understanding of these areas. For this project, it will be important to understand the surgical method and what can cause tissue damage, so that an appropriate and safe design can be generated. To prove that a new proximal humeral plate is safe for use, relevant testing and documentation is used to prove the implants performance. The results are compared to currently used implants reinforcing the new designs performance, significantly reducing the cost and the time required of designing a new plate. These tests will also provide surgeons with information on the properties of the plate so they can make the best decisions for treatment.

## 1.2 Risk

When developing a new implant, it is important to understand what increases the risk of the injury, as this will provide insight into the likely demographic that will require treatment. It is well known that the risk of proximal humeral fractures occurring increases with age. Most often these fractures in the elderly occur due to falling and/or tripping with the patient falling directly on the shoulder, or by falling with outstretched arms. This results in a direct fracture or by the arm being forced up into the glenoid cavity which compacts the proximal humerus. It is common for these fractures in the elderly to occur from standing height (2,3). Currently 90 % of proximal humeral fractures that occur due to a fall are in the elderly, with an increased risk of falling being prevalent in this age group but also in patients with disabilities (3). An increase in conditions such as osteoporosis, which is more prevalent in older patients, will also effect the risk for these individuals. Other factors that often affect the likelihood of these fractures, that are a by-product of age, are: vision, balance, previous fractures, chronic illness, and lifestyle. Like many conditions smoking has also been shown to increase the risk of fractures (2,3). Younger patients still suffer from proximal humeral fractures, however these occur due to high energy impact injuries, such as a car accident. Falls can also result in fractures for younger individuals, however, usually require a fall from greater than standing height, unlike the elderly. Due to the high-energy nature of injuries in younger patients, they often have significantly more, soft and bone tissue damage.

As an example of the effect of age on proximal humeral fractures, Table 1 and 2 below show some interesting effects of age groups on the occurrence of these fractures. From Table 1 largely patients over the age of 60 will suffer from proximal humeral fractures at home, where younger individuals are more likely to suffer these fractures in public areas. From Table 2 younger individuals suffer from proximal humeral fractures, equally between low and high energy injuries, where there is a high chance for fractures to occur as a result of a motor vehicle accident. Older patients suffer largely just from low energy injuries, where this study found a small amount of fractures occur due to motor vehicle accidents and one altercation.

*Table 1 Places of accident for different age groups* (3)

| **Place of Accident** | **Under 60 years (%)** | **Over 60 years (%)** |
|---|---|---|
| **At home** | 27.9 | 53.3 |
| **Public areas** | 45.1 | 31.1 |
| **Place of work** | 4.7 | 0.2 |

*Table 2 Mechanism of injury* (11)

| **Mechanism** | **Frequency (%)** | **Younger than 60 years** | **60 years or older** |
|---|---|---|---|
| Low-energy fall | 36 (54) | 10 | 26 |
| High-energy fall | 11 (16) | 11 | 0 |
| Motor vehicle | 17 (26) | 12 | 5 |
| Motorcycle accident | 1 (2) | 1 | 0 |
| Altercation | 1 (2) | 0 | 1 |
| Total | 66 (100) | 34 | 32 |

The incident rate of proximal humeral fractures is around 3:1 for women compared to men, which makes women over the age of 60 years the most likely to suffer from these fractures (2). This discrepancy in women compared to men is a result of lower bone mineral density (BMD) (3). Women normally have lower BMD and are more likely to suffer from conditions such as osteoporosis. The hormonal changes in women, especially menopausal changes, also affects BMD, which will overall increase risk of these fractures. Due to the increasing lifespan of individuals, the rate of men suffering from osteoporosis and having, on average, a lower BMD has also increased, presenting potential risk (3). A plot of the occurrence against age for both genders can be seen in Figure 4.

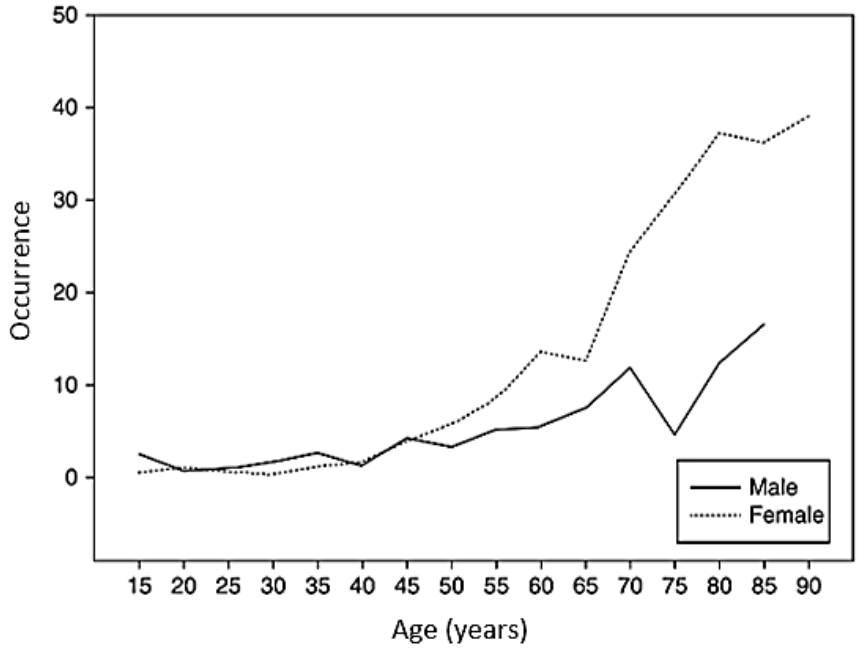


*Figure 4 Incidence of proximal humeral fracture dependent on age and gender* (3)*. (Data from* (12)*)*

The risk of proximal humeral fractures is largely related to age and BMD (4). This suggests the main patients that will be using proximal humeral plates are the elderly. This is an important factor and should be considered in the design and testing of a new proximal humeral plate. During testing the use of cadaveric bones from older individuals, as well as performing pre-testing on BMD may be important. For these reasons, and in many studies, the average age of the cadaveric specimens is over 65 years, and the specimens undergo pretesting involving medical imaging to determine bone quality (4,9,13). It will be important in testing to see the failure of the implant for patients with lower BMD and to see if the bone is strong enough to secure a proximal humeral plate. In a study on stability of locking plates performed by Schliemann et al. it was stated that complication rates of up to 49% have been seen in locking plate treatment, where one of the two most important factors in implant stability is the BMD of the patient (14). It also should be mentioned that the deviation in age of patients requiring proximal humeral plates is quite large, with patients in there 20's also requiring this treatment. This means that although elderly patients will be the main consumers of proximal humeral plates, the design also needs to be adequate for more active lifestyles of younger patients. It will therefore be important to look at relevant clinical reviews to understand what is required performance wise for both age groups.

## 1.3 Anatomy

The humerus is the long bone in the upper arm that runs from your shoulder to your elbow. The proximal region refers to the end of the humerus that inserts into the shoulder. This positioning makes the proximal humerus the main connecting surface for the arm to the shoulder, being important for arm movement and support.

The humerus is categorised as a “long bone” due to its structure, containing a long cylindrical midshafts with rounded ends. These bones have a large compact strength due to the cylindrical midshaft being curved, even compared to other materials (Table 3). The midshaft is referred to as the diaphysis and is made of compact tissue which encircles the central cavity, called the medullary canal. The thickness of the compact tissue thins moving towards the ends of the bone, where larger portions of cancellous tissue can be found. The ends of the midshaft expand into larger rounded shapes, which are referred to as epiphysis. These rounded structures are used for articulation and muscle attachment (2,15). A diagram of the components of a humeral bone can be seen in Figure 5.

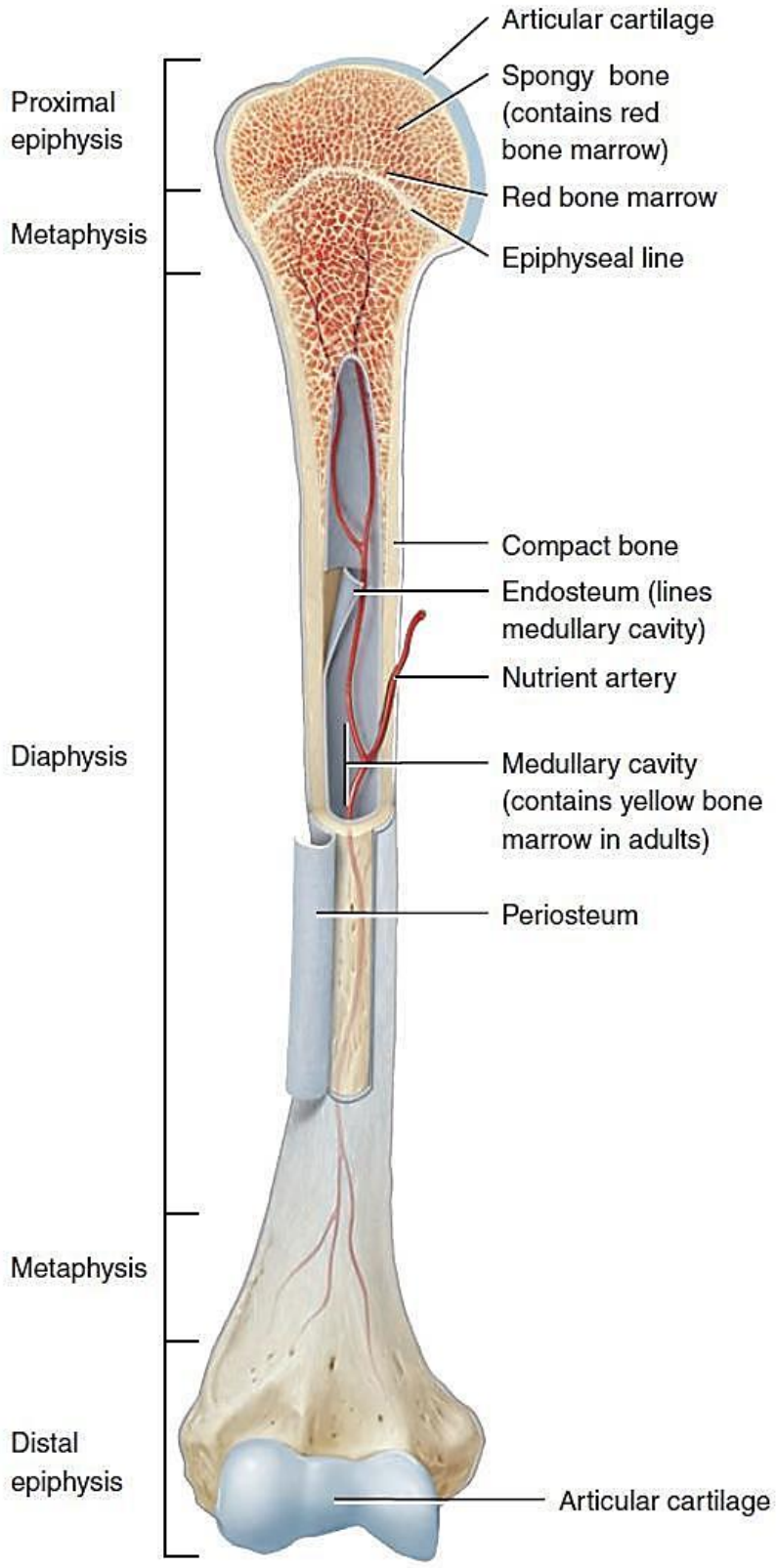


*Figure 5 Diagram of the Humerus (72)*

*Table 3 Mechanical strength of bone compared to other materials* (15)

| The Strength of Bone Compared with Other Materials | | | | |
|---|---|---|---|---|
| Substance | Weight in Kg per Metre Cube | Ultimate Strength. MPa. | | |
| | | Tension | Compression | Shear |
| Medium Steel | 7849.05 | 448.16 | 413.69 | 275.79 |
| Granite | 2723.14 | 10.34 | 103.42 | 13.79 |
| Oak, white | 736.85 | 86.18 | 48.26 | 27.58 |
| Compact Bone (low) | 1906.20 | 91.01 | 124.11 | 81.36 |
| Compact Bone (high) | ….. | 122.04 | 165.47 | 49.30 |

Bone is permeated by blood vessels which are enclosed by a fibrous membrane called the periosteum. The periosteum attaches to the surface of each bone in nearly every part, except those covered by cartilage. The periosteum is incorporated in the attachment of tendons and ligaments. The structure consists of two layers; the outer layer consisting of connective tissue and the inner layer consisting of finer elastic fibres which form a dense network. In young people the periosteum is very vascular with a thicker appearance. It connects closely at either end of the bone at the epiphyseal cartilage separated by a layer of tissue. This tissue contains granular corpuscles or osteoblasts, which are used in the ossification processes of the bone. Later in life the periosteum thins as it becomes less vascular. The periosteum serves as the site of the vessels before being directed into the bone. Injury or disease to the periosteum membrane can lead to exfoliation or necrosis. Nerves and lymphatic ducts accompany vessels through the periosteum and can also be effected (15). This provides support to why younger patients have faster and often better recovery to proximal humeral fractures, as there is a better supply of blood to support osteoblasts and osteoclasts (2). Interference of the periosteum is one of the reasons why compression fixation plates are no longer used, as these devices held the plate tightly

against the bone, and often cut off blood supply (16). The newer locking plates have overcome this by creating a stable structure while not compressing the plate against the bone.

The proximal end of the humerus is made of cancellous tissue, covered with a thin layer of compact tissue. The main features of the proximal humerus are the head, neck, and greater and lesser tubercles. The end is a large rounded surface that tappers down to the mid-shaft at the surgical neck. The head is circular in shape, which protrudes from the humerus on a slight angle, this allows it to fit with the glenoid cavity of the scapula for the shoulder joint. At the base of the head is a slight groove which is referred to as the anatomical neck, which supports the humerus position in the glenoid cavity. The anatomical neck can be seen separating the head from the tubercle and allows attachment of the articular capsule of the shoulder joint. The surgical neck is the section that connects the proximal end of the humerus to the rest of the humerus (2,15).

The greater tubercle is located laterally on the humerus and has a rounded surface with three flat impressions. These give the tubercle an anterior and posterior face which allow the insertion of the supraspinatus, the infraspinatus and the teres minor. The lesser tubercle is smaller but is more prominent than the greater tubercle. It is medially located, allowing for an anterior face, which allows insertion of the subscaularis. The greater and lesser tubercle are separated by a groove which is called the intertubercular groove or the bicipital groove. This groove allows for the head of the biceps brachii to run through the groove, as well as separate it from the pectoralis major and the teres major (2,15).

The cancellous tissue in the head of the proximal humerus is the affected area for patients who suffer from lower BMD. As this is the major supporting surface for bone screws of

proximal humeral plate, there is a potential stability risk, where lower BMD bone cannot support the screw and plate.

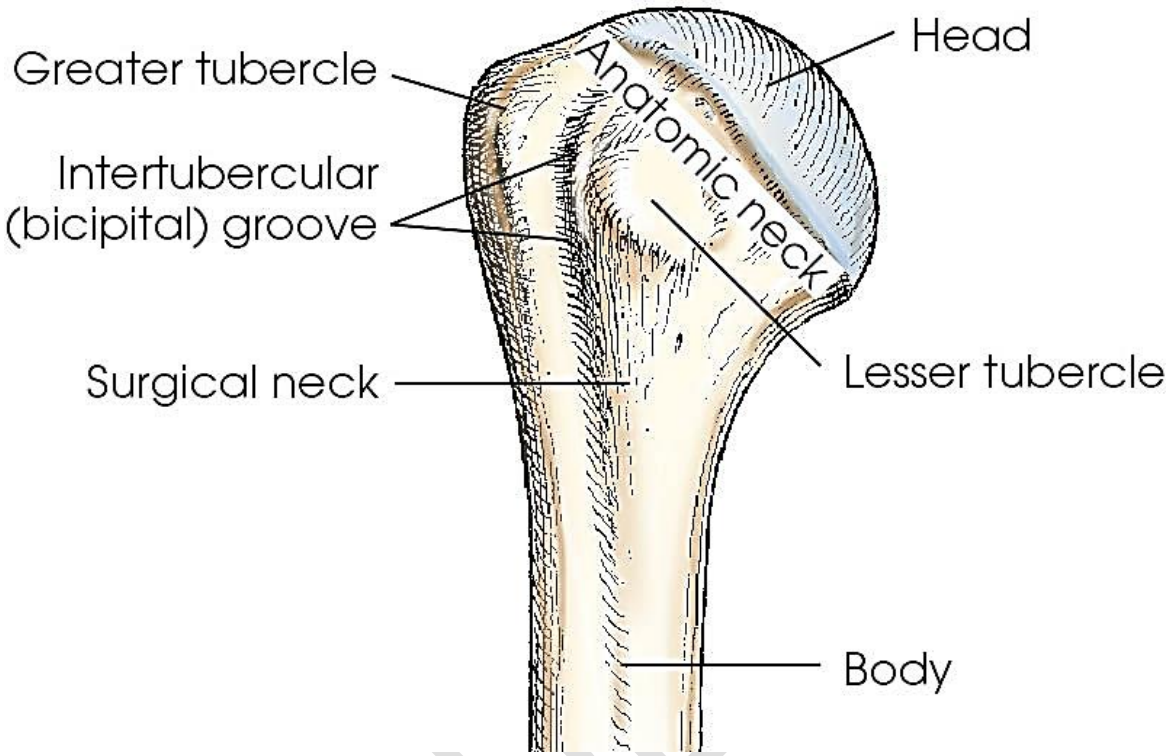


*Figure 6 Diagram of the proximal humerus (73)*

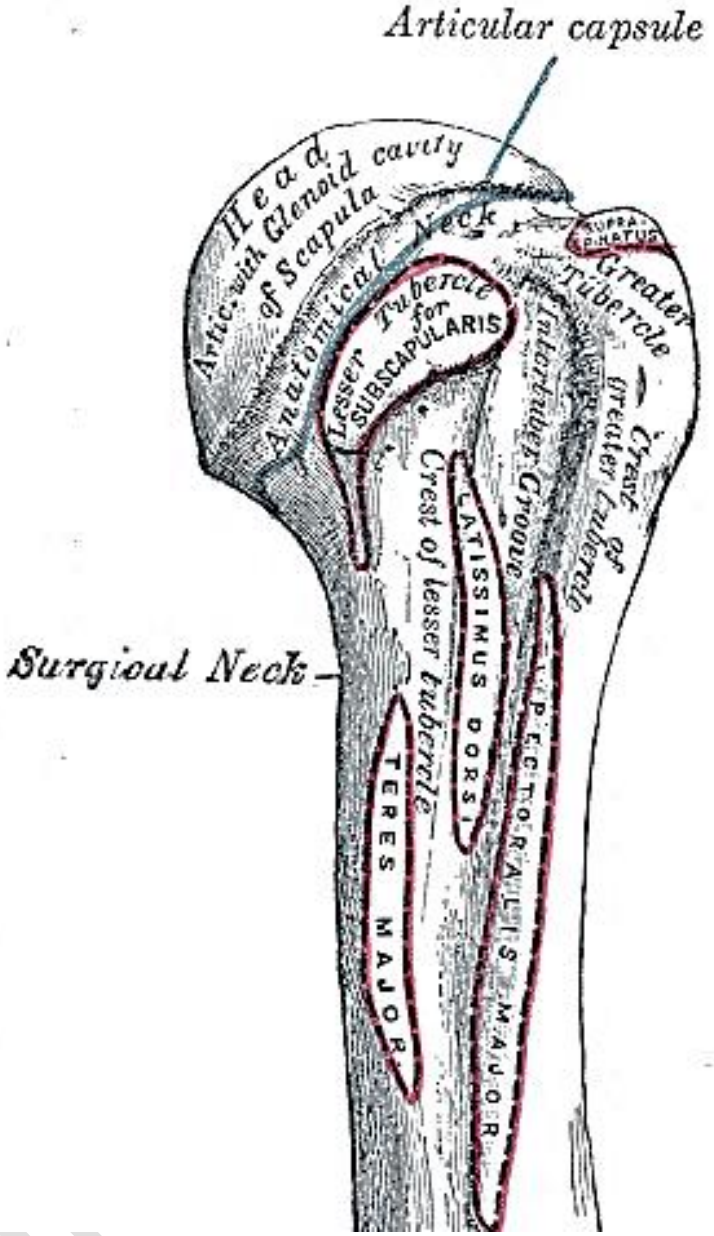


*Figure 7 Left Proximal Humerus - Anterior view* (15)

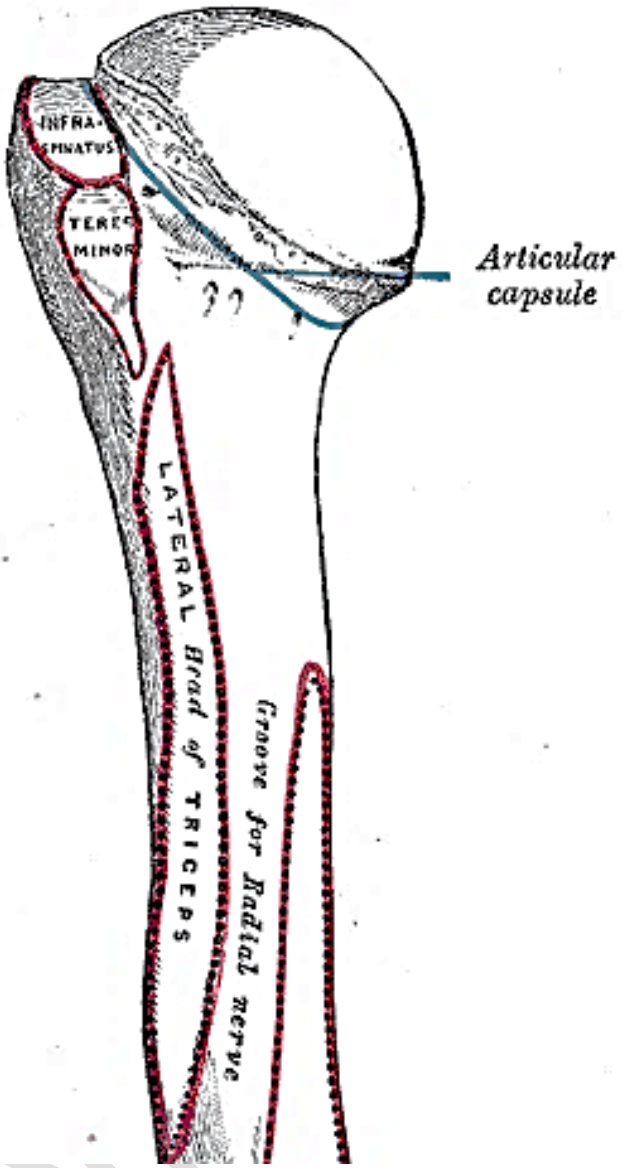


*Figure 8 Left Humerus - Posterior view* (15)

The shoulder is made up of the clavicle, scapula and the humerus. The proximal humeral head sits in the glenoid cavity, a socket that is formed by the scapula and supported by the clavicle. Although the humerus has a wide range of movement it is secured by the coracoid process and the acromion, which support ligaments and tendons for the shoulder. The clavicle supports the shoulder and attaches to the main body connecting to the scapula at the acromion forming the acromioclavicular joint (15,17). When considering proximal humeral plate designs it is important to consider any areas of interference. In terms of bone structure the acromion is a potential source of contact and may restrict movement when a fixation plate is used. The design will therefore have to consider this to prevent any movement restriction, as much as possible.

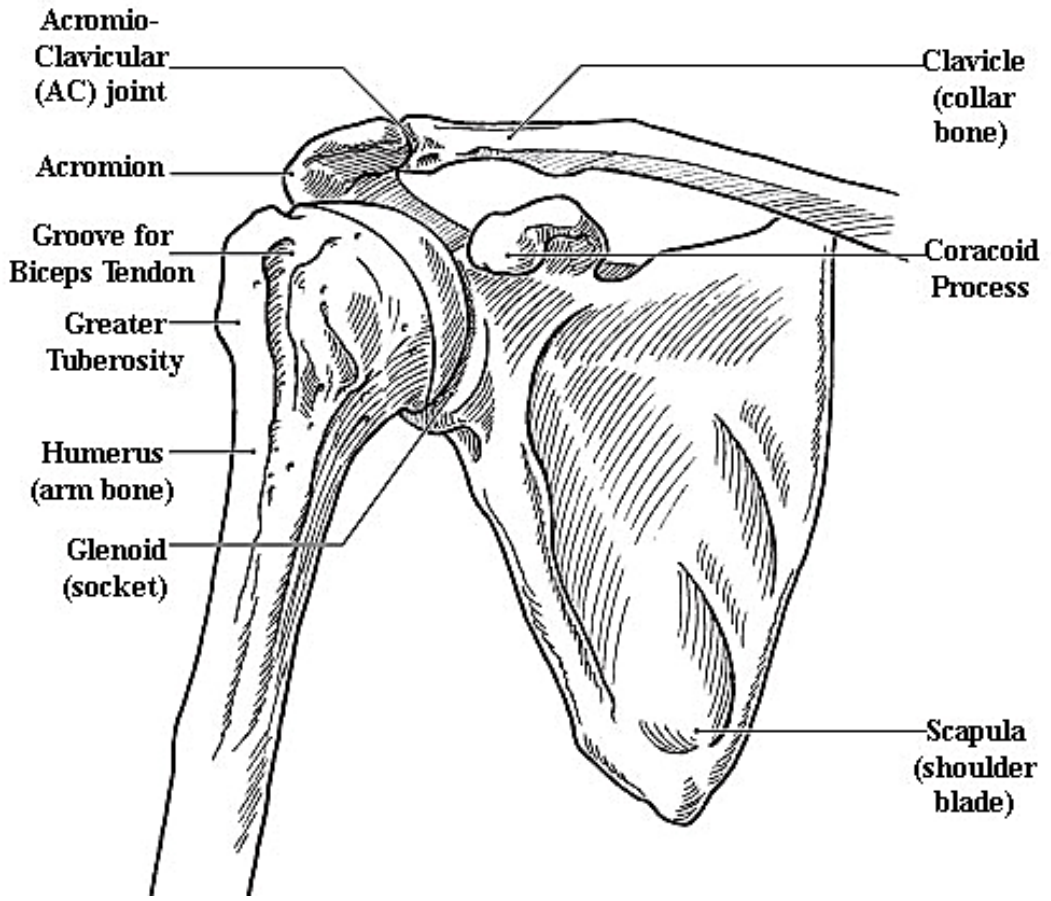


*Figure 9 Bone anatomy of the shoulder joint (74)*

The largest ligament structure in the shoulder is the articular capsule which surrounds much of the shoulder joint. It runs from as far down as the surgical neck of the humerus and follows the anatomical neck, this connects to the scapula just under the glenoid cavity following down the edge of the scapula. The articular capsule inserts into the articular cartilage of the respective areas on the scapula and humerus. The capsule is extremely loose for this type of ligament and does not provide any support in keeping bones in contact, instead it allows movement of the bones up to about 2.5 cm. The articular capsule is supported by the supraspinatus from above, the triceps brachii from below, the infraspinatus and teres minor from behind, and the subscpularis from the front (2,15,17).

The coracohumeral ligament is a supportive ligament of the articular capsule. The coracohumeral ligament is a broad ligament that originates from the coracoid process of the scapula and inserts into the greater tubercle. It is important in strengthening the upper section of the articular capsule and is believed to help suspend the humeral head (2,15).

The glenohumeral ligaments are a set of three ligaments that originate from around the glenoid cavity and insert into the lesser tubercle and anatomical neck area. These ligaments are band like and help strengthen the articular capsule. These three ligaments are the superior, the middle and the inferior glenohumeral ligament. The superior ligament resists inferior translation of the adducted shoulder; the middle ligament resists inferior translation of the externally rotated and adducted shoulder; and the inferior ligament resists humeral head anterior and posterior movement. These ligaments also help prevent dislocation of the shoulder because of restraining these movements (2,15,17).

Additional to the ligaments that help connect the humerus to the rest of the shoulder, there is the transverse humeral ligament. This ligament does not connect the humerus to another bone but instead originates and inserts in the humerus. This ligament is a band that passes from the lesser to the greater tubercle. This allows the biceps brachii to run through the intertrabecular groove while holding the brachii, maintaining anatomical location (2,15,17).

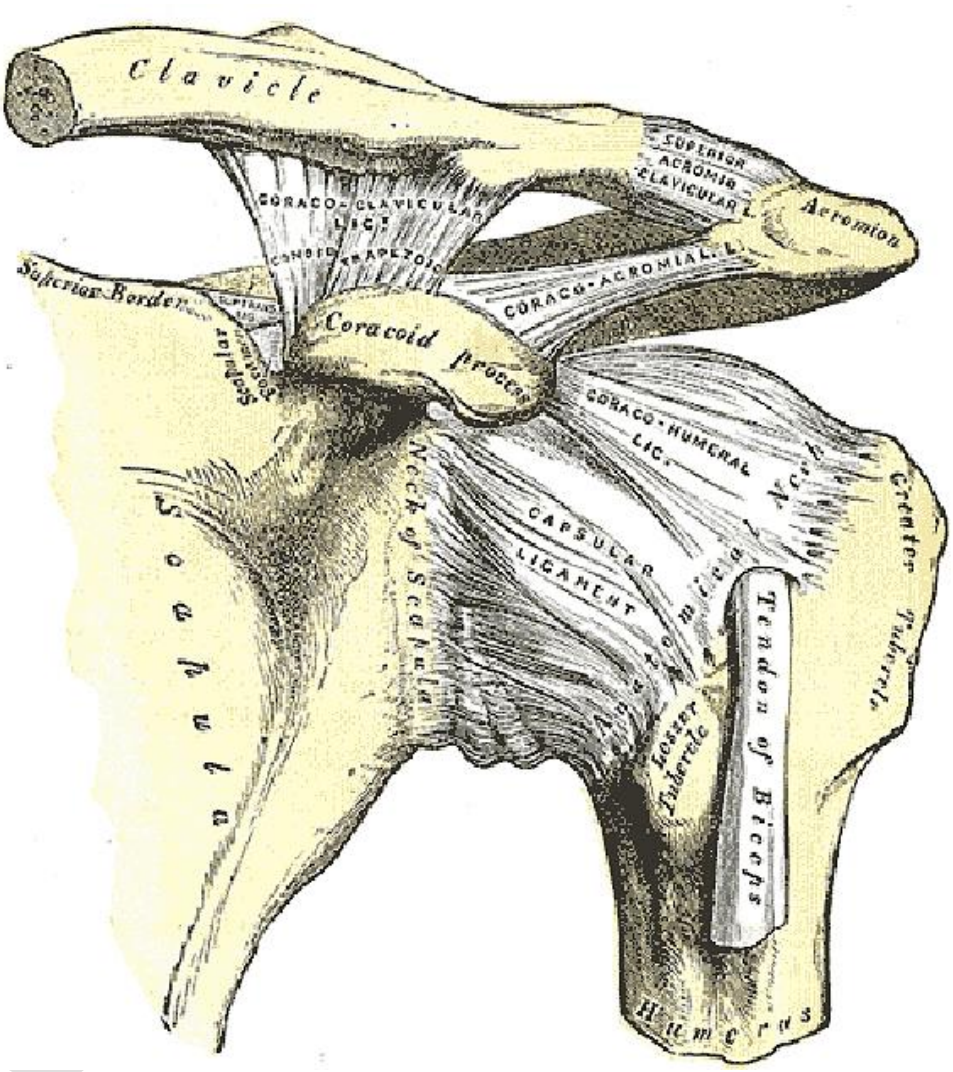


*Figure 10 Ligament structure of the shoulder* (15)

The shoulder has a large group of tendons that make up what is known as the rotator cuff. The rotator cuff tendons allow connections of muscle to the humerus, and thus provides the ability to move the arm and raise it from our side. The key importance of the rotator cuff is that it supports and holds the humeral head in the glenoid cavity while at the same time helping with movement. The muscles that act on the rotator cuff are the supraspinus, infraspinatus, teres minor and the subscapularis.

*Table 4 Shoulder muscle information* (2,15,16, 44)

| Muscle | Origin | Insertion | Action | Nerve Supply |
|---|---|---|---|---|
| Supraspinatus | Supraspinous Fossa | Greater tubercle | Abduction of the arm ≈ 30 $^{o}$ | Suprascapular nerve |
| Infraspinatus | Infraspinatous Fossa | Greater tubercle | Lateral rotation of the arm | Suprascapular nerve |
| Teres Minor | Upper lateral border of the scapula | Greater tubercle | Lateral rotation of the arm | Axillary nerve |
| Subscapularis | Subscapular Fossa on the anterior surface of the scapula | Lesser tubercle | Medial rotation of the arm | Upper and lower subscapular nerves |

It is important that the design and use of proximal humeral plate does not affect tendons and ligaments. This is highly important in the shoulder due to its complexity in anatomy and the movement it allows. Due to this complex structure of tendons and ligaments it is important that the fixation plate doesn't cause any unwanted contact or irritation. From the structure of ligaments and tendons discussed, this may explain why surgically proximal humeral plates are inserted on the external side of the humerus. As this area avoids these structures.

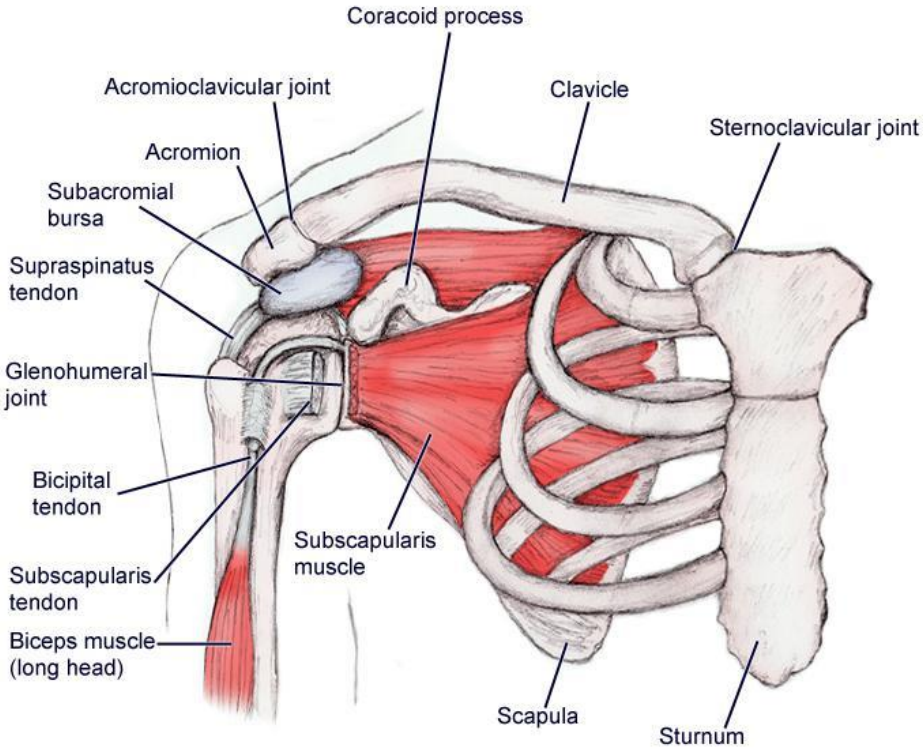


*Figure 11 Shoulder anatomy - Anterior view (75)*

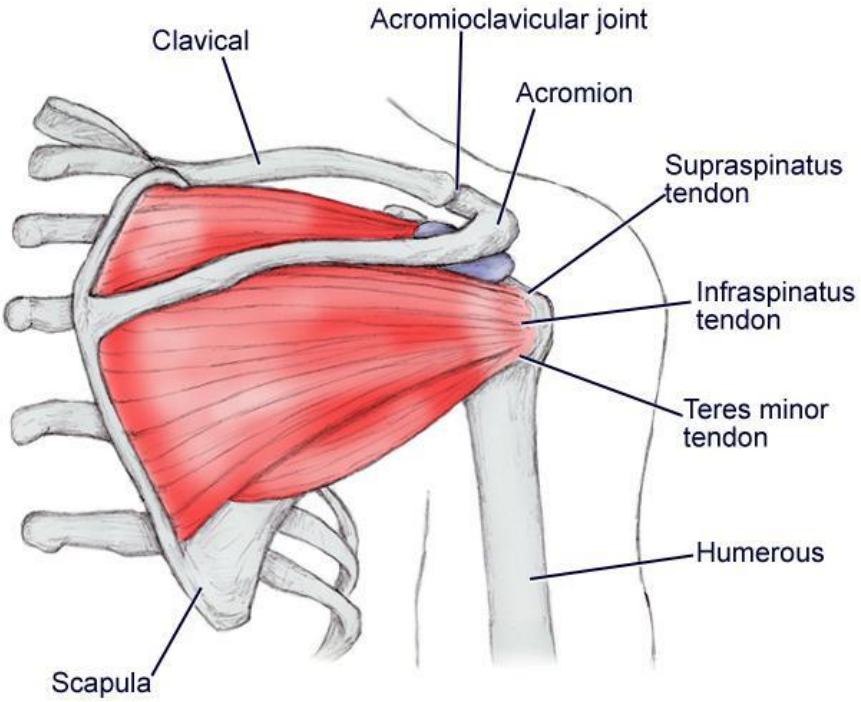


*Figure 12 Shoulder anatomy - Posterior view (75)*

There is one large artery in the shoulder that supplies blood to the extremity; the subclavian artery. The right subclavian artery originates from the brachiocephalic artery to the right side of the body and the left subclavian artery originates from the arch of the aorta to the left side of the body. These subclavian arteries run up the body to the scalenus anterior at the highest point and then run downward to the outer side of the first rib. At this point the subclavian arteries branch out and become the axillary artery. The axillary artery continues over the shoulder and ends at the lower section of the teres major, where it becomes the brachial artery. Over the length of this artery it moves from being deeply imbedded in the body to a shallow position only covered by skin. The axillary artery eventually branches into the radial and ulnar arteries that supply blood all the way down the arm. Importantly the posterior and anterior humeral circumflex arteries arise from the axillary artery. The posterior circumflex artery originates around the lower border of the subscapularis and runs through a section called the quadrangular space which is made by the subscapularis, teres major, teres minor, triceps brachii and the surgical neck of the humerus. It winds around the neck of the humerus and supplies blood to the shoulder joint. The anterior circumflex is much smaller and arises opposite the posterior circumflex artery. It runs horizontally past the short head of the biceps brachii, in front of the neck of the humerus. At the intertubercular sulcus, it branches supplying blood to the head of the humerus and the shoulder joint (2,15,17).

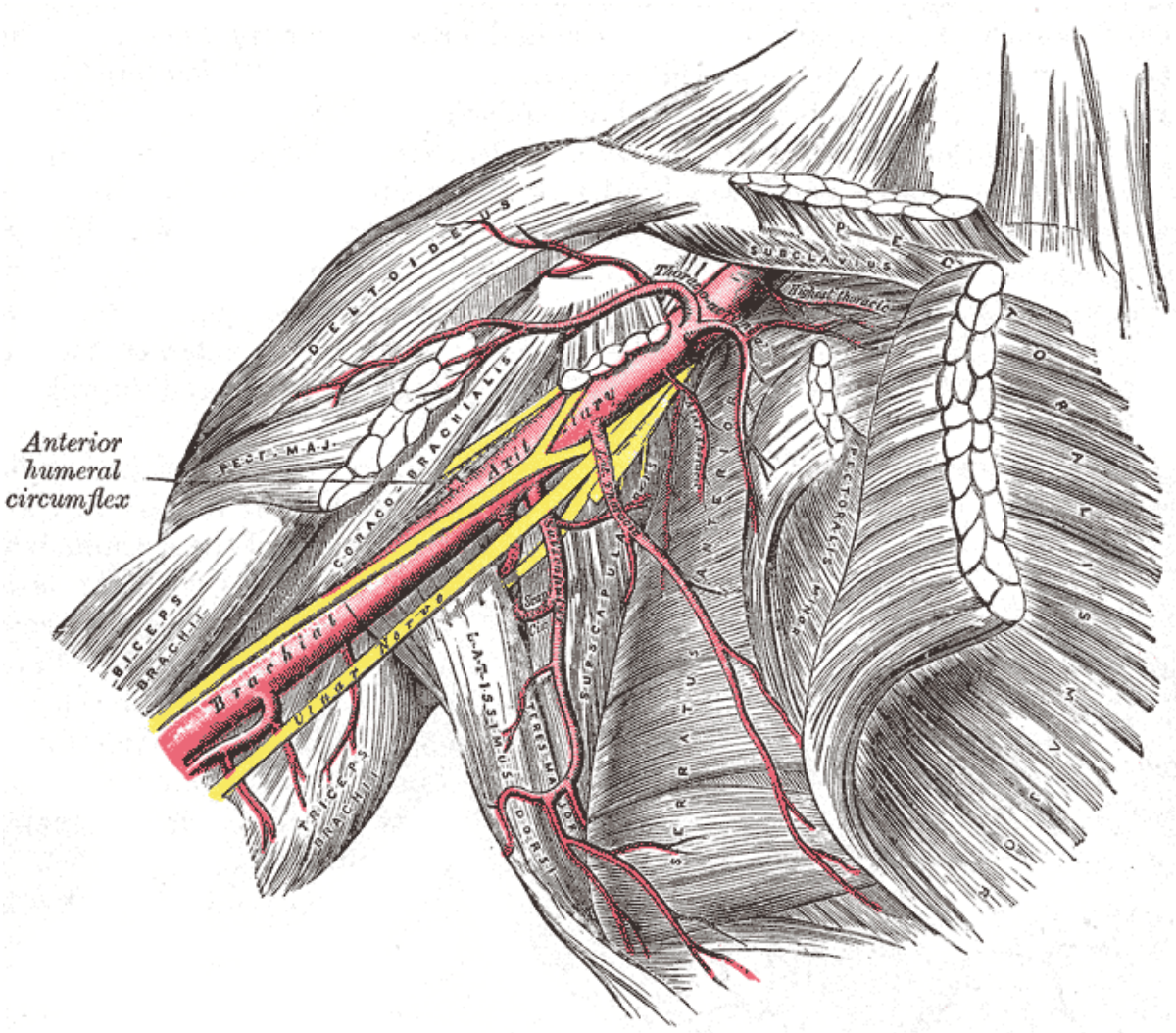


*Figure 13 The axillary artery and its branches* (15)

The circumflex, axillary and subclavian veins follow a similar route to their artery counterparts. The circumflex veins join to the axillary vein at the lower region of the teres major, which is the continuation of the basilica vein. Now as the axillary vein, the vein follows the armpit around to the outer border of the first rib. At this point the axillary vein is referred to the subclavian vein. The subclavian vein combines with the internal jugular and becomes the innominate vein (2,15).

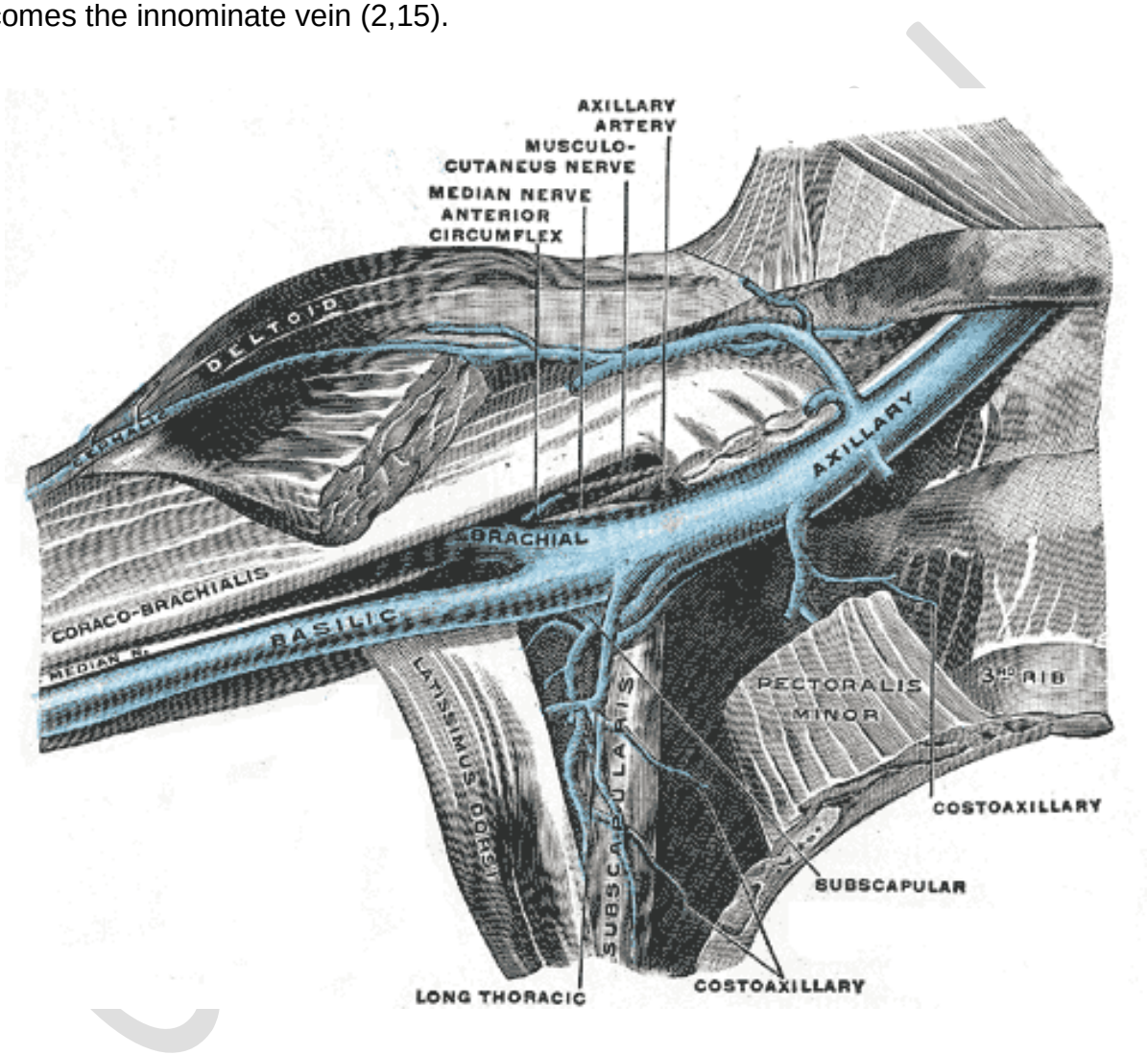


*Figure 14 The veins of the right axilla, viewed from the front* (15)

When proximal humeral fractures occur blood vessels can also be damaged, studies have shown up to 80 % of cases the humeral circumflex blood vessels is disrupted (2). The disruption of the blood supply to the proximal humerus has been a discussion point of the occurrence of avascular necrosis, which can be as prevalent as 34 % of cases (2). The disruption of these vessels also includes the potential damage done by implants and surgery. A study by Hettrich et al. on the blood supply to the humeral head showed that 64 % of the supply comes from the posterior circumflex artery (18). This artery is in the region where proximal humeral locking plates are used. Although locking plates have shown a greater ability to not disrupt blood vessels than previous implants, there is still a potential risk (2).

The main nerve that runs through the shoulder is the axillary nerve, which originates from the brachial plexus and contain fibres from the C5 and C6 cervical nerves. The axillary nerve follows the axillary artery until it separates to the anterior of the subscapularis muscle, following the circumflex artery through the quadrangle space. The axillary nerve branches off into three branches that terminate; being the anterior branch, posterior branch, and the articular branch. The anterior branch moves down and around the surgical neck (within 1.7 cm) under the deltoid, allowing it to supply the section of deltoid muscle, eventually terminating in the skin. The posterior branch supplies a posterior section of the deltoid and the teres minor. This nerve ends as the superior lateral cutaneous nerve of the arm. The articular branch inserts into the shoulder joint inferior to the subscapularis (2,15,17). In a study performed on 143 patients who suffered low energy proximal humeral fractures 67 % suffered from nerve injuries, with the axillary nerve being the most commonly damaged (2). This would suggest a treatment method that supports soft tissue recovery are favourable.

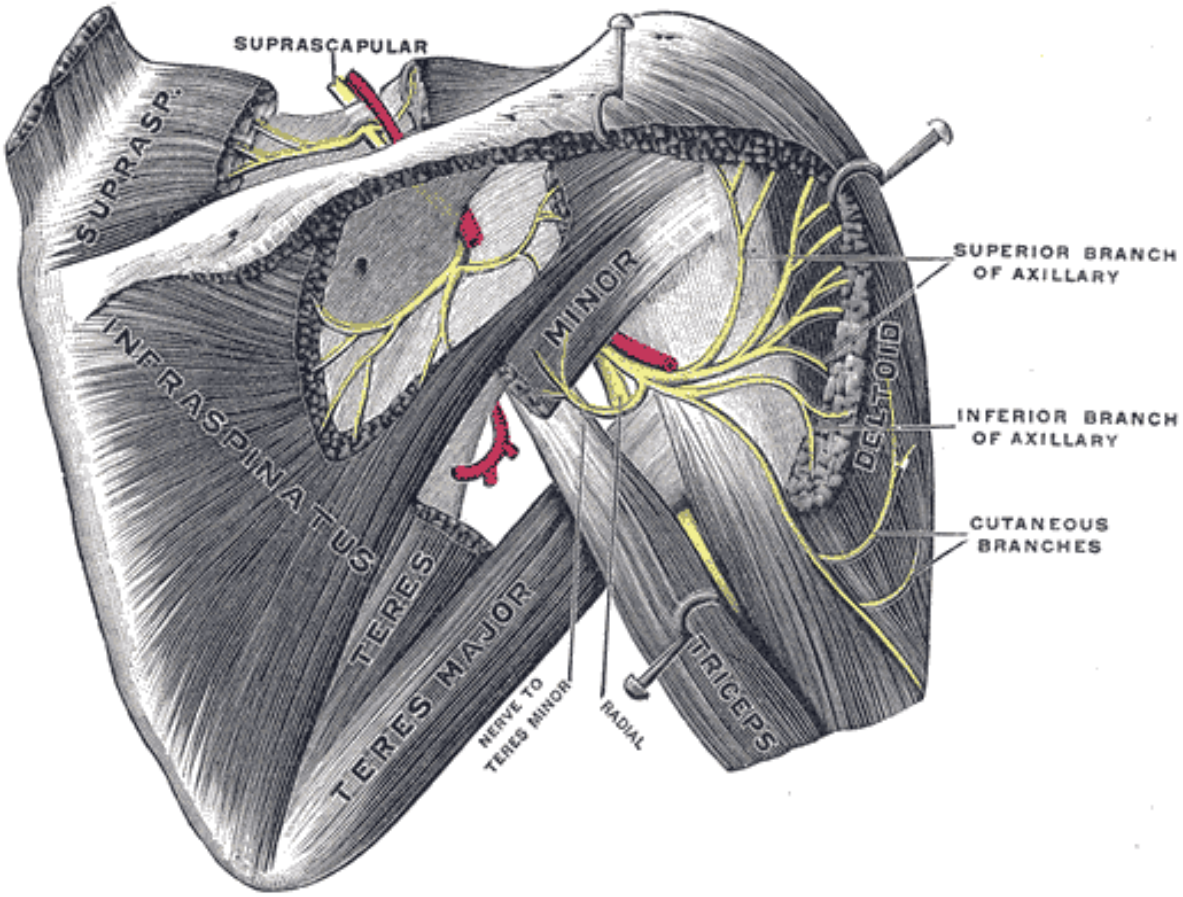


*Figure 15 Suprascapular and axillary nerves of right side, seen from behind* (15)

Considerations of the anatomical structure of the proximal humerus is important in the design of a new proximal humeral plate; as the anatomical structure effects the biomechanics of the area and therefore the forces and moments that will be specifically applied to the proximal humeral region. Biomechanical modelling methods have become more common and sophisticated in analysing these forces in laboratory settings. However, the movements in the upper limbs are varied and require insight into a variety of tasks to represent daily activity. There have been studies to determine these forces, but there remains a lack of knowledge and variability in the results. This is due to variations in movement, anatomy of individuals, and the large variation of "daily movements" that the upper extremities experience (19). For example, Murray et al. looked at the external forces and moments of the shoulder in 10 daily tasks and found a maximum flexion moment of 14.3 Nm and maximum abduction of 4.2 Nm, which compared to an earlier study looking at 6 daily tasks found that maximum abduction was 10.0 Nm and maximum flexion was 22.5 Nm (19). Additional biomechanical studies performed by Sander et al. and Ahrens et al. used previous studies which generalised the force on the glenohumeral joint as 0.9 times body weight for 90 $^{o}$ abduction (3,9). A study by Inman and later Poppen et al. also supports this as their studies calculated a maximum force on the glenoid surface, in compression, being 89 % body weight at 90 $^{o}$ (3). Again, there is a variation in stated forces and moments for the shoulder and they differ due to testing methods. These forces are seen through the muscles and ligaments and may be a contributing factor to fractures of the tubercle. This knowledge is used in test methods for studies such as Walsh et al. which uses the supraspinatous, infraspinatous and subscapularis muscles to generate a tension force on the proximal humerus during testing (4). Studies like this are useful for explaining why the 5 distinct fracture planes of the proximal humerus exist (2). Largely the limitations

in determining forces and moments in the shoulder is due to the current models that have been generated to calculate these parameters.

Considerations for the design and surgical technique used for these implants also includes the effect of screw depth and plate positioning. The screw depth is hard to gauge in some situations as there is no visual cue in operation and a depth gauge must be used. If a screw is too long the screw will protrude too far and may enter the glenohumeral joint cavity, which can cause additional injuries and irritation. From a design view this has been minimized with locking plates by using round tipped screws to provide a smooth surface. The plates are also designed to be minimal in size to not irritate muscles and ligaments. However, if the plate protrudes too far or is placed too high it can reduce movement due to the fixation plate contacting the acromion.

## 1.4 Classification

Classification systems are used for proximal humeral fractures to allow comprehensive and clear information to be conveyed about the injury. This is particularly useful for surgeons and clinicians to convey relevant information for a patient. The classifications should be repeatable and allow different surgeons and clinicians to come to the same classification for a specific fracture case. Most classifications utilize a system that describes the fracture site and location. The most popular of these classifications are the Neer, Hertel and the Association for Osteosynthesis (AO) classifications.

### 1.4.1 Neer Classification

The Neer classification represents the most common type of classification used today. This type of classification is a modified version of Codman classification of four segment theory and was established by Charles Neer II in 1970. Therefore, the Neer classification utilizes the displacement of the 1 to 4 segments of the proximal humerus, being the head, greater and lesser tubercle, and the surgical neck. In the Neer system a fracture that is displaced greater than 10 mm and/or of an angle greater than 45 $^{o}$ is considered as “displaced”. This classification puts fractures into a certain group based on the type of fracture and its location (2,3). Although there are more in-depth classification systems, due to the Neers systems simplicity and ease of use it might explain why it is popular, as well as it being updated over the years to be more comprehensive.

*Table 5 Neer Classification groups (2,3)*

| Group | Details |
|---|---|
| **Group I** | consists of fractures that are considered un-dislocated, regardless of number of fractures. The treatment for this group is identical in most cases and is conservative. |
| **Group II** | consists of fractures with a displaced articular segment at the anatomical neck without separation of one or both tubercle, being a two-part fracture. This type of fracture is rare. |
| **Group III** | consists of fractures that occur at the surgical neck, being displaced > 10 mm and/or > 45 $^{o}$, resulting in a two-part fracture. There are three versions of this type of fracture, being impact and angulated surgical neck, separated surgical neck, and comminuted surgical neck. |
| **Group IV** | consists of fractures of the greater tubercle, which can result in a two, three or four-part fracture. Two part fractures consist of an intact articular surface with a minimally displaced surgical neck. Three part fractures are characterized due to an additional fracture of the surgical neck due to force applied by the subscapularis tendon. Four-part fracture consists of a further detachment of the head. |
| **Group V** | consists of fractures that displace the lesser tubercle. Two part fractures are characterized as displacement of the lesser tubercle. Three part fractures consist of dislocated surgical neck which causes abduction and external rotation of the articular segment. The four-part fractures add retractions of both tubercle. |
| **Group VI** | Consists of fractures that are caused by dislocation of the proximal humerus. Dislocation may occur in two, three and four part fractures. |

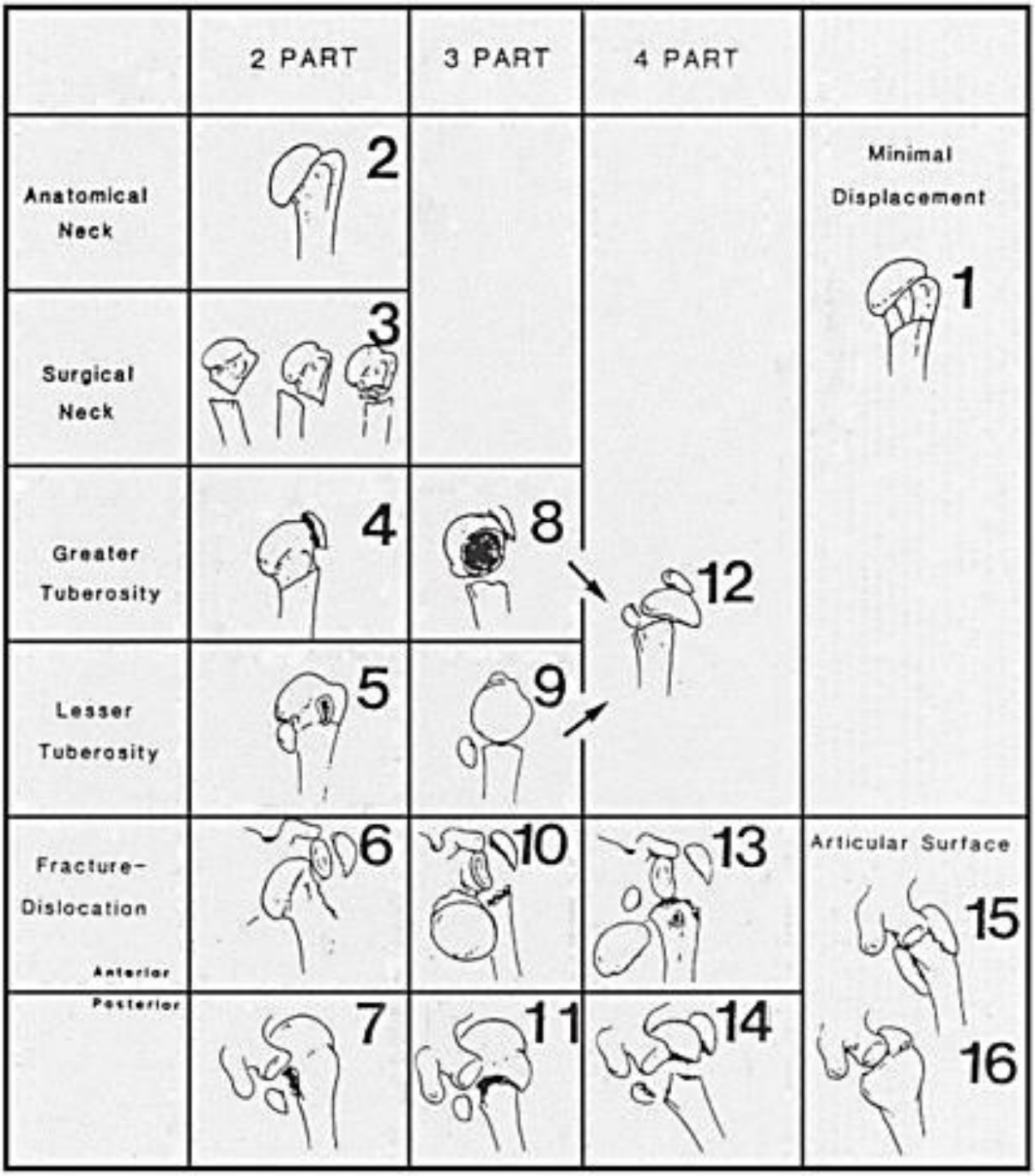


*Figure 16 Neer classification of proximal humeral fractures* (20)

### 1.4.2 Hertel Classification

The Hertel classification is another classification that was born from Codman's classification. Like Neers classification this system utilises the four-segment theory and allows classifications based on five fracture planes that occur in proximal humeral fractures. These fracture planes are: between the greater tubercle and the head, between the greater tubercle and the shaft, between the lesser tubercle and the head, between the lesser tubercle and the shaft, and between the lesser and greater tubercle. This allows the fracture patterns to be broken into twelve different possibilities (2,3). Figure 17 shows a simplified version of this, representing fracture fragments with Lego blocks. Each block represents one of the major fracture fragments seen, being: the greater tubercle, the lesser tubercle, the surgical neck and the head.

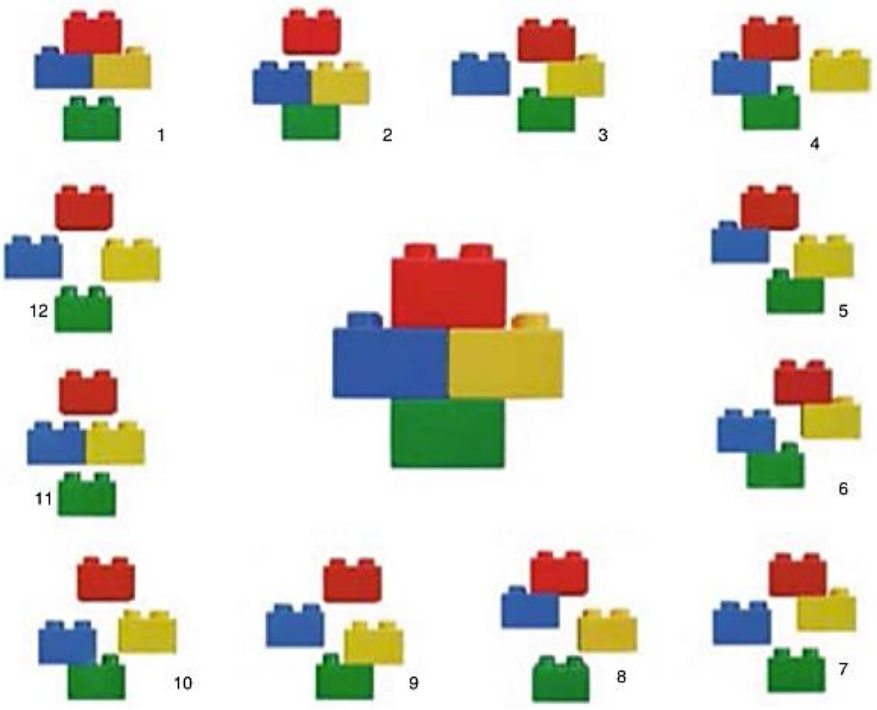


*Figure 17 Binary descriptor system of the 12 possible basic fractures based on the Hertel classification* (3)

### 1.4.3 AO (Association for Osteosynthesis) Classification

The AO classification was developed in 1990 and was further developed by surgeons and researchers of the Association for Osteosynthesis and the American Orthopaedic Trauma Association. This classification is more comprehensive than the Neer classification and overall may be able to provide the most accurate description of fractures. In this classification fracture location is referred to by a number, where the humerus is referred to as 1.1-fractures. The humerus fractures can then be classified by a type (3). Where the list of types is:

*Table 6 AO Classification types* (3)

| **Type** | **Description** |
|---|---|
| **Type A** | Contain fractures that are non-articular and definite fractures that will not develop necrosis in the humeral head. |
| **Type B** | Bifocal fractures |
| **Type C** | Fractures that are severe, articular and are associated with a high risk of osteonecrosis. |

An extensive view of some of the common fracture patterns and how they are classified using this system are shown below in Figure 18. This shows how the fracture patterns are classified for the different types.

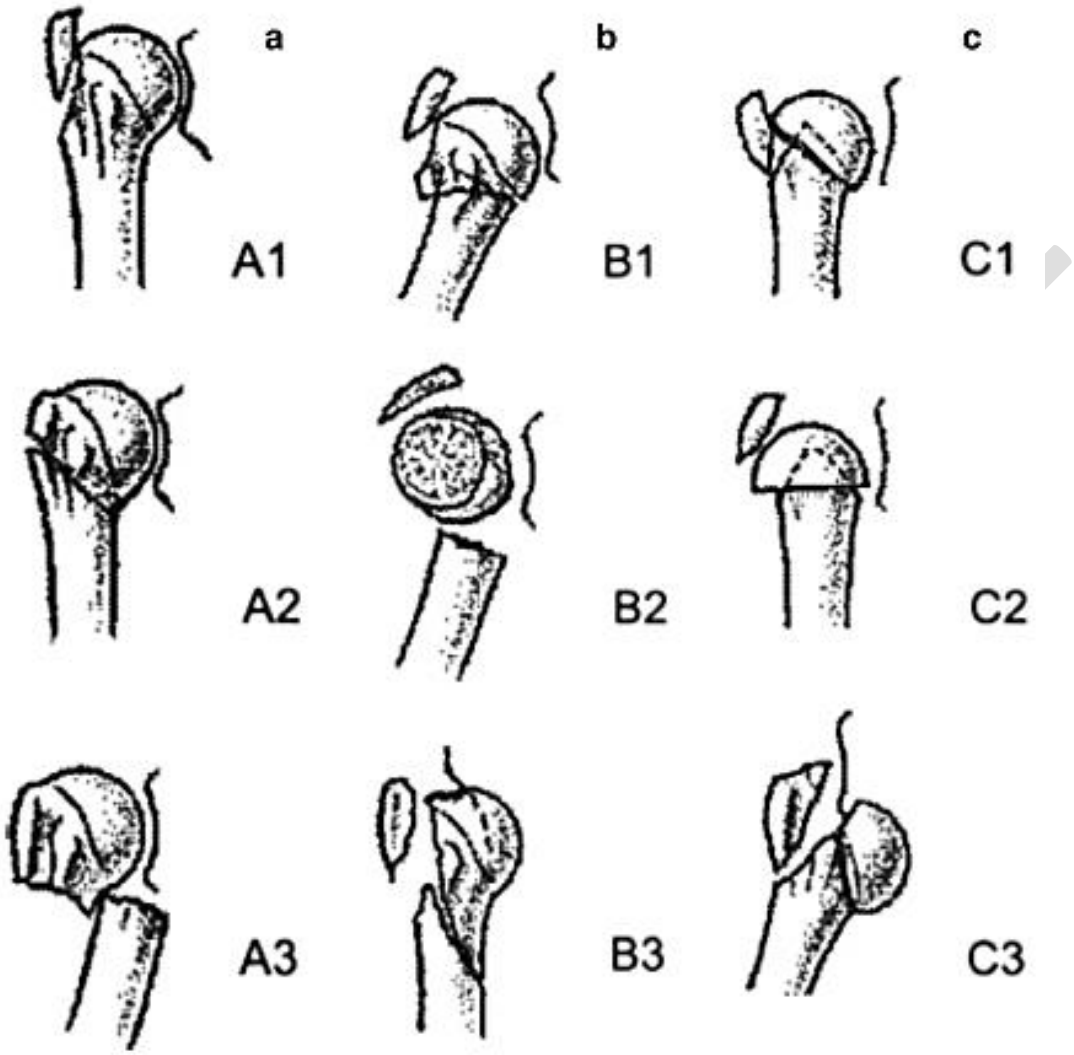


*Figure 18 Illustration of the AO classification system* (3)

Although Neer is the commonly used classification method it is arguably not the best current classification method, with all the methods having some advantages and disadvantages. The major issue with classifications is that it is hard to convey all the relevant information of a fracture. As seen from some of the above classifications there are many fracture types and even these are generalised. This is due to the number of different factors and how fractures differ from person to person. The classifications are mostly generalised due to the lack of knowledge for proximal humeral fractures as well as provide a technique of classifying all proximal humeral fractures seen. Due to this further development is needed with classifications to have a unified method of classification that expresses all the information on the patients fracture. In regards to proximal humeral plates it is important to consider these different types of fractures, as the classification of a fracture will affect the treatment a surgeon chooses. Unfortunately, the classifications do not give a grading for things such as BMD which would be useful information for surgery. These classifications express the complexity of some fractures and the variety in which they occur, which is important in the design and testing of proximal humeral plates. Proximal humeral plates are designed to include all fractures of the proximal humerus and thus need to be able to perform significantly well with all of these fractures.

## 1.5 Treatment and Surgery

There is debate on the best way to treat proximal humeral fractures, this is a result of limited knowledge as well as differing factors between patients. Treatment for proximal humeral fractures is dependent on the patient, the surgeon, and the fracture type. When a patient suffers a fracture, they will be clinically assessed to identify any issues and to plan the treatment. The methods of treatment come down to operative and non-operative techniques, which will be chosen largely based on the classification and displacement of the fracture (21). Around 80 % of fractures are minimally displaced and don't require surgery, but depending on the individual, the patient may decide to have surgery as there is arguably a better outcome (2). The fractures are classified to help the surgeons judge the best treatment, which allows insight into some of the fractures details. As an example of what is considered during treatment, Figure 19 illustrates some considerations.

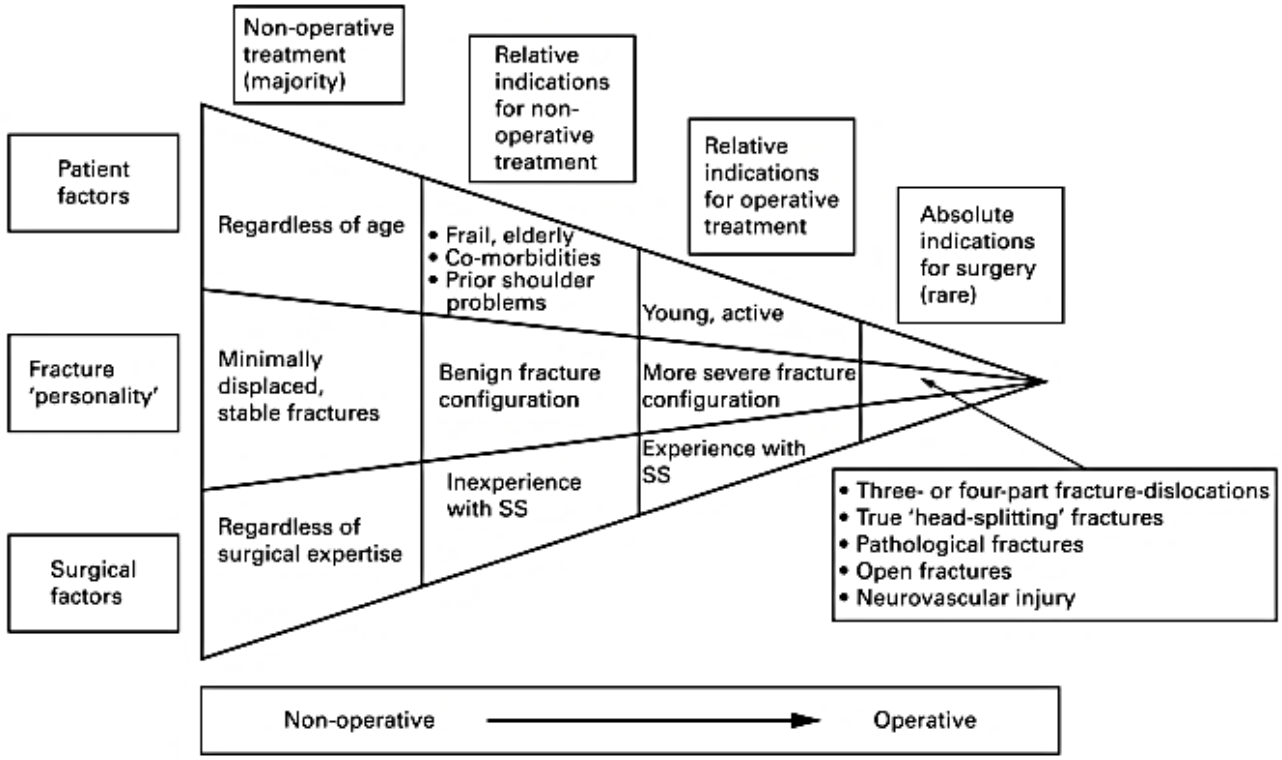


*Figure 19 Flowchart showing the way certain factors influence treatment* (21)

In many cases the fractures are stable and therefore do not require surgical management (2,21). This is an area of debate amongst surgeons for what the best method of treatment is for an individual; where the patient may be a younger individual and require a greater level of mobility during and after recovery they may decide to have surgery even if it is not required. However, it is considered that there is insufficient information to give appropriate information about management of proximal humeral fractures, where the selection of patient for surgery is normally subjective (5,21). It is normally suggested for those that have minimally displaced fractures, valgus impacted and some two part displaced fractures, that non-surgical method be used (2,5). Whereas surgery is heavily considered for head- shaft displacements that have a displacement of greater than 50 % of the diaphyseal diameter, as well as varus or valgus displacement of more than 20 $^{o}$ from the normal 130 $^{o}$ head-shaft angle (5).

Non-operative treatment is a method that does not use surgery as a part of treating proximal humeral fractures. In many cases this type of treatment is used because the configuration of the fractures is stable enough, which will allow for good healing and outcome. This type of treatment typically utilizes a sling, with hot or cold compression. Slings are used as it has been found that casts may reduce functional recovery and cause non-union of fracture fragments. Using a sling also allows for easier/earlier physiotherapy sessions, as it has been shown that shorter periods of immobilization result in lower pain scores (22). It is now more recognised that earlier mobilisation is more beneficial with recovery than extended periods of immobilisation. A disadvantage is that there may be considerable pain early on during treatment which leads to sleeping discomfort and may cause a patient to stay in hospital if they are unable to cope at home (21). This method of treatment is still considered in some multi-segment displaced fractures, but is controversial. With more complex fractures this method of treatment is mainly considered for those

patients that have little activity, such as the disabled or elderly. This type of treatment normally consists of a sling and slight compression on the fracture for the first 2 weeks and followed by passive motion and rehabilitation activities. For minimally displaced and slightly displaced fractures in elderly this method has provided good results with 80% of patients report good or excellent outcomes, with patients regaining around 80% of the abduction and flexion strength (22). In most cases the age of the patient was the most significant factor which affected the outcome of the treatment. Although this is a reasonable method for treating these fractures, there are situations that require operative techniques for treatment. Due to this method of treatment depending on the patient and fracture type, the patient may experience poor outcomes compared to operative treatments. These outcomes can include results such as osteonecrosis, non-union, stiffness and rotator cuff dysfunction (21)(2). These outcomes are heavily dependent on the individual and factors such as age and osteoporosis, but remains a rare occurrence for the usual non-displaced fractures seen in this type of treatment. One main reason that patients, especially younger individuals, decide to have surgery even if not required is the common complication of malunion in nonoperative treatment (2). This results in poor functional outcome and increases the force required to be used in some of the muscles in the shoulder (2).

Operative techniques have a few implant options being: locking plate fixation, intramedullary nails and in more extreme cases humeral head replacements, among others. Plate fixation is an open reduction internal fixation technique which utilises a bone fixation plate and bone screws to attach the plate to the proximal humerus. The fractured bone is reduced into its original anatomical position using sutures and then the plate is secured to the bone to make a stable structure. The aim for the outcome of this procedure is to reduce the bone to restore anatomical structure and to stabilise the fracture which should provide restoration of mobility, relieve pain, and promote bone growth/restoration.

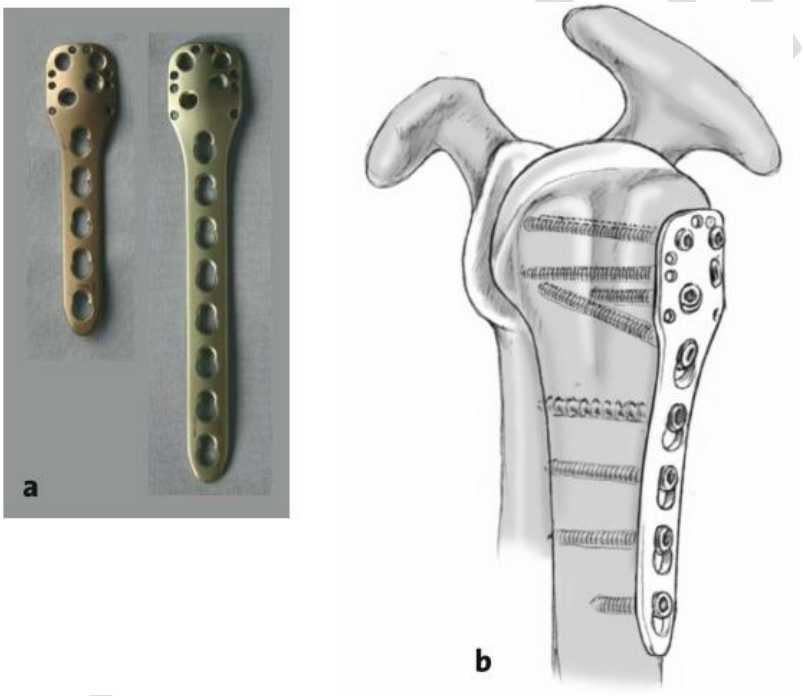


*Figure 20 Example of proximal humeral locking fixation plates (a), and example of proximal humeral locking fixation plate attachment (b)*(23)

It is currently not well established what the ideal fixation method is, however the locking plate (Figure 20) design is popular and has shown good functional outcomes (2,24,25). Locking plates are an adaption of the older compression plates, where studies show that locking plates consistently perform better than these traditional plates (4). Locking plates have also shown they can compete biomechanically with well researched implants like the intermedullary humeral nail (9). On top of being equivalent or better to the other implant designs the locking plate has other advantages such as: rotational stability, high resistance to avulsion, high initial stability, little risk of damage to the rotator cuff during surgery, ability for MRI imaging after implanted (titanium) and a shorter period of immobilization (23). The use of locking plates has been shown to have superior outcome to other implants when being used on osteoporotic bone (2,24,25). However, with advantages comes disadvantages, most of which stem from the difficulty of visualisation during surgery (23). This can lead to extensive deltopectoral movement, poor placement for locking screws, increased difficulty in examining required screw length and higher cost implants (23). Due to the nature of this operative technique considerations need to be made into disrupting blood vessels and nerves, including the periosteum. Disruption of the vascularization of the humeral head is a major concern, as the major blood supply comes from the anterior humeral circumflex artery. The major concern for this is that disruption can cause avascular necrosis of the humeral head and also reduce the effectiveness of bone recovery as blood supply plays a key role (2,26). Locking plates provide a better integration with bone and on average have a better outcome for maintaining blood supply.

Proximal humeral plates are used in many situations and include treatment for two, three and four-part fractures, where the most common treated fracture being the two-part surgical neck fracture and three-part fractures which involve the surgical neck and the greater tubercle (2,23,27). These fractures are normally displaced as to warrant a surgical method of treatment, which involved a displacement of fracture fragments of more than 1 cm and/or at a greater angle than 45 $^{o}$ (2). The decision to use this method is heavily based on the fracture but also will consider age, bone quality, and required movement/active lifestyle (2). Before surgery a type of imaging will be used to observe the fracture to classify the type of fracture which will also provide insight for the surgeon to whether a locking plate will be suitable. These imaging methods differ in each hospital but CT, X-rays, radiography and MRI have been used (2,23,27).

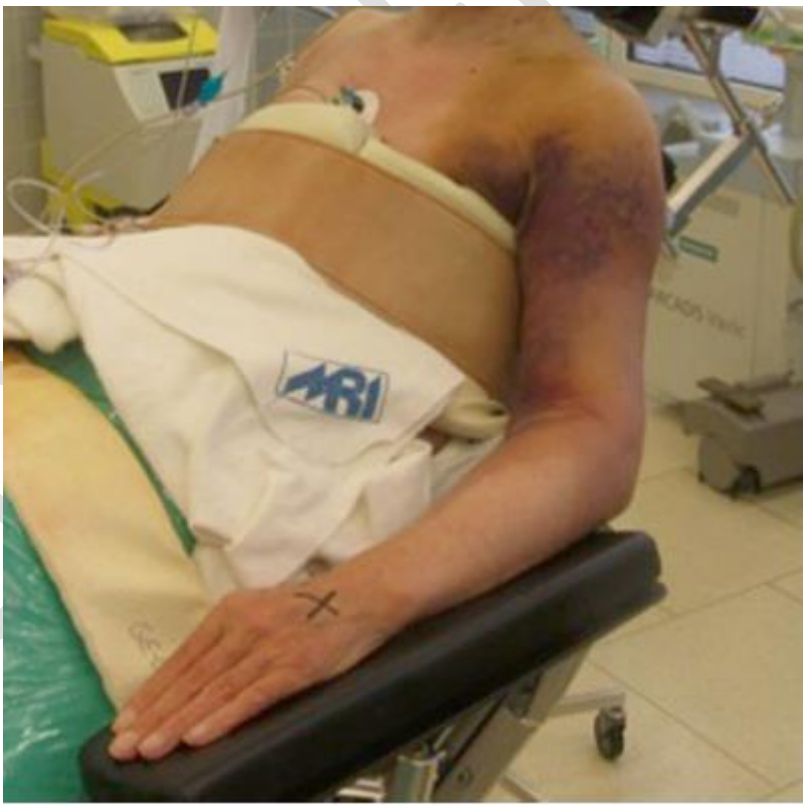


*Figure 21 Common beach chair positioning for proximal humeral fixation surgery* (3)

For surgery, the patient is put under anaesthetic and is supported in the beach chair position, lying down. The arm is supported by a table to allow for correct approach to the proximal humerus (Figure 21)(23). There are a couple of surgical approaches, being the deltopectoral split, the deltoid split and the two-incision approach. The most commonly used and the benchmark technique is the deltopectoral split techniques (Figure 22), with the second most common technique being the deltoid split (2,21,27).

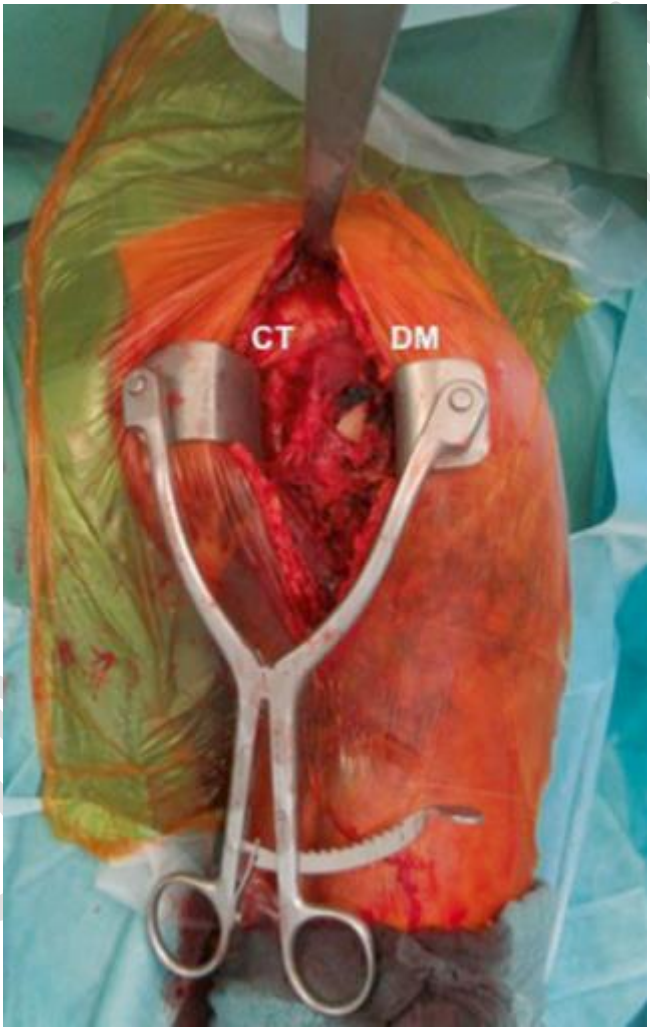


*Figure 22 Example of a deltopectoral approach, separating the conjoint tendons (CT) and the deltoid muscle (DM).* (3)

Each technique has its advantages and disadvantages. The deltopectoral split reduces the risk of damaging the axillary nerve or deltoid muscle but makes it harder to access three and four-part fractures. Whereas the deltoid split has increased risk to damaging the axillary nerve and deltoid muscle but allows easier accesses to the tubercle for three and four-part fractures (2,21). In a study by Hepp et al. which compared these surgical approaches there was better constant score given by those of the deltopectoral split technique, as a result of impeded movement in those who underwent the deltoid split technique due to the deltoid muscle being split (28). Once access to the bone has been made sutures or K-wires are used to reposition the bone fragments back to their original position and initially hold the plate in place. This is important for the success of the treatment and will be an important factor in preventing malunion and necrosis. The plate is placed against the humerus and its position is gaged by clamping it to the bone, using the K-wire and using imaging techniques, such as x-rays, to find the position during surgery. It is important that the position of the plate is not too high or too low as to reduce movement or reduce fixation, respectively. The plate will have small holes or guides for the sutures which will help stabilise the plate before it is screwed to the bone. A drill is then used to cut out holes in the bone for screw insertion, once two screws have been inserted into the head and into the neck the clamp can be removed. The remainder of the screws can then be inserted, the number of screws and the type of screws used is based on the surgeons discretion and their experience. The design of locking plates that use fixed angle screws often have screw directions that converge or diverge to provide the best stability. With this fixation method post operation rehabilitation begins one or two days after surgery with simple passive movements. Active shoulder movement can commence in 4 to 6 weeks with loaded exercises after 12 weeks (2,21,23,27).

## 1.6 Design

For the design of a proximal humeral plate, it is important to follow the standards as they outline what is required. The standards are there to make sure that the correct process is followed, so that the fixation plate performs to an appropriate level. Largely this process focusses on the intended purpose of the device and the considerations that need to be investigated when designing a proximal humeral plate. In the standard ISO 14630: Non-active surgical implants - General requirements, explains what is required for the intended performance and design considerations. The intended performance is the purpose of the implant and its characteristics. The intended performance should be described and documented to maintain safety and prove that it performs accordingly. This considers the purpose of the implant, functional characteristics, conditions of use, and lifetime. This needs to be proven using standards, literature, and validated testing (29).

A list of design considerations is also given in this standard so that the implant meets the intended performance. These considerations are:

- biocompatibility
- material properties (Mechanical, chemical, physical, etc.)
- effects of wear and wear particles
- degradation of material and its by products
- safety, with respect to biological materials such as viruses and animal tissue
- the effect of manufacturing processes on material properties
- integration effects of the implant material with other implant material and substances of the body
- interconnections and their effects on the intended performance
- interfaces relative to fixation, connection, and surface conditions
- shape, dimensions, and their possible effects on the tissues and body fluids
- biocompatibility of the implant in its implantable state
- physical and chemical effects
- effects of radiation, electromagnetic and magnetic fields on the implant and its function
- the ability of the implant to be removed or replaced
- the ability to visualize the position and orientation of the implant by imaging procedures
- microbiological/particulate contamination
- anatomical features of the population for whom the implant is intended
- condition and pathology of tissue
- operative techniques and handling of the implant

As an example of the steps that are taken during design, the following image (Figure 23) from a review study by Aitchison et al. shows the design process of implantable orthopaedic medical devices (30). This process shown closely follows what is required by the standards in proving and reviewing the design at each stage of development so that it is safe to use and functions appropriately.

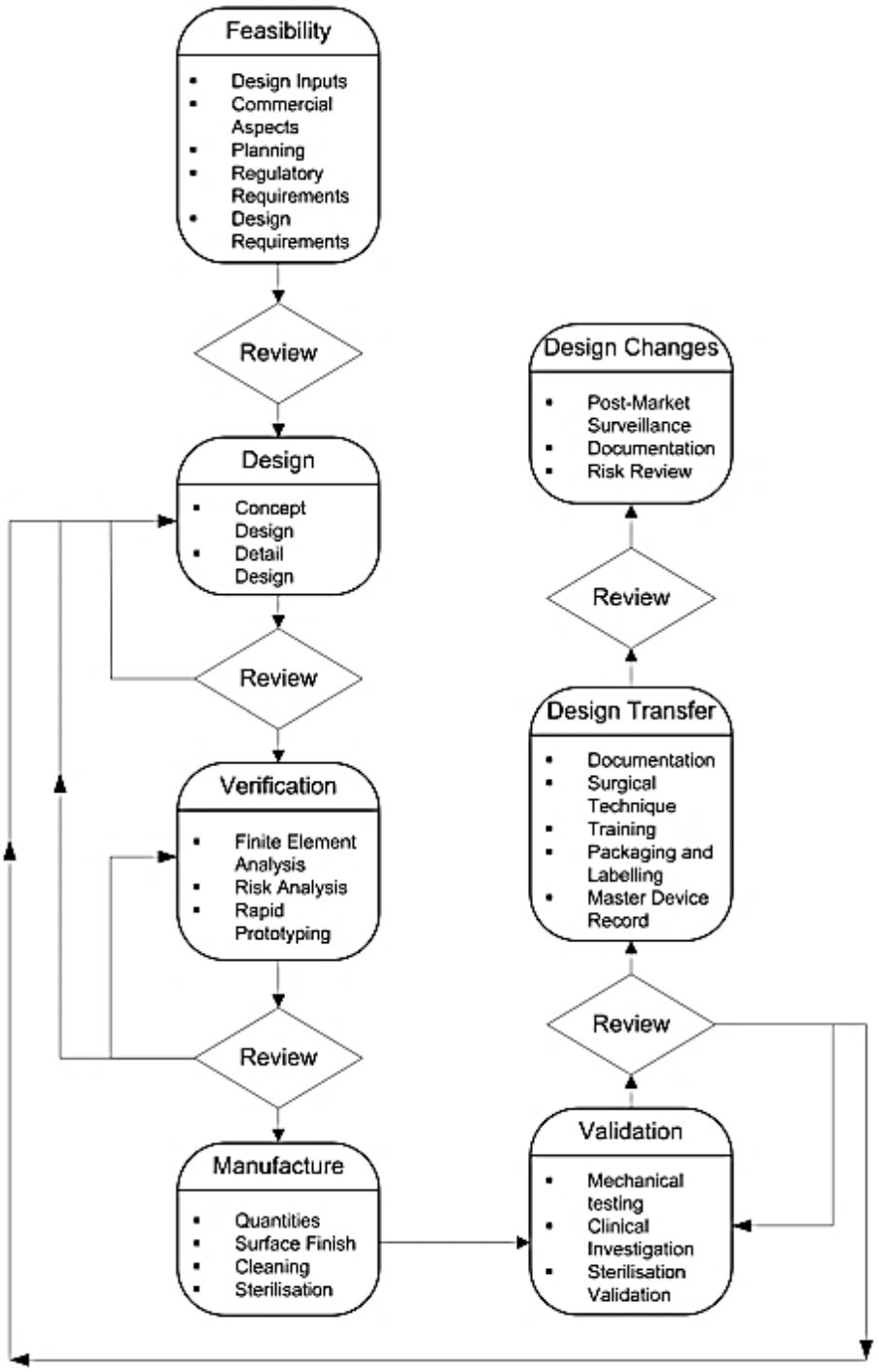


*Figure 23 The medical device design process* (30)

A large part of the design of orthopaedic implants, such as proximal humeral plates, is the material they are made from. As these implants are being inserted into the body, an acceptable level of biocompatibility is required (29). This should also consider how the material was manufactured, sterilized, stored, and all treatments the material underwent. Performance should also be examined, in terms of instance strength and factors that affect the material like radiation or magnetic fields seen in medical imaging methods. When considering the material for an implant it needs to be biocompatible to an acceptable degree with tissue, cells, blood, and bodily fluids. Some materials such as titanium and stainless steel have had extensive use as implantable materials and therefore have a reliable source of information about their biocompatibility (29). For materials, such as these there are standards that outline the required properties of the materials including composition and mechanical strength. However, for materials that aren't used as frequently there is a lack of knowledge on how they will perform in the body, for these materials testing must be performed to show the materials biocompatibility (31–33).

Additional to performance, the way patients and surgeons perceive certain materials is also important. For instance, titanium implants are not necessarily better than stainless steel implants, but titanium is often viewed as a "cleaner" material. This will affect the decision of patients and possibly be the reason why more titanium proximal humeral plates exist. Titanium is considered to be more biocompatible than steel and is used in some implants as titanium promotes bony ingrowth. This however is an unwanted side effect of the material for the purpose of proximal humeral plates, as these implants are designed to be removable.

The design of an implant and its use will largely be determined by appropriate design evaluation. All implants are required to demonstrate their safety and performance, which is done by biomechanical testing, using literature and analysis of available predictive data (29). This is to put the implant in simulated conditions like what would be seen during its intended use. These tests are performed using synthetic and cadaveric bone and mechanical testing devices. The standards provide generalised tests for bone plate implants which are required to be performed but state that the results should be compared to those from a currently used design, where additional testing should also be used. Tests are required to be compared to current implants as it shows the level of performance of the new implant (29). Unlike standards for mechanical designs, for biomedical implants many standards do not provide values to beat as there is insufficient information on how the implant will react. Therefore, new implants are compared to currently used implants as there is evidence that the currently used implant has had appropriate success in its use. By proving the new plate is comparable to the currently used plates biomechanical performance it provides evidence to support the ability of the new plate (34,35).

The proximal humeral plate that will be designed for this project will be designed to utilise variable angle locking screws. Variable angle screws can be inserted through the plate into the bone at any angle within a given range, for this version the range will be 30°. The idea behind this technology is that it gives surgeons more freedom in deciding what the best location is for bone screw insertion. This could be used to avoid low BMD areas or aiming to place more screws through those sections. This works to overcome one major concern of proximal humeral plates, being the stability of the plate. For this design two materials of differing hardness will be used, where the plate is made of a softer material and the screws being made of a harder material. This will allow the thread on the head of the screws to

generate a thread in the plate holes as it is being screwed into the bone. The holes in the plate have flutes that protrude into the hole, which allows generation of the threads.

Variable angle locking screws are based on the current standard type of screw, the fixed angle locking screw (36–38). Locking screws have become the most popular type of plate fixation device due to their high mechanical performance, good ability to fixate implants as well as being more anatomical considerate towards blood flow around the effect area. These screws replaced traditional compression screws which had smooth screw heads and held the plate to the bone using compression. This method cause blood supply to be lost, especially under the plate as well as generate a solid construct of all of the screw, the plate and the bone, which caused excessive stresses and also stress shielding of the bone. Locking screws utilise a thread on the head of the screw which locks into the implanted plate. This provides a strong fixated construct, while also maintaining blood supply and being better mechanically. Both fixed angle and variable angle screws follow this design, and both cause a bridging construct instead of holding the plate against the bone. As such VA screws are the next step in designing better fixation, improving on the current form of locking screws, providing more freedom during surgery.

As this technology is new there is not an abundance of literature that specifically looks at VA screw behaviour compared to fixed angle screws. A couple of studies were observed in the literature such as Tidwell Et al. and Lenz Et al. which both came to similar conclusions of VA screws showing similar characteristics to fixed angle screws (36–38). This is good to see from studies as this helps support this technology, as well as show that VA screws are improving on the current standard of screw. One of the concerns that came from reading some of these studies is that they report weakening of the screw as the angle from nominal increases (36,38,37), however this only seemed to be an issue in some studies at an angle above 10° (39). The studies do however say that the analysis results in similar mechanical

strengths of VA screws versus fixed angle screws. The aim however is to eventually create VA screws that are equivalent to fixed angle screws for all angles not just up to 10°. This should be an obtainable goal in the future as fixed angle screws and VA screws have many of the same characteristics.

Due to the freedom of angular insertion this will also effect the considerations that need to be made. Firstly, plates with fixed angle screws are designed so that they have the best locking structure to provide as much stability as possible, with variable angle screw this is not the case as the structure of the screws will change. It will therefore be important to see what a best case and worst-case scenario looks like in these screws performance as well as the effect of differing orientations of screw. From this information on performance can be obtained and used to generate acceptable redesigns or provide appropriate guidelines for its use. Secondly the screws are required to cut out a thread in the plate holes, this could potentially lead to debris from this action which may affect the body, which if so must be shown to not be harmful to the body. Lastly, as this is not a standard thread it is important to make sure that it is still as strong as fixed angle screw threads, which will include investigation into screw pull out strength, torque and loosening (40).

As mentioned there is a lack of testing performed on VA screws and features. This makes it increasingly hard to design and test, as many companies such as Synthes and Stryker have their own unique versions and methods of generating VA features. The Synthes design utilises normal threaded holes with 4 circular cut-outs at each 90°, while Stryker uses a design that contains a ring inside the hole allowing for different screws to be used. As these designs become increasingly different and therefore not comparable, it can be seen why there are more tests that observe VA plate performance against the equivalent fixed angle plate, instead of observing individual screws. This testing is still relevant for comparison as both VA and fixed angle screws represent locking screw technologies, which

aim to secure the bone plate while maintaining a bridging position off the bone (41). As these screws represent such a close relationship with fixed angle screws, their success has already been proved in terms of fixation. This allows testing to be focussed on the behaviour of the VA screw and plate interface.

## 1.7 Testing

Testing is one of the most important parts for designing a new proximal humeral plate and is required for showing the designs capability. Due to the safety that is required for implantable devices it is important to prove the implants performance (29). The lack of knowledge for how these implants react to the body has left the relative standards for testing generalised, as there is not enough information to provide defined values for mechanical properties required for proper function. Instead implant performance is proven by comparing to currently used designs (34). By comparing to a design that is already being used there is significant evidence that supports a similar design will be safe to use based on the performance of this existing design in clinical settings. This also makes it cheaper and require less testing if there is a comparable device to test against. However, to compare to an existing design it requires the existing design to be significantly similar. To be significantly similar requires that there are no big advancements, as more improvements are made the larger the gap is between the designs. This means the designs can't be significantly different as to show that the new implant and the existing implant are comparable (34). New designs can be proven and approved for commercial use without testing against existing designs, but this requires significantly more documentation and testing, which can be expensive and requires more time. Additionally, it may be expensive to acquire competitor's plates, so the use of pre-existing studies is useful, where a test that has been performed on another design can be recreated and allow the designs to be compared non-directly.

The testing methods that are used therefore need to be of a design that allows comparison of significant mechanical properties of the new design compared to an existing design. The standards provide testing methods for bone plates, but are generalised and not specific for a particular type of bone plate, such as proximal humeral plate. Generalised test methods for bone plates are established in the ISO 9585 and the ASTM F382 – 14 standards, these standards are set up to help establish consistent methods to classify performance of bone plates (34,35). As mentioned the standards specifically state that they are not there to provide levels of performance of specific bone plates, as there is insufficient knowledge to predict performance for specific individuals. The standards also suggest that their testing methods may not be suitable for all situations, where possible alterations may be required. In these two standards, the method of testing is a four-point bend test under a single cycle and fatigue cycling load. This method allows for results in bending stiffness, structural stiffness, bending strength, failure mode and M-N diagram for fatigue strength (34,35). These testing methods used an apparatus as shown in the diagram in Figure 24.

The standards make it difficult from which to generate an appropriate testing method, as they are generalised in a way to incorporate as many different products and only focus on one characteristic of the plate. It is therefore important to generate a testing method that is capable of testing an implants performance overall.

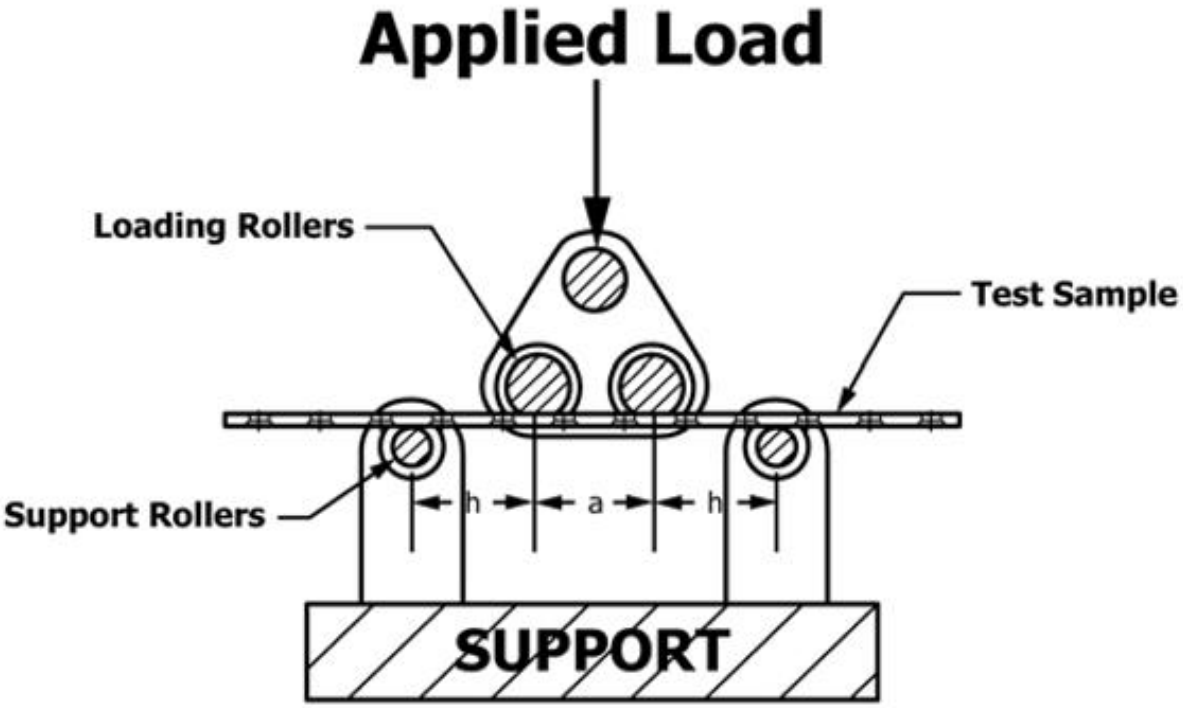


*Figure 24 Four-point bending apparatus* (34)

The issues with these tests are they are not specific for proximal humeral fracture plates, and required flat bone plates which, contoured proximal humeral plates are not. These methods do allow for alterations to the method design to incorporate different plates, however this method may not be the most applicable to proximal humeral plates (34,35).

The bone screws used with the fixation plate also need to be considered and tested. In the USA, FDA approval is required, which may be accepted by other countries, and revolves around performing the testing methods from ASTM F543 – 13 (40). This standard outlines test methods for determining torsional properties, driving torque, pull-out strength, and self-tapping performance. There are multiple tests outlined in the standard but not all of them may be applicable to the design, like the bone plate standards these tests are generalised. There are several apparatuses outlined in the standard which are shown below, the first focusing on the torsional properties and driving torque and the second focusing on pull-out strength. Figure 25 and 26, are images from the ASTM F543-13 standard which represent examples of equipment that should be used for these tests.

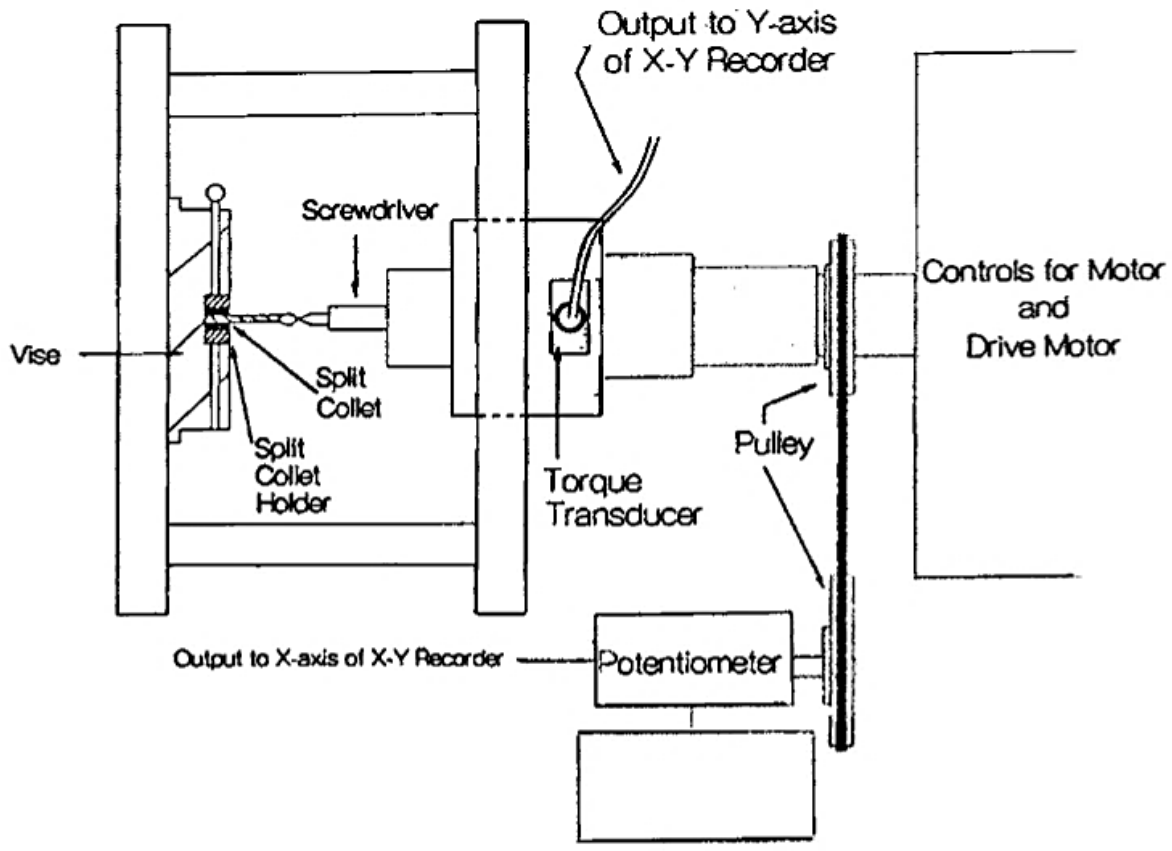


*Figure 25 Standard bone screw torsional testing apparatus* (40)

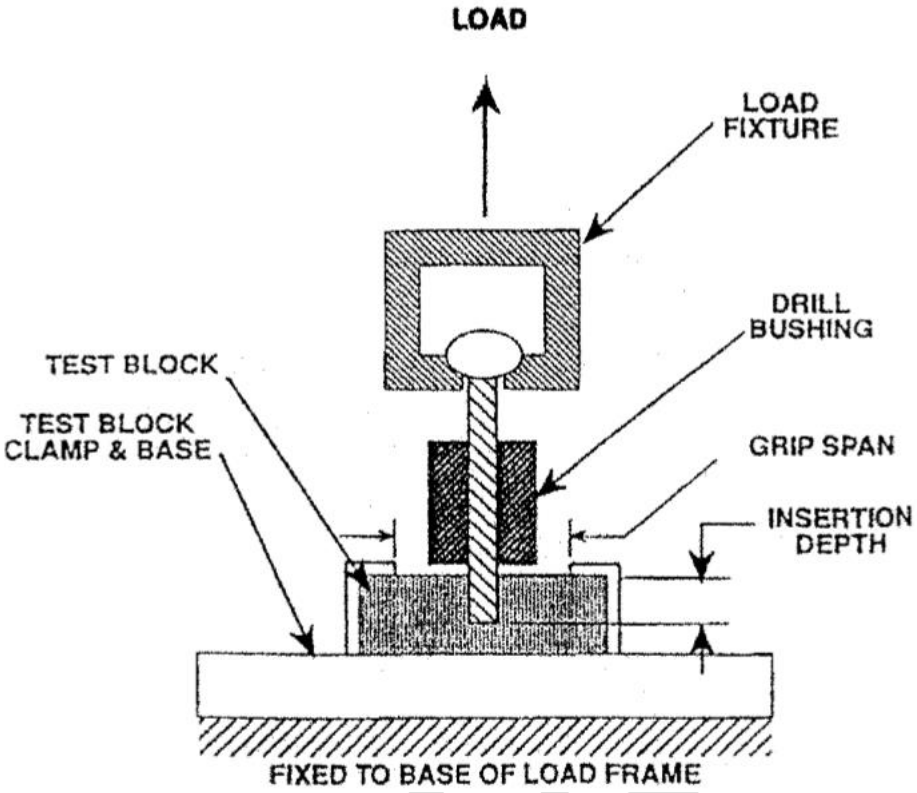


*Figure 26 Standard bone screw pull-out testing apparatus* (40)

For the design and testing of a proximal humeral plate, the bone screw tests in this standard seem to be more significant than the bone plate standards mentioned before, although both are generalised. For TGA approval in Australia these bone screw standards are required, whereas the bone plate standards aren't and are arguably less applicable to proximal humeral plates. However, it is still important to follow the bone plate standards to maintain proper documentation and proof of the implants intended purpose, including biomechanical performance (34,35,40).

In addition to the standards that are used for the design and testing of proximal humeral plates, there is a magnitude of testing that has been performed on proximal humeral plates, both clinically and biomechanically (13,24,42). The number of these studies performed has been increasing over the last couple of years (43). This is an indication that there is a large amount of knowledge that can still be gained as well as the increased use of proximal humeral plates. As the standards mention these studies are important for comparing plate designs and proving the safety and performance of new designs. Each study was seen to perform their own testing methods that focus on a certain aspect of the properties of the plate and often only focus on one classification of fracture (13,24,42). The purpose of these studies is either to analyse mechanical properties of the plate or to gain more knowledge on how a proximal humeral plate has performed in the body, under different conditions and for different people. Investigation into the studies that have been performed, including reviews, will provide valuable insight into the preferred methods of testing and their features. This will help the development of testing methods for this project, using studies reviewed as justification of testing parameters (13,24,42).

The type of specimen used in testing differs from study to study, with cadaveric, synthetic and animal specimens being used. Some other studies opt to not use specimens for testing and focus purely on the mechanical aspect of the implant, removing the biological element of the test. The use of cadaveric specimens is important to try and evaluate an implant as close to in vivo as possible and gain behavioural understanding about the bone-plate interface. Cadaveric bone can provide a better insight into the reaction of proximal humeral plates in different age groups, with most studies performing cadaveric testing on specimens with a mean age of around 65 years or older. In a review of testing by Cruickshank et al. (13) 87 % of testing was performed by using cadaveric specimens, with 7 % on synthetic bone. The mean age was found to be 73 years for the cadaveric specimens, with a mean

sample size of 27. This is congruent with other testing seen, where cadaveric bone is a favoured testing specimen type (4,9,10,44). Most of these specimens are frozen before testing, with 76 % found during the review (13). These cadaveric bones are usually frozen as fresh as possible and are defrosted for a given time before testing (9). Depending on the testing being performed, the tests have either been on a full humerus bone or on a potted specimen, making up around 2/3 of the humerus. It is common for the humerus to be cut at around 1/3 distally and then potted, usually using a substance such a polymethylmethacrylate (PMMA)(4)(9)(10). For looking specifically at proximal humeral fixation plates the use of a whole humerus is not required, however it may be useful for getting a better representation of moments applied to the humerus if required by the test (10).

For testing of proximal humeral fixation plates the ability to create repeatable, similar synthetic “fractures”, on the specimens being tested is important. Most commonly these fractures are made by an oscillating saw and made to be 1 cm in width. This 1 cm distance is most likely taken from the way fractures are categorised, where a displacement of 1 cm or greater is considered “displaced”, however depending on the testing method the thickness of the cut has been between 1 to 7 cm in the studies observed (2,4,9). From clinical reviews it can be seen that the most common fracture type is 3-part fractures at 45 %, with 2-part fractures at 34 % and 4-part fractures at 21 % (42). This is interesting to consider when the most common fracture type that is tested is the 2-part fracture, this would largely be due to the ease of making repeatable 2-part fractures (13). Depending on the type of fracture that is being tested, will depend on where the saw cut occurs. Largely for 2-part fractures it seems common to make the cut at the surgical neck, which is a common fracture site. In tests where 3-part fractures occur an additional cut is made, for instance at the intertubercular groove (9). The positioning and dimensions of these cuts is

dependent on the testing methods. The simulation of fractures is one area in which comparison with clinical behaviour is hard, this is due to the large variety of fractures making it impossible to simulate a real-world fracture that would provide significant biomechanical information for fractures. This is one of the reasons why cadaveric testing is not directly comparable to clinical testing.

When using cadaveric specimens, the specimens are evaluated before biomechanical testing begins. This is to investigate the quality of the bone and to see if there are any tumours and other irregularities that may exclude the specimen from the testing. Commonly radiographs (48 %) are used to investigate the bone, but CT imaging (18 %) is also used, but is less common. Due to the effects of BMD on mechanical stability in fracture plates and the overall effect on fixation, BMD testing (46 %) is another largely used evaluation technique (2,13). These pre-testing methods are important for removing non-ideal specimens from the testing group as well as presenting information on the trends of plate performance in specimens with different BMD values. Many tests also use specimens that have been removed of soft tissue before testing, this would help with testing the mechanical properties of the fixation plates. As it is hard to show a direct relationship between in vivo and in vitro testing, the preservation of the soft tissue is not important in the testing to prove the mechanical performance of the plate. However, in some testing the investigation into anatomical forces being applied to the bone may require the use of some soft tissue, such as a study performed by Walsh et al. which used cadaveric specimen with muscles still inserted into the proximal humerus to apply a tension force to the bone (4).

Due to the lack of knowledge and the lack of a specific standard method of testing there are many different test methods for different situations for proximal humeral fixation plates. Largely the testing for any study will revolve around three main types, torque, axial loading, and bend testing. However, how the force is applied, the location and how the specimen is

positioned/constrained will differ from test to test (13). Most tests aim to have relevant anatomical factors as a part of the test so that the test can provide some form of insight into how the fixation plate will perform clinically. This is most commonly seen by either constraining the specimen at an angle to represent an angle of abduction of the arm, or trying to produce a force that represents what would be seen through the humerus in normal use (4,13,44,45). As mentioned previously this is hard due to the wide range of movements and complex tasks that the upper extremities perform. To prove the strength of a fixation plate, even if it is not directly comparable to clinical use, the application of a cyclic load to the specimen and then load till failure can be used. This provides insight into the strength of the plate while also looking at fatigue life and the failure mode of the plate. Again, these tests have been performed differently between studies, in some the cyclic loading is at a set force whereas some increment the force each cycle. Other studies perform either one cyclic test or one load to failure test on a specimen where some tests do both tests on the same specimen. Interestingly though, the method of testing that is suggested by the standards (four-point bend test) is the least common construct of testing that has been seen (13). This on its own suggests the lack of knowledge in terms of mechanical testing for these plates but also suggests as testing has become more common a possible update for the standards to provide more relevant testing. When cyclic loading is performed the number of cycles vary significantly, with the difference being as great as 5 cycles to 1,000,000 cycles (13). The same can be said for the rate at which the force is applied and the Hz of the cyclic loading. The magnitude of force for both cyclic and load to failure tests also varies, but are mainly still forces that have been described in other studies to occur through the shoulder joint or the humerus.

The testing for screws is usually performed in separate studies, however some studies choose to measure screw loosening or sometimes the difference in screw torsion required to undo a screw before and after testing. The usual tests seen for studies based on screw testing are, torsional tests and pull out strength tests. Unless specifically looking at the bone-plate interface many of the screw testing doesn't use bone specimens to perform testing. For screws they use either a plate in which they are made for or a custom plate which has holes of the same dimensions (39). For this report an important test consideration will be the use of the variable angle screws technology. In regard to testing the mechanical strength of variable angle screws there is an important study performed by Lenz et al. in which screws are inserted through a custom-made plate at different angles and are cyclic loaded using a ball joint and protective sleeve to protect the screw from bending. This will be important to see if any loosening occurs and to see the strength of the screw at different angles (37). This test is used to measure a difference in torque but could be adapted to measure pull out strength due to a shear force, which can generate a moment. Other screw tests have been found to be similar to those shown in the standards and suggests that there is a better understanding of what is required from bone screws than the plate itself.

## 1.8 Literature Review Conclusion

The information obtained through this review of relevant literature will help the progression and understanding of this project. There are considerations that need to be made for the process of developing a proximal humeral plate, which include aspects such as anatomy, failure causes and design aspects. These considerations are repeatedly being reviewed due to the general lack of knowledge in these areas, specifically to do with situations often caused by patient factors and the complexity of the shoulder and its movements. This is also effected by the minimal comparison that can be made between biomechanical testing and clinical results. Overall, the process of justifying a new design for fixation plates revolves around proper testing to show the performance of the device. Due to the general understanding in the field and the available standards, testing must be significantly justified by relevant literature, in terms of parameters and method. This information has set up common parameters and patterns seen in testing, such as the use of ramp and cyclic loading tests. This helped define testing methods and parameters in accordance with what was required by Austofix. Using this literature, testing methods and processes were generated and followed in this project, which can be seen in the justification section of each test chapter. These tests helped develop aspects of the new proximal humeral plate designed by Austofix. These methods were often based on previous testing, which was important in setting up a basis for testing aspects such as the Variable Angle (VA) screws and Variable Angle Screw Technology (VAST) hole features of the Austofix design. This can be seen by the modified use of testing methods, seen in the Lenz et al. studies. Additionally, general information that was collected through the literature review was also used where considerations needed to be made, such as the main reasons devices fail.

# 2 Project Introduction

## 2.1 Aim/Scope

The aim of this project was to develop testing methods that would facilitate in the development and justification of a new proximal humeral plate, developed by Austofix. The company is developing a new proximal humeral plate, which aims to incorporate variable angle locking technology. This project will facilitate the development of this design, as well as the design of the full construct. The development of testing methods will be performed using information sourced from standards and biomechanical studies, which will be used to justify conditions such as parameters, loading method, equipment design and methods used. Testing was also designed based on the recommendations and requirements set it place by Austofix, to help justify the performance of their designs. This included the use of testing methods to justify and observe the performance of a single VAST hole feature/VA screw interface, as well as a method designed for a complete construct test. The information gained from these testing methods either proved the current design or generated design alterations to optimise performance, based on the success or failure of the specimens under the testing conditions.

## 2.2 Background

The development of fixation plates is not a straight forwards process. Due to the many differences between individuals, types of fractures, daily tasks performed and the way the implant may react in the body, there are many unknowns. With this lack of knowledge, there lacks a basis to generate a standardized method of design and manufacture of these devices. To overcome this when a fixation plate is being designed, its performance is proven by comparing it to a competitor's fixation plate which is already being used clinically. Alternatively, performance can be shown by using justified biomechanical testing, which uses relevant literature and studies to justify and base testing parameters on. This can be used to then test performance characteristics that are required to be observed. The justification is usually based on past testing that observed testing of similar fixation plate designs. Additionally, justification can be made by using studies such as models of anatomy that are performed to understand different forces and moments acting in the body. However, as each study will perform their own literature review and aim to test specific situations where it is rarely seen that a study is repeated (13,24,42).

This report will show the outline of testing methods designed for this project in helping develop a new proximal humeral fixation plate. The report will outline the designed methods including equipment used and testing parameters, as well as some results and discussion points. Due to the necessity for justification to show a valid test is being performed, a justification section has also been included for each testing method. These tests were largely based on the requirements provided by Austofix, and have been adapted based on literature or limitations imposed by the available testing equipment.

# 3 Button Testing

## 3.1 Background

Due to the complex nature of testing the performance of proximal humeral plates, before a total plate construct was tested the design was broken down into a single Variable Angle Screw Technology (VAST) hole feature to allow testing of a single Variable Angle (VA) screw. This type of testing would make it easier to focus on one of the most complex aims of the testing, by allowing the observation of the performance of a VA screw and its associated VAST hole feature. To allow for this type of testing, instead of using a fixation plate, a small disc plate with a single VAST hole was designed. These discs were dubbed “buttons” and subsequently led to the general name of Button Testing, used for all tests that involved the use of these single VAST hole discs.

The VA technology is a relatively new technology to Austofix and therefore it was important that the design of the VAST hole feature and the VA screws was to be tested. Bone screws play a large role in proximal humeral plate outcomes, which makes it important to show that the design can achieve an appropriate level of performance using this VA technology. This method includes preliminary testing of the interface of the VA screw and VAST hole feature. The basis of these methods originated from similar testing designs for an earlier Austofix project. This method was modified to support larger 3.5 mm VA screws which are used for this proximal humeral plate design, and subsequently are required to support larger loads than the previous project.

## 3.2 Aim

Button testing aims to test and determine an appropriate tolerance range for the design of the VAST hole feature for the final design. The button testing methods represent preliminary testing performed for this project. Aiming to observe the mechanical performance of the VAST design to adapt and improve the design based on the results of these test methods. In particular testing methods will be utilised to observe the insertion parameters under normal surgical conditions, as well as the mechanical strength of the VA screw/VAST hole interface to determine the best tolerance range based on performance.

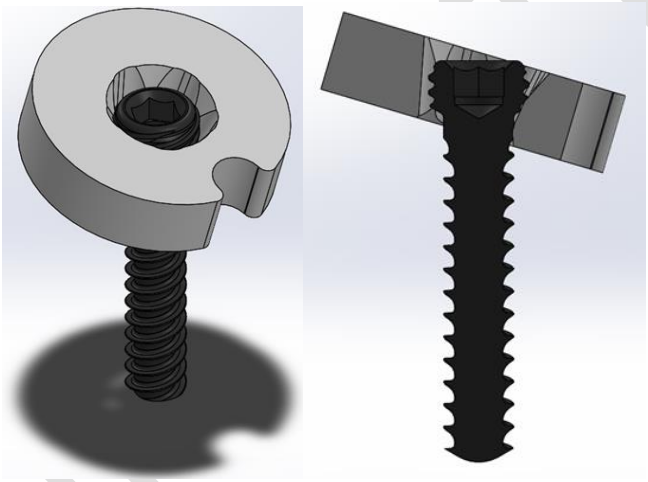

*Figure 27 Button disc plate and associated variable angle screw*

## 3.3 Design

### 3.3.1 Variable Angle Design

Austofix has designed a unique variable angle method of inserting fixation screws in bone plates. There are differing designs used by different companies, with the aim to provide the surgeons the freedom to insert fixation screws at different angles within a given range. The Austofix variable angle design uses two materials that differ appropriately in their hardness. This results in the VA screw being a harder material than the plate material, allowing the thread on the head of the screw to cut its own thread into the VAST hole feature, providing a locking mechanism. After a review of material properties as well as currently used materials for bone fixation plates and bone screws, the use of two different grades of titanium was incorporated into the design. This resulted in the screws being made of Ti-6Al-4V Grade 5 titanium and the buttons being made of commercially pure Grade 3 titanium. The resulting design aims to produce a range of 15° insertion from perpendicular to the plate.


*Figure 28 Example of variable angle screw insertion (Not the design for this project) (76)*

### 3.3.2 Variable Angle Screw

The VA screw is a 3.5 mm screw of 20 mm length, which utilise custom designed shaft and head threads. For the purpose of the button tests the screws were manufactured without shaft thread, making the diameter of the shaft equal to the major thread diameter of 3.5 mm. This was done to reduce cost and time of manufacturing, as ultimately the shaft threads were not required for testing of the VAST hole feature/VA screw interface. The screw head thread was maintained as designed, this is important for these testing methods as it is this thread that allows locking of the screw into the VAST hole. All VA screws for button testing were manufactured to be identical, with their dimensions being checked using Coordinate measuring machine (CMM).

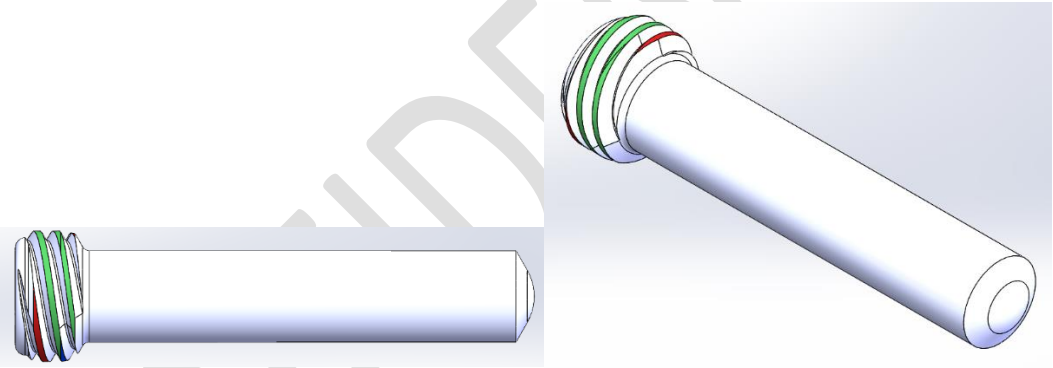

*Figure 29 Variable angle screw used during testing*

### 3.3.3 Button/VAST Hole Feature

The button disc plates were designed to be of 15 mm diameter and of 4 mm thickness. These dimensions were appropriate to allow a significant amount of plate material as to not affect material properties during testing and to maintain a thickness that is representative of the plate design. The VAST hole feature was centred in the middle of the button, and were manufactured to the appropriate dimensions as designed by Austofix. The minimum VAST hole diameter was altered in size from the designed dimension to test the effect of different tolerances. The diameter of the VAST hole was adjusted from the nominal design by 0.05 mm increments. This resulted in 11 different diameter VAST holes being: nominal, ±0.05 mm, ±0.10 mm, ±0.15 mm, ±0.20 mm and ±0.25 mm. These tolerances were confirmed using a Coordinate Measuring Machine (CMM). The buttons also incorporated a small circular cut out, this cut out allowed for appropriate locating of the button for screw insertion and specimen testing.

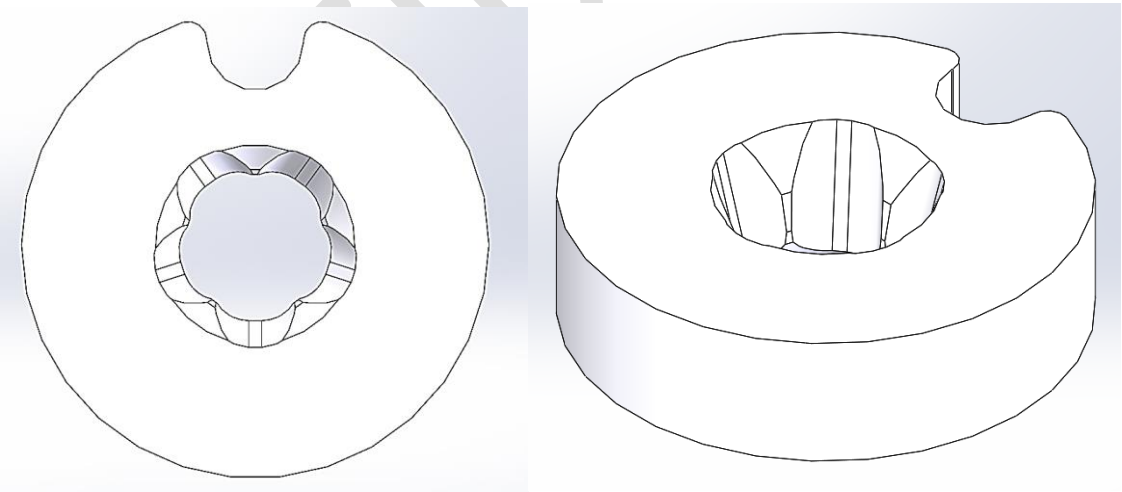

*Figure 30 Example of "buttons" used for testing, including a single VAST hole feature.*

## 3.4 Method Summary

The methods summarised below make up the testing methods that were incorporated under the button testing title. These tests are preliminary tests aimed to observe the performance of the VA screw/VAST hole feature interface under different mechanical conditions with differing VAST hole diameters. This was performed in an attempt to generate the best design, largely based on the effect of differing tolerances of VAST hole dimensions.

### 3.4.1 Test Method 1 – Torque Test

This method represented the first testing performed for this project. This testing observed the insertion of the VA screws into the VAST hole feature of the button plates. The VA screws were inserted within predetermined torque ranges, which represented the maximum and minimum insertion torque limits that would be seen during surgery based on the currently used 2.5 Nm torque limiters used for this kind of fixation plate. The distance of the top of the screw head to the face of the button plate was measured to observe if an appropriate insertion depth could be made for the design with these insertion torque values. This testing included inserting specimens at angle of 0° and 16.5°.

### 3.4.2 Test Method 2 – Ramp Loading

This method used the button/screw specimens that passed the torque testing method. In this test, the specimens were inserted into a testing jig and were tested mechanically using an Instron material testing machine. The specimens were loaded in shear at a rate of 5 mm/min until failure of the interface between the VA screw and VAST hole feature occurred. Data was recorded from the Instron during the test, which provided information on the strength of the interface and the design.

### 3.4.3 Test Method 3 – Cyclic Loading

This method of testing utilises the same testing jig as the ramp loading test. In this method, instead of the specimen being loaded till failure the specimen will undergo a cyclic load between 24 – 120 N. This testing method has not yet been performed, where the use of this testing method will be performed on the second iteration of Button designs, which will utilise a differing set of tolerances. This testing method will be performed using the same Instron testing machine and will allow the observation of the fatigue failure of the specimens and the interface of the VA screw and VAST hole feature. Due to constraints of the project this testing method has been finalised but not used, where some aspects of the design or equipment may be subject to change before it is used.

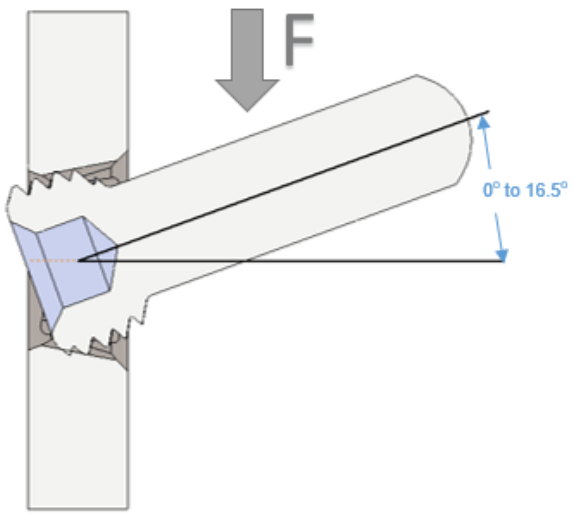


*Figure 31 Representation of specimen during testing for ramp loading and cyclic loading tests.*

Both the ramp loading and cyclic loading tests will utilise the VAST test jig. This test jig will allow the specimens for each test to be loaded with a compressional shear. The loading that will be seen in the tests is shown in Figure 31, where this will occur for an insertion angle of 0° and 16.5°.

# 4 Torque Test

## 4.1 Aim

The torque test will observe the behaviour of VA screw insertion over a range of different tolerance VAST hole features. This will help determine appropriate tolerancing sizes of the hole as well as investigating the appropriateness of the currently used torque range. This will be observed for insertion angles of 0° (perpendicular to plate) and 16.5°. This will determine at what tolerance a screw will lock into the VAST hole at normal insertion torque, as well as providing information about screw head height after insertion.

## 4.2 Testing Justification

This testing method was designed to observe the locking performance of the VA screw in a VAST hole feature for a range of tolerances at an appropriate torque. The torque value range that will be used is based on the 2.5 Nm torque drivers that are currently seen in competitor products for similar 3.5 mm VA screws, which are also commonly used in surgery (46). A torque limiter has been chosen for this project as a result of past projects performed by Austofix, where it was found that there is a large variation of insertion torque between surgeons, with surgical techniques not always being followed. According to ISO 6789, the ISO standard of manufacturing torque drivers, torque drivers must be designed with a ±6% tolerance range. This testing method will utilise an additional 10% safety factor on top of the 6% tolerance range. To achieve an upper and lower limit a 10% offset from the minimum and maximum calculated torque will be used.

This test will also be observing the effects of differing angles on the interface of the VA screw and VAST hole feature. The design aims to provide an angle variation of 15° from perpendicular to the plate. The use of a 0° insertion as a control and 16.5° insertion as the maximum angle of insertion will be used for this testing method. The 16.5° insertion angle was calculated using a 10% safety factor, from the recommended 15° maximum insertion angle for this design. These angles will represent the optimal insertion angle and the “worst case” insertion angle.

### 4.2.1 Minimum Insertion Torque Range

Nominal Torque – Tolerance – Safety Factor = Highest Minimum Torque

(2.50 Nm – (2.50 Nm * 0.06)) – (2.50 Nm * 0.10) = 2.10 Nm

Highest Minimum Torque – 10 % insertion range = Lowest Minimum Torque

2.10 Nm – (2.10 * 0.10) = 1.89 Nm

Lower Torque Range is 1.89 Nm to 2.10 Nm

### 4.2.2 Maximum Insertion Torque Range

Nominal Torque + Tolerance + Safety Factor = Lowest Maximum Torque

(2.50 Nm + (2.50 Nm * 0.06)) + (2.50 Nm * 0.10) = 2.90 Nm

Lowest Maximum Torque + 10 % insertion range = Highest Maximum Torque

2.10 Nm + (2.10 * 0.10) = 3.19 Nm

Upper Torque Range is 2.90 Nm to 3.19 Nm

## 4.3 Testing Parameters

### 4.3.1 Insertion Angle

- Angular insertion of 0° (perpendicular to plate)
- Angular insertion of 16.5°

### 4.3.2 Insertion Torque Ranges

- Lower torque range = 1.89 Nm to 2.10 Nm
- Upper torque range = 2.90 Nm to 3.19 Nm

### 4.3.3 Screw Head Displacement Parameters

Screw Head distance from plate surface will be observed and recorded in this testing method. There are however, no studies that have been investigated that suggest a maximum allowable protrusion/screw depth or method of measuring this distance. In this test, the distance from the surface of the head of the screw will be measured from the top face of the button. This measurement will be done using a micrometre. This measurement is being performed for this testing, as it was deemed important to understand how far the screws would protrude from the surface of the button. This is based on information from literature about the potential of protruding services of implants irritating soft tissue, such as muscles.

## 4.4 Testing Equipment

1. Test Specimen
    a. 3.5 mm VA screw of 20 mm (x 110)
        - Manufactured without shaft threads (shaft diameter equal to major thread diameter, 3.5 mm)
    b. Button disc plate 15 mm diameter by 4 mm (containing a single, centred VAST hole feature) (x 110)
        - Utilizing differing hole diameter dimensions (nominal, ± 0.05 mm, ± 0.10 mm, ± 0.15 mm, ± 0.20 mm, and ± 0.25 mm)
2. Norbar Torque Screwdriver Tester Series 2. (0.5 – 10 Nm)
3. Locating collar (0 º and 16.5 º)

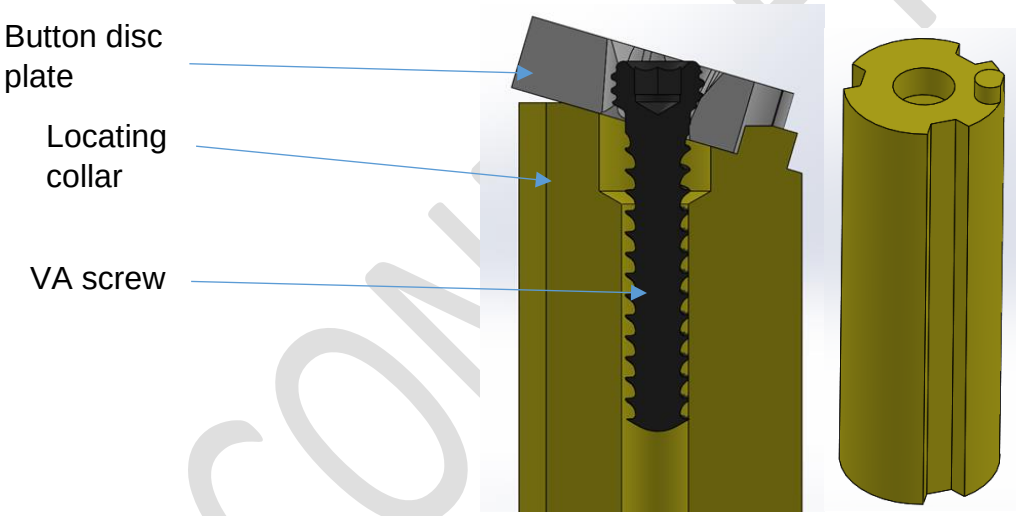


*Figure 32 (a) example of a 16.5° locating collar being used with a cut view, (b) full view of a 0° locating collar*

The locating collars were designed and 3D printed to provide proper angulation of the button in respect to the direction of the screw. From Figure 32, the button is placed on the collar, where the screw sits through the central hole of the collar, and rests in the VAST hole feature of the button. When this construct is clamped in place by the chuck of the torque tester, the screw can be driven into the button. The close fitting central hole of the collar maintains proper orientation of the screw during insertion. These collars were printed for 0° and 16.5°, with side flutes to allow for proper grip of the chuck on the button and the collar (Figure 33).

*Figure 33 Norbar Torque Tester set up for screw insertion*

The Nombar torque tester was used to determine the highest torque achieved during insertion of a screw. The testing machine was clamped, with a g-clamp, to prevent any movement of the equipment during testing. The chuck has a hexagon cut out centred on the bottom which fits with the torque tester hex-key protrusion. Torsion of this axis is measured by the torque tester, which is why it was important to centre the axis of screw insertion on this point. The screws were driven in using a T-handle hex key driver.

## 4.5 Data Collection

Data collection was included for all VA screw/button specimens. The information that was recorded for each test includes data obtained by measurements and results based on subjective observation. This information is presented in the results section of this chapter. Any malfunctions of equipment or errors in testing were recorded, specifying which specimen was being tested and the nature of the fault.

Data recorded:

- Button specimen number
- Button hole dimensions (e.g. nominal, ± 0.05 mm, ± 0.10 mm, ± 0.15 mm, ± 0.20 mm, and ± 0.25 mm)
- Angle of insertion (0 $^{o}$, 16.5 $^{o}$)
- Maximum torque during insertion
- VA screw head distance from top face of button

## 4.6 Sampling Technique

Specimen for this test method were taken from a batch of buttons and VA screws that were manufactured, which had the appropriate dimensions. The VA screws were selected randomly from a batch of 123 VA screws, testing appropriately the dimensions of randomised specimens using CMM (Coordinate Measuring Machine). A batch of 110 Buttons were made, which represents the total number of specimens tested. The buttons were measured using the CMM to ensure they were dimensioned appropriately, including the different tolerances (e.g. nominal, ± 0.05 mm, ± 0.10 mm, ± 0.15 mm, ± 0.20 mm, and ± 0.25 mm). A specimen was excluded if it didn't meet the requirements of dimensioning as outlined by the designs provided by Austofix.

### 4.6.1 Sample Size

This test method utilised 110 VA screws and buttons, for testing 11 different tolerances and two different angles of insertion. The table below represents the spread of the specimens for each test (Table 7). Each test is performed using 5 specimens, a test is represented by a single tolerance at a given angle. This results in 10 specimens per tolerance and 55 specimens for each angle of insertion.

*Table 7 Sample Size for Torque Test*

| BUTTON DIMENSION | $0^O$ | $16.5^O$ |
|---|---|---|
| **-0.25** | 5 | 5 |
| **-0.20** | 5 | 5 |
| **-0.15** | 5 | 5 |
| **-0.10** | 5 | 5 |
| **-0.05** | 5 | 5 |
| **NOMINAL** | 5 | 5 |
| **+0.05** | 5 | 5 |
| **+0.10** | 5 | 5 |
| **+0.15** | 5 | 5 |
| **+0.20** | 5 | 5 |
| **+0.25** | 5 | 5 |

## 4.7 Testing Method

This test will observe the insertion of VA screws at 0° and 16.5° for given tolerance increments. The VA screws were first inserted at a torque range of 1.89 – 2.10 Nm and then at 2.9 – 3.19 Nm, representing a lower and upper torque range based on torque drivers used in surgery. The testing started at the nominal tolerance and was incremented outwards from nominal. Testing was stopped when a tolerance range in a certain direction (±), had all 5 specimens for a given test fail. The method that was followed for testing is as follows:

1. Using a new VA screw and a nominal button
2. Place the 0º locating collar in the chuck of the torque tester and place the button on top of the collar, positioning so that the cylindrical protrusion from the collar locates with the cut out of the button
3. Close the chuck until the collar and the button are firmly secured, making sure that there is no movement of the button and that the button is flush and centred with the top of the collar.
4. Place the chuck on the torque tester, and zero the machine
5. Place the VA screw in the hole and insert the screw into the button, using a T-handle hex head driver
6. Stop driving the screw when a torque of 1.89-2.1 Nm is reached
7. Record the maximum torque from the screw insertion, and head protrusion from the buttons top face (negative value if head sits below face surface)
8. Reset the torque tester and drive the current screw to the upper torque range (2.9-3.19 Nm)
9. Once complete record the results of the screw torque and protrusion, and place the specimen aside

10. Repeat this process with a new screw and button of the same tolerance offset
11. Once 5 tests have been performed on the same offset dimension, alternate the locating collar to the 16.5° collar and repeat the process using new screws and buttons for this angle
12. Once all 10 specimens for a give tolerance have been tested, test the next tolerance range closest to nominal and repeat the testing process
13. When an offset tolerance fails on all 5 specimens do not continue with testing tolerance ranges in that direction, further from nominal (e.g. positive tolerance range or negative range)

### 4.7.1 Failure Criteria

- The screw fails to tap into the button with the required torque
- The screw falls through the button before the required torque is reached
- Insertion torque fails to be with in the acceptable range of (as stated in the justification section):
    - 1.89 Nm to 2.10 Nm or,
    - 2.90 Nm to 3.19 Nm

For this test method if all 5 specimens from the same tolerance and angle categories resulted in a failure, as a result of the above failure criteria, the progression of testing further tolerances was cancelled. This is because tolerances that have a larger increment in the same direction would also result in all 5-specimen failing.

## 4.8 Assumptions

- No movement occurs in the torque tester during testing, as a result of G-clamps securing the testing machine to the desk

## 4.9 Testing Results

*Table 8 Table showing the specimens that passed the torque test for 0° and 16.5°*

| Testing at 0º | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Specimen No. | -0.25 | -0.20 | -0.15 | -0.10 | -0.05 | Nominal | +0.05 | +0.10 | +0.15 | +0.20 | +0.25 |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | | | | | | | | | | | |
| **Testing at 16.5º** | | | | | | | | | | | |
| Specimen No. | -0.25 | -0.20 | -0.15 | -0.10 | -0.05 | Nominal | +0.05 | +0.10 | +0.15 | +0.20 | +0.25 |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | | | | | | | | | | | |

Note:
= Passed
= Operator Error
= Failed Testing Criteria
= Not Tested
Testing runs from smallest dimensions to largest

*Table 9 Minimum and Maximum screw head insertion, for each tolerance and angle*

| **Testing at 0°** | | |
|---|---|---|
| **Tolerance** | **Minimum head protrusion (mm)/Torque applied (Nm)** | **Maximum head protrusion (mm)/Torque applied (Nm)** |
| **Nominal (0 mm)** | -1.19 / 2.925 | -0.64 / 2.100 |
| **-0.05** | -0.93 / 2.918 | -0.39 / 2.048 |
| **-0.1** | -0.70 / 2.917 | -0.09 / 2.006 |
| **-0.15** | -0.21 / 2.004 | -0.01 / 2.014 |
| **-0.2** | -0.50 / 1.978 | -0.10 / 2.002 |
| **-0.25** | -0.70 / 2.114 | +0.50 / 2.035 |
| **Testing at 16.5°** | | |
| **Hole Tolerance (mm)** | **Minimum head protrusion (mm)/Torque applied (Nm)** | **Maximum head protrusion (mm)/Torque applied (Nm)** |
| **Nominal (0 mm)** | -1.20 / 2.991 | -0.01 / 2.116 |
| **-0.05** | -0.79 / 2.903 | -0.12 / 2.068 |
| **-0.1** | -0.54 / 2.922 | +0.21 / 2.254 |
| **-0.15** | +0.04 / 2.017 | +0.25 / 2.004 |
| **-0.2** | +0.31 / 1.99 | +0.60 / 1.961 |
| **-0.25** | +0.27 / 2.012 | +0.60 / 1.993 |
| Note: negative values represent a screw head insertion depth below the plate surface, a positive value represents a protrusion of the screw head from the face of the plate. | | |

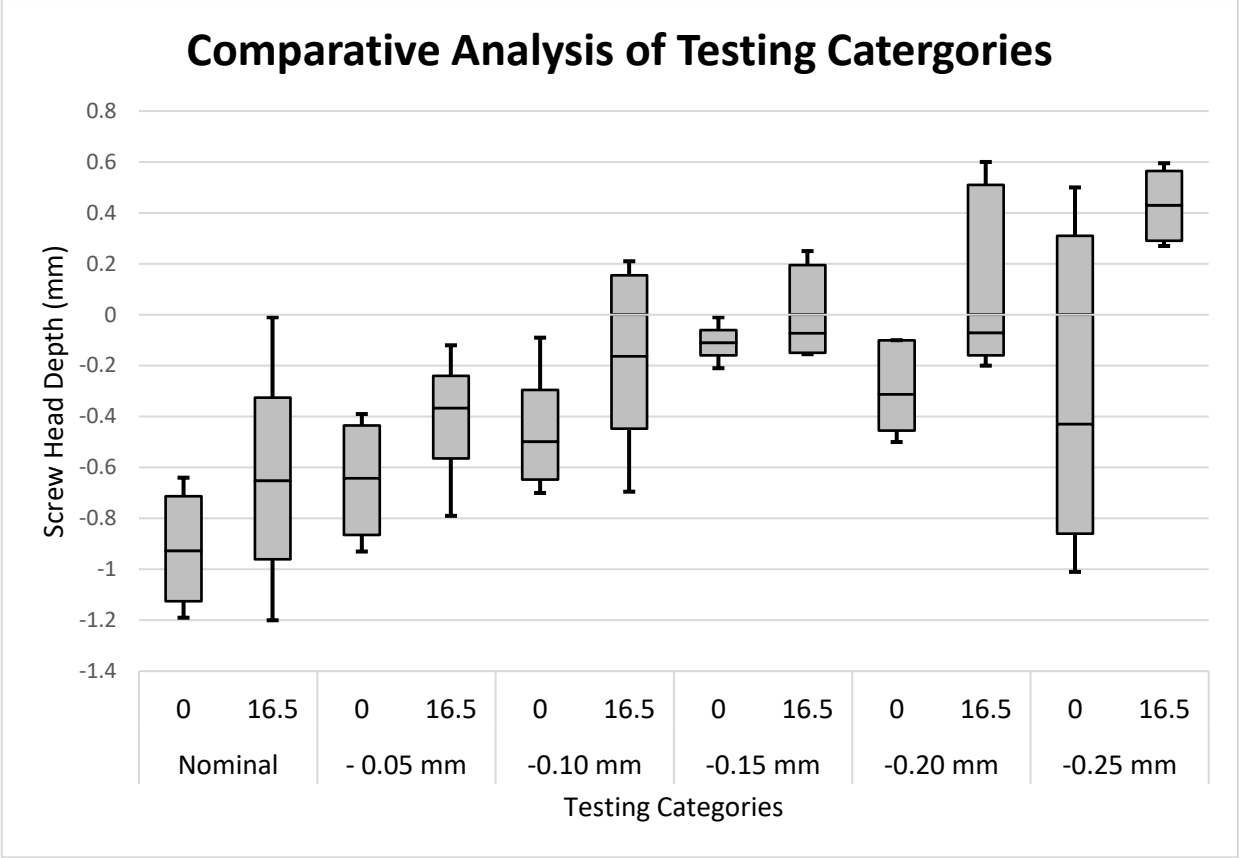


*Figure 34 A Box and Whisker plot showing the comparison of testing categories for the distance of the screw head from the plate surface*

Note: Negative values represent a screw head insertion depth below the plate surface, a positive value represents a protrusion of the screw head from the face of the plate.

## 4.10 Discussion

The VA screw specimens for this testing method were driven in by hand using a T-handle hex driver and the locating collars. This allowed the operator to generate appropriate torque for screw insertion as well as achieve the right angle of insertion. The T-handle driver however may have been a source of error as five specimens failed as a result of the operator exceeding the required torque range. This was evident for the 5$^{th}$ specimen at 0° of the -0.25 mm tolerance, the 2$^{nd}$ specimen at 16.5° of the -0.20 mm tolerance, the 5$^{th}$ specimen at 16.5° of the -0.10 mm tolerance, and the 3$^{rd}$ and 4$^{th}$ specimen at 16.5° of the nominal tolerance.

When the screws were being driven into the button a constant speed was maintained, however the torque would reduce and then increase at certain intervals. This was the cause of the operator error for generating a maximum torque outside the required range. This was hypothesised as when the screw is generating the thread in the VAST hole feature there are segments which are more resistant to the cutting of the thread. It was also difficult to apply specific torques by hand, where a T-handle driver may have made it too easy to apply a large torque to the specimens. As a future test it may be important to observe what torques on average are applied in surgery when a torque driver is not in use, to see if the variation is seen clinically. Additionally, testing to observe the highest insertion torque for each specimen before the screw pushes through the VAST hole feature may be another option.

The other failures, occurred in the +0.05 and +0.10 mm tolerance categories. These failures were a result of the screw passing through the button before the required torque was achieved. Due to all five specimens in +0.10 mm tolerance category, at 16.5° failing, testing of tolerances of larger increments (e.g. +0.15, +0.20 and +0.25 mm) was cancelled as this would provide the same results.

Insertion of the VA screw required differing amounts of effort depending on the tolerance and angle of insertion. All the specimens, required some form of downforce to initiate a thread. The thread on the head of the VA screw was incapable of initiating a thread, and only a few occurrences seen at 16.5°, in conjunction with the smaller tolerances (e.g. -0.20 and -0.25 mm) resulted in a thread initiating with very little downforce. Once the thread was initiated with downwards force, the thread on the screw head was capable of generating the thread in the VAST hole feature and pulling the screw head into the plate. This was not a parameter that was initially considered or aimed to be investigated for this test but important to note as a side effect of the testing.

From Table 9 in the results section, the minimum and maximum head insertion depth can be seen with their respective torque values for screw insertion. Figure 34 also shows similar information, where the minimum, maximum, mean and first and third quartiles are shown for each category. Unfortunately, there was an error in the testing procedure which resulted in the specimens at tolerances -0.15 mm, -0.20 mm and -0.25 mm not being inserted to the upper torque limit. This error will largely explain some of the differences in the data obtained. Specifically, this will explain the differences seen in the minimum insertion results, as this would result from higher torques and a further driving distance of the screw into the plate. This can be seen in the graphs and tables, as the first three tolerance ranges use the higher torque range and the last three use the lower torque range, as they were not inserted to the higher torque range. The maximum table however has a better data

representation as it would be expected that the lower torque values would present the smallest distance for a screw to be driven into the button, resulting in the head protruding from the surface of the button. This category has one result seen in the -0.25 mm category at 0° for maximum protrusion that does not match other results. The result for this data were +0.50 mm protrusion above the face of the plate. It is unknown why this occurred as the method error should not have effected only this tolerance category.

Unfortunately, due to the small sample size for this testing the results may be unreliable, this can also be seen due to the large variation in the results seen in Figure 34. This may be a result of the variability of inserting screws by hand, and may require further investigation and the use of a drill.

Overall an increase in the maximum protrusion can be seen for both the 0° and 16.5° category as the tolerance dimension is reduced, where the -0.25 mm tolerance has the largest protrusion values. For the 16.5° category, the minimum protrusion also follows an increase, as the depth of the screw head decreases with the decreasing dimension tolerances. The 0° minimum protrusion however doesn't follow the same trend. As it can be seen for minimum protrusion for 0°, there is first an increase in screw head depth up till -0.15 mm tolerance, which at this point the screw head depth starts reducing again. As mentioned this would be an effect of the error of the testing procedure which resulted in -0.15 mm, -0.20 mm and-0.25 mm tolerances not being inserted to the maximum torque range. Unfortunately, due to the error of the test it is not appropriate to comment if this screw head protrusion is appropriate.

This testing method has provided information that observes what the best tolerancing range could possibly be for the VAST hole features. The original nominal value dimension ended up being quite accurate for what is required, with the tolerances that were incremented

smaller also being viable dimensions. The specimens in the tolerance categories nominal, -0.05, -0.10, -0.15, -0.20 and -0.25 mm will be selected for testing in the next test method which will observe the maximum load each specimen can withstand before failure.

Due to the error of insertion, this will also effect the results in the following test. This error will therefore transfer to the next test which means that only the tolerances that were inserted to the upper torque limit may be viable as results. This error was transferred as it was not known until after the next test method was utilised.

## 4.11 Conclusion

Using this testing method, it was able to be seen which of the tolerances tested were most appropriate for the design. It was found that none of the tolerances larger than nominal were acceptable, but all tolerances that were smaller than nominal were acceptable for the required torque. Unfortunately, there was an error with the insertion torque of some of the specimens, where not all specimens were tightened to the higher torque range which effected results. This specifically effected the depth of the screw head as higher torques saw a larger insertion depth. Overall this testing method has set up the appropriate specimens for the ramp loading test. The insertion torque error was not noted until after the ramp loading test, so this error has been passed on to the ramp loading test. Otherwise this testing has shown appropriate information about tolerance ranging as well as the relationship between insertion torque and screw head depth for different angular insertion. The ramp loading test method will test these specimens to identify the maximum load the specimens can withstand.

# 5 Ramp Loading Test

## 5.1 Aim

The aim of this testing method is to observe the maximum load, during a shear loading cycle, that the VA screw/VAST hole interface can withstand before failure. This will allow preliminary observation of the mechanical strength of the screw hole interface under a “worst-case” loading condition. This testing method will utilise those specimens that passed the torque test.

## 5.2 Testing Justification

The observation of a single VA screw/VAST hole interface was suggested by Austofix to allow the observation of appropriate tolerancing of a functional unit of the proximal humeral plate design. Through the research of relevant literature and studies for this report there has been seen only two studies, both performed by Lenz et al. (38,37), that have shown a similar method of testing a single VA screw and hole interface. Due to the similarity in testing design and that there were found to be no other testing methods that tested single screws and hole interfaces, the use of a similar testing jig was deemed appropriate for this testing method. The Lenz et al. testing method also showed a promising testing method, able of observing interface failure or screw shaft failure of a specimen, being able to see what parameter was the limiting factor of performance. The testing equipment was based on the Lenz et al. studies (38,37), with design alterations based on suggestions given by technical personnel at Flinders University and the restrictions in place by the available testing equipment. To make sure testing could be performed using the current testing equipment, the addition of bearing slider rails was included. These bearing rails allow for frictionless movement along their axis. When combined perpendicular to one another they generate a construct that removes friction along 2 axes. This was used to remove any

shear forces on the equipment and reduce strain on the testing machine actuator. The testing jig and equipment was also designed to have an appropriate size, so that it would fit accordingly in the testing bed of the machine, with the required connecting pieces and tooling.

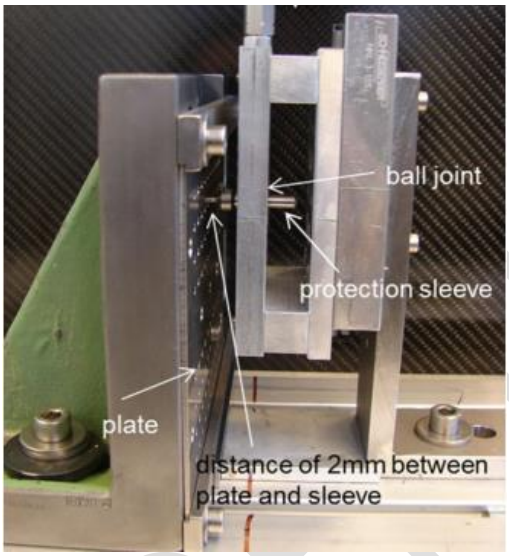


*Figure 35 Testing setup used by Lenz et al.* (38,37)

The testing parameter used for this testing method was 5 mm/min loading rate. This loading rate was used in the Lenz study but is also seen as a standard loading rate in material testing experiments and suggested by technical personnel at Flinders University (37). Like the Lenz et al. studies the equipment was designed to remove the bending force on the screw, by placing the full shaft of the screw inside a collar. This allowed the observation of the effect of shear force without causing bending of the screw. As this test still represents preliminary testing for this project the properties of the design are still unknown. That makes this testing method a key part of determining and understanding a reachable goal in terms of mechanical capacity, including loads the constructs can withstand. This test specifically is important for observing the effect of different tolerances on the strength of a VA screw and VAST hole interface.

## 5.3 Testing Parameters

- Single ramp loading cycle
- Loading rate of 5 mm/min

## 5.4 Testing Equipment

The testing apparatus for this test is a modified version of the testing apparatus found in Lenz et al. study (38,37). The equipment includes:

1. Test jig
    a. VAST01 Rev 0
    b. VAST02 Rev 0
    c. VAST03 Rev 1 (x2)
    d. VAST04 Rev 0
    e. VAST05 Rev 0
    f. VAST06 Rev 0
    g. VAST07 Rev 1
    h. VAST08 Rev 0 (x2) (Modified Toolmaster Angle Plate – C.I. 112x88x75mm)
    i. VAST09 Rev 1
    j. THK SR 25TB 280mm bearing slider (x2)
    k. THK SR 25TB 120 mm bearing slider

Note: Drawings of manufactured testing jig components can be found in Appendix 1

2. Instron Material Testing Machine model 5969
    a. 50 kN load cell
3. Test Specimens
    a. Those specimen categories that passed test method 1 (e.g. -0.25 mm, -0.20 mm, -0.15 mm, -0.10 mm, -0.05 mm and nominal categories)

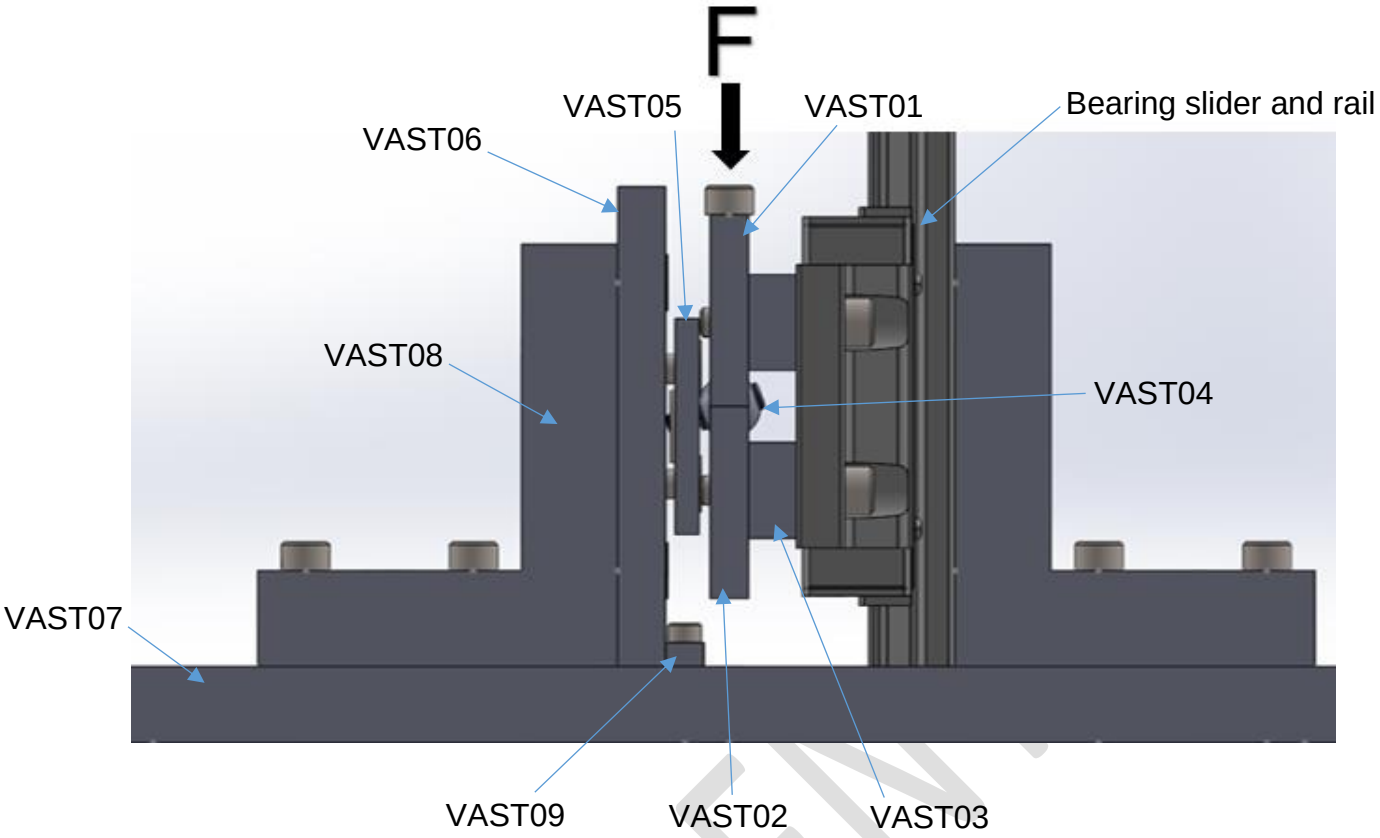


*Figure 36 VAST testing jig setup, showing direction and position of applied load.*

The VAST testing jig was designed based on the study by Lenz et al., where the study used a similar method of testing singular VA screws. The VAST jig was based upon this design but incorporated design considerations based on the type of testing required as well as the testing machine to be used. Some of these considerations were the use of bearing sliders and rails to form a frictionless x-y axis table. This x-y table was attached under the VAST jig and was used to remove any loads in the x and y axis. This project required the VAST jig to be able to hold the buttons designed for testing, which was another alteration from the Lenz study. To hold specimens the buttons were inserted into a plate that had a cut out of the same shape, and then clamped using a backing plate. The button sat out 2 mm from the cut out which allowed the button to be clamped appropriately.

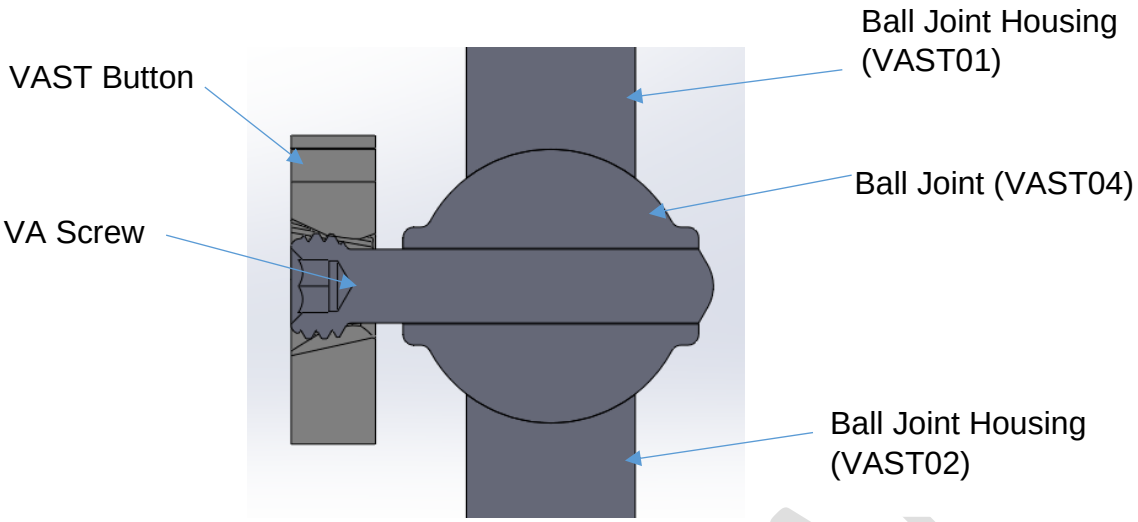


*Figure 37 Sectioned view of how the specimen is loaded*

Figure 37 shows an example of the positioning of a specimen when being tested. The plates that hold the specimen have been removed from this image to focus on how the specimen in loaded. The Lenz study utilised a ball with a protective sleeve inserted, for this design the combination of the two was designed. This allows the ball joint to act as the protective sleeve as well. It was necessary to use a protective sleeve, as point stresses or bending of the screw needed to be minimalised. When the specimen is loaded and displaced, the ball joint can rotate as the section is moved down. As the screws have been manufactured without shaft threads, this minimizes the friction that would have been generated between the screw shaft and the inside sleeve of the ball joint.

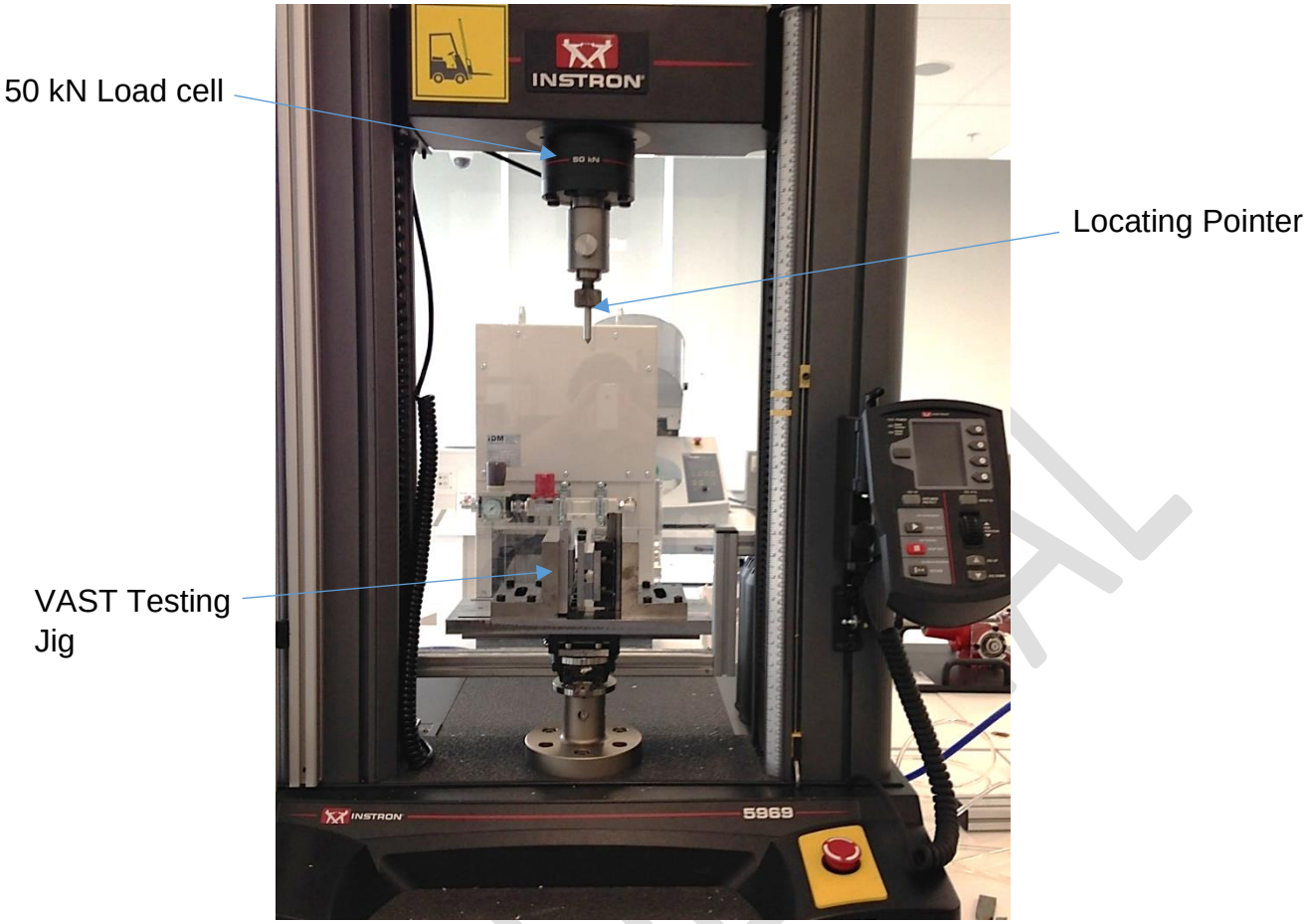


*Figure 38 Image of VAST testing jig positioned in the 5969 series Instron testing machine*

For testing, the use of a 5969 series Instron Material Testing Machine was used. This testing machine was available to be used at Flinders University for this thesis project. Design considerations were made during the design period of the testing jig, so that it would fit appropriately in the testing area. This machine has protective guards at the back and front, which results in a test bed that is small in dimension, where the VAST test jig was designed accordingly to this area. The VAST testing jig connected to the Instron testing bed using a pin connection, which with the x-y table centred the jig with the axis of the actuator. The tool used to apply a load for this test was simply a pointer connected to the actuator with a pin. The pointer had a section that narrowed to a point which allowed it to position the jig using the location hole on the jig at the point of loading. This would specifically apply force along the appropriate axis for testing of the specimen.

## 5.5 Data Collection

Data collection was included for all VA screw/button specimens. The information that was recorded for each test including data obtained by measurements and results based on subjective observation. This test included the use of a 5969 series Instron testing machine, which had an associated data logging program for testing. Data was recorded from the test at intervals of 0.001 seconds, where time, current force and displacement were recorded. This information collected is presented in the results section of this chapter. Any malfunctions of equipment or errors in testing were recorded, specifying which specimen was being tested and the nature of the issue.

Data recorded:

- Button specimen number
- Button hole dimensions (noted during torque testing for associated specimen number)
- Load at each data interval (N)
- Displacement at each data interval (mm)
- Failure Mode
- Measurement of time during testing

## 5.6 Sampling Technique

From the original batch of 123 VA screws and 110 button specimens, 110 of each were used for the initial testing performed in the torque test. From the results of the torque test all specimen that were in tolerance categories -0.25 mm, -0.20 mm, -0.15 mm, -0.10 mm, -0.05 mm and nominal were used for this ramp loading method. This however excluded specimen 18 as it was the only specimen in those categories to push through the plate before the appropriate torque was achieved. This resulted in a total number of specimens for this test being at 59.

### 5.6.1 Sample Size

Like the torque test each test consisted of testing a specimen of a certain tolerance and one of two angles of screw insertion. This resulted in the same specimen size for each test except one due to the failure of specimen 18. As this specimen pushed through the plate during the torque test, it was not eligible for this testing method and had to be excluded. Although other specimens failed, due to operator error exceeding the torque range, these specimens were still included in testing as they still achieved locking in the VAST hole. The layout of sample size for each test can be seen below.

*Table 10 Sample size for ramp loading test*

| BUTTON DIMENSION | $0^{O}$ | $16.5^{O}$ |
|---|---|---|
| **-0.25** | 5 | 5 |
| **-0.20** | 5 | 5 |
| **-0.15** | 5 | 5 |
| **-0.10** | 5 | 5 |
| **-0.05** | 5 | 5 |
| **NOMINAL** | 5 | **4** |

Note: specimen 18 has been removed due to the type of failure it underwent in the torque test, this can be seen in the nominal tolerance range at an angle of 16.5° which as a result has one less sample.

## 5.7 Testing Method

The VAST test Jig will be pre-assembled on the base plate (VAST07) and then will be attached to the Instron using a cylindrical insertion and pin. The Instron will have a 50 kN load cell on the actuator cross bar of the Instron, which is used to apply a load to the testing bed. A 50 kN load cell was used as the only other available load cell was a 500 N load cell, which it was unknown if the specimens would pass this load and damage the cell. It is important that the loading axis of the screw is in line with the actuator as to not introduce any shear movement of the actuator, this should be prevented using the x-y axis bearing sliders. Complete assembly of VAST test jig can be seen in **Appendix 1A**.

1. This test will utilise the specimens that passed the torque test method.
2. Insert the test specimen into the VAST05 insert
3. Align VAST05 with VAST06 and bolt the pieces together making sure that the specimen is clamped between the pieces appropriately
4. This assembly is attached to the right angle VAST08, which is also attached to the base plate VAST07 using slots. This assembly slides up to contact the VAST09 stopper to provide the appropriate positioning of the specimen
5. As the specimen is moved to the stopper the ball joint housing will need to be adjusted in height so that the screw shaft of the specimen slides smoothly into the ball joint (VAST04), once in place the right angle (VAST08) will be securely tightened to the base
6. The VAST testing jig can now be placed in the bed of the testing machine, this is held in place using a locking pin
7. The Instron will be set up using the manual provided, including balancing the load cell before testing

8. The actuator is moved up to the VAST testing jig so that the pointer tool located in the loading hole of the testing jig. This should not introduce force, only locate the central axis for loading
9. The test can now be initiated, which will apply a displacement rate of 5mm/min in compression
10. This test will be stopped if failure of the screw occurs, or a testing limit is tripped
    a. The testing limit for this test was set as a displacement of 7 mm from starting position
11. Data for this test is automatically recorded through the Instron software, data will be taken at every 0.001 seconds. The data recorded was force (N), displacement (mm), and time (sec).

### 5.7.1 Failure Criteria

- Measured load dropping to less than 20 N after maximum load has been achieved
- A displacement of greater than 7.0 mm from the starting position of the Instron actuator

## 5.8 Assumptions

- There is a removal of bending deformation on the screw shaft due to the protective sleeve of the ball joint
- The weight of the test jig is centred on the axis of the load cell
- There is minimal shear movement due to the testing jig only allowing 1 axis of freedom
- The test jig is centred on the load cell using x-y-axis bearing sliders, which also remove shear stress on the actuator

## 5.9 Testing Results

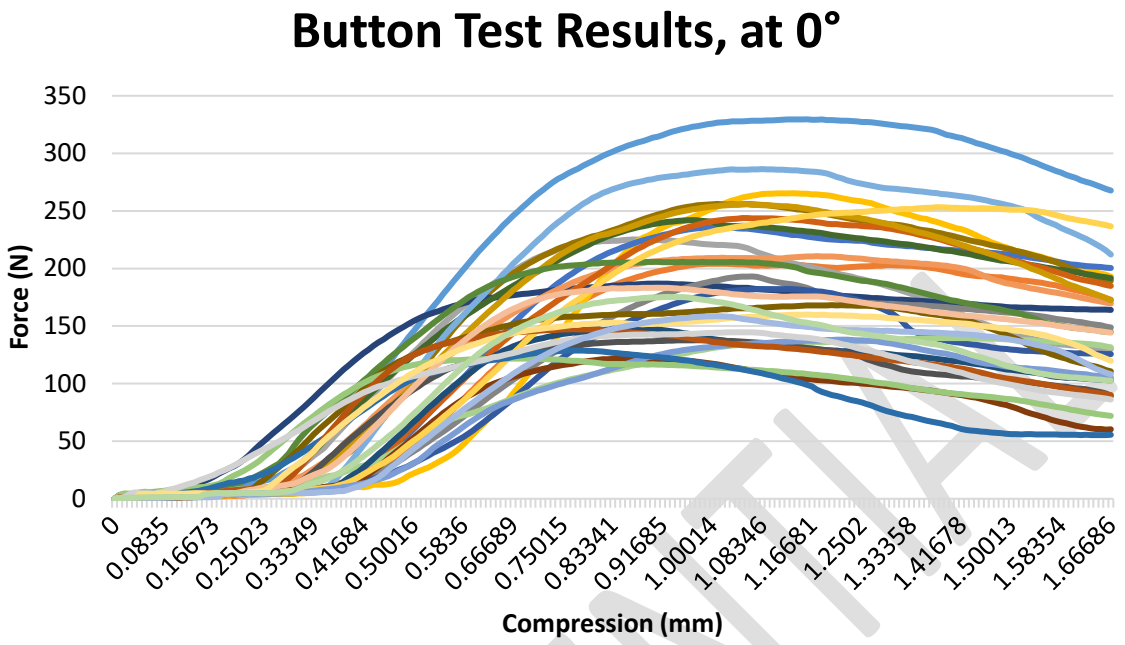


*Figure 39 Force vs Displacement graph for 0° specimens*

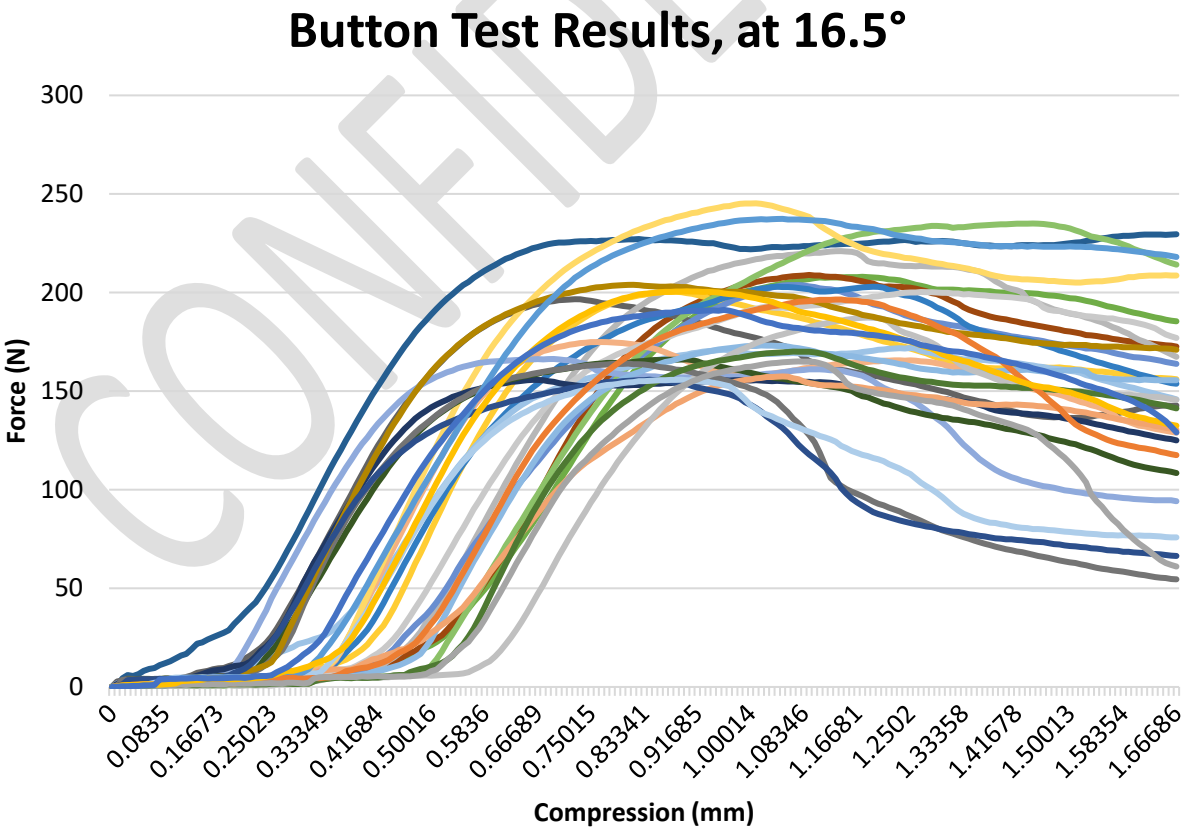


*Figure 40 Force vs. Displacement graph for 16.5° specimens*

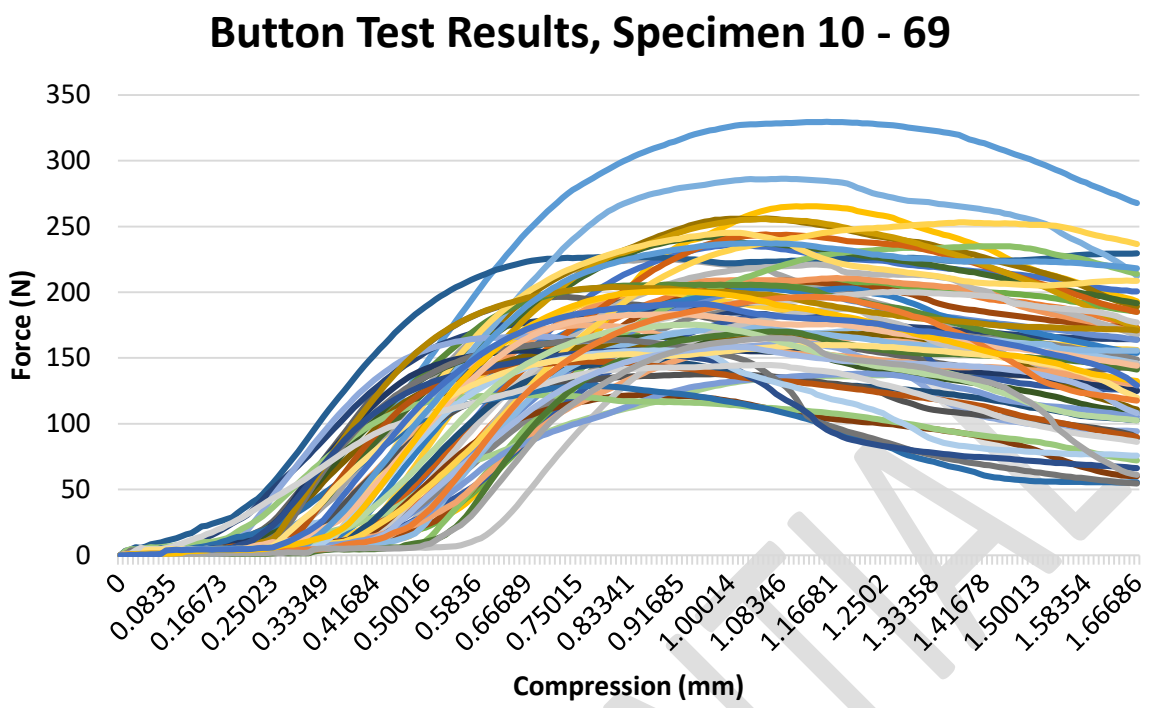


*Figure 41 Force vs. Displacement graph showing all specimens tested in the ramp loading test*

Note: The three Force vs. Displacement graphs have been cut to a time length of 20 seconds, to better observe the linear section of the graph and the peak loads achieved.

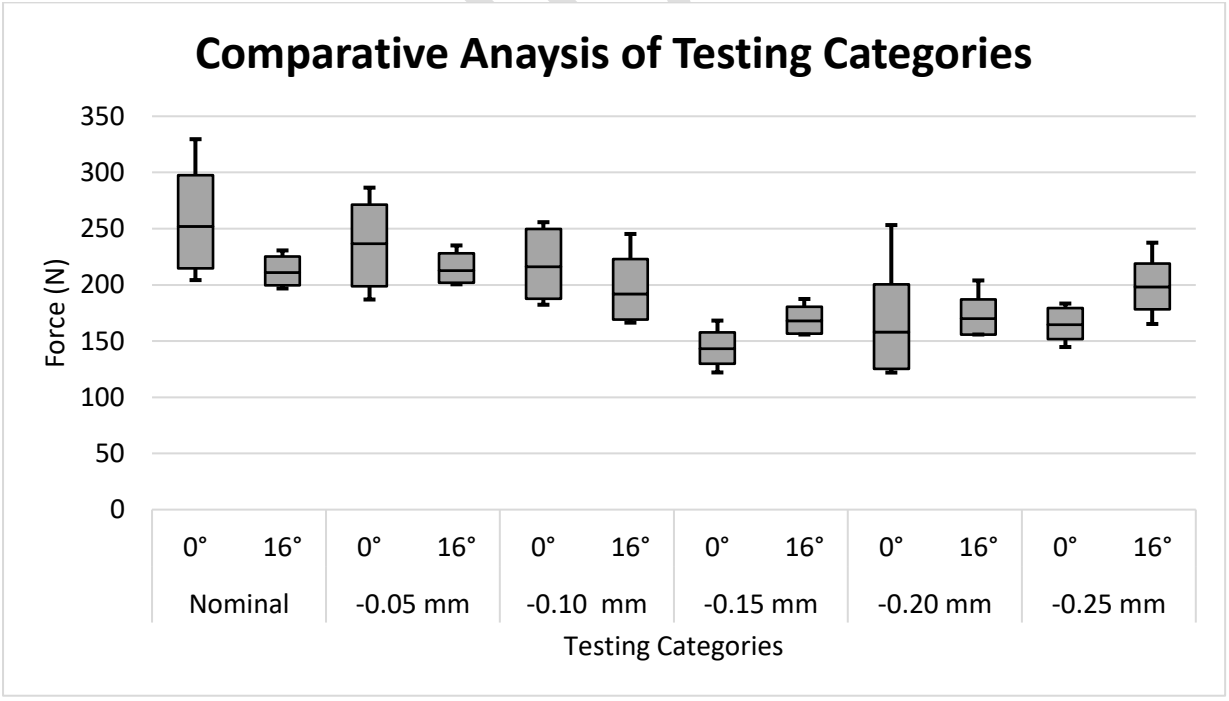


*Figure 42 Box and Whisker plot contrasting the spread of maximum forces seen for each specimen*

Note: The data shown in the Box and Whisker plot is generated using the maximum forces found for each test specimen.

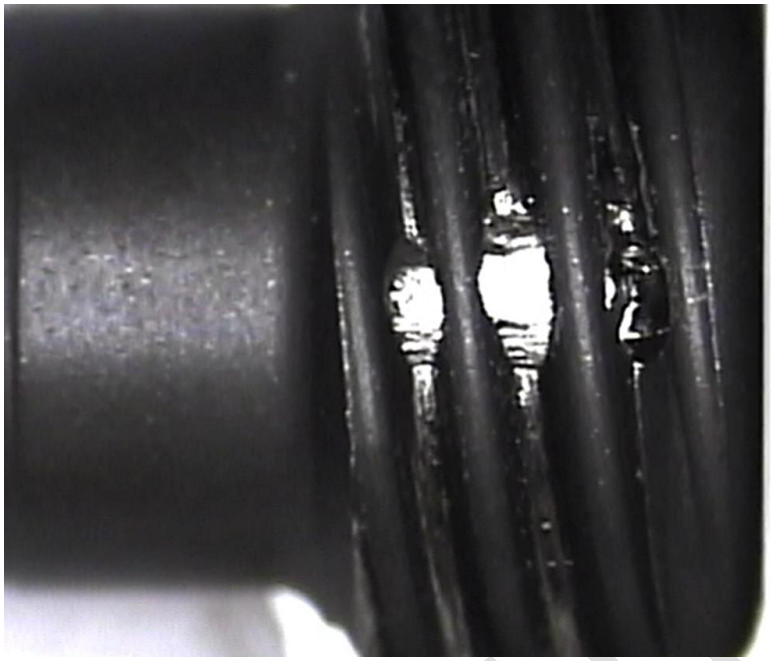

*Figure 43 Screw wear from ramp loading test*

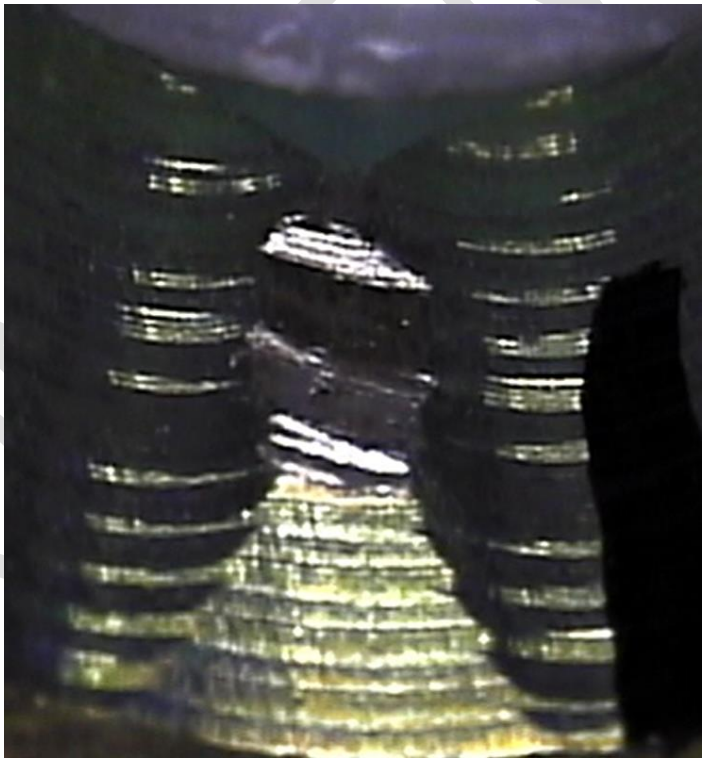

*Figure 44 VAST hole feature wear from ramp loading test*

Note: Figures 30 and 31 are images taken of specimen 24 after the ramp loading test when the VA screw was removed from the VAST hole feature.

## 5.10 Discussion

The method outlined in the ramp loading test saw the testing of the specimens that passed the torque test. This resulted in 59 specimens being tested. The ramp loading test was used to observe the force vs. displacement of each specimen, and ultimately the failure load of the specimens. This was performed using an Instron material testing machine which applied a compressive load at a rate of 5 mm/min. Above there are three plots (Figures 39-41) that show force vs. displacement of each specimen, in comparison to each other. Additionally, there is a graph in Figure 42 that observes the comparative analysis of the maximum loads each specimen achieved, for the differing categories.

The main aim of this testing was to observe the maximum failure force for each specimen that passed the torque test, to observe the best tolerance range. From the testing results, there is a trend in the force vs displacement graphs. In the data, there are a couple specimens that had outlying results, such as the specimen that managed to reach a maximum load of 330 N. However, the majority of specimens had a common band of results. From the load vs. displacement graphs there can be seen a large variation between results. Looking at Figure 42, there is less variation of specimens in the 16.5° group compared to the 0° group. It must be noted though that there were three types of trend lines seen in the force vs. displacement plots. Firstly, some of the specimens reached their maximum force and then held a relatively constant force until the end of the test. Secondly, some of the specimens reached maximum force, where a decreasing waveform was seen for the results. Lastly, there were specimens where once they reached maximum load the force registered dropped dramatically. This is interesting as there were no factors evident for this behaviour and these differences were not due to different tolerances or angle, as they were seen across all categories. Comparatively, all the specimen's other than a few had a nice linear segment of loading.

In Figure 42, a comparison of the maximum forces for each specimen were used to compare each category. This was done in the form of a box and whisker plot to show the maximum, minimum, mean, and first and third quartiles for each category. There is a large variation in the results obtained for the 0° tests over the 16.5° tests. Where most of the 0° categories have a significantly higher deviation than the 16.5° categories. The deviation of the 0° categories however does decrease as the tolerance gets smaller, not including the variation seen in the -0.20 mm tolerance. The 16.5° test variations almost has the opposite effect, where over the first three tolerances the variation is increasing. Table 11 shows the standard deviation for each category.

*Table 11 Standard deviation observed of results for each category that underwent ramp load testing*

| **Standard Deviation (N) Per Category** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Nominal** | | **-0.05 mm** | | **-0.10 mm** | | **-0.15 mm** | | **-0.20 mm** | | **-0.25 mm** | |
| **0°** | **16.5°** | **0°** | **16.5°** | **0°** | **16.5°** | **0°** | **16.5°** | **0°** | **16.5°** | **0°** | **16.5°** |
| 44 | 12 | 35 | 13 | 29 | 29 | 15 | 12 | 48 | 18 | 14 | 23 |

The trend of the results is interesting as the maximum force obtained was at 0° at the nominal dimension. This is expected as the 0° angulation should be the angle that expresses larger force capabilities. However, it is interesting that this occurred at the nominal tolerance. In this project nominal refers to the starting dimension of the design, and does not represent the best tolerance. It makes sense that this nominal tolerance would be accurate as it has been adapted from a previous project, however it was hypothesized that other tolerance ranges would surpass its capability. The results however, suggest that the nominal tolerance is one of the better tolerances as it achieved some of the highest forces at both 0° and 16.5°, out of all tolerances. The -0.05 mm tolerance also had similar results, with a lower average maximum force obtained for 0° but a slightly higher average maximum force for the 16.5° angulation.

The nominal tolerance category also had one of the highest deviations of a category, suggesting that the data may not be accurate. Largely due to the small sample size, there isn't enough data available for the results to be reliable. From the results that compare each category, there is no real trend due to the different tolerances. This may be an addition of error due to the testing method, but largely the sample size can be considered too small. Additionally, error introduced by the improper use of the torque test would not have caused the variation seen in the nominal tolerance, as the insertion torque error is only observed in tolerance categories -0.25 mm, -0.20 mm and -0.15 mm. Therefore, this would not have affected the variation for the other tolerances. It has been considered that the overall stiffness of the VAST test jig may be a factor in the large variation of results where an investigation into this will be performed later in the project. It should also be noted that deformation of the base plate of the testing jig occurred at the slots used to fixate one of the right angle supports. These slotted pieces may be a large factor in the variation of these results, as they may allow motion during testing. From the results and performance of the VAST test jig during this method, the testing jig will be modified. This is largely due to how long it took to change over specimens during testing, where a test would take up to 1 minute where the swap over of specimens could take upwards of 5 minutes. The observation of equipment stiffness will also be observed when altering the testing jig.

The specimens themselves were found to fail by the compression or failure of the thread on the screw head and of the VAST hole feature. In most cases failure of the material could be seen on both the thread of the head of the screw but also by the generated thread in the VAST hole. This can be seen in Figure 43 and 44, where both threads failed. In some specimens, the failure was more one sided where either the failure of the screw thread was more severe or the failure of the VAST material was more severe. However, even though the specimens failed, they were still firmly locked into the button, where only 2 accounts of

screw loosening after testing occurred. These were both 16.5° inserts, with one at -0.20 mm tolerance and the other at -0.25 mm tolerance. This is hypothesized to be because of these screws not being inserted up to the higher torque range before testing, as a result of error introduced in the torque test.

The 0° angulation was utilised as a standard insertion angle and has been shown to provide comparable results to normal fixed angle screws (38,37). The use of 16.5° angulation was in an attempt to test the worst case scenario of angulation for the current design. From the results seen, the 0° angulation provided more strength at the larger tolerances but was lower in the smaller tolerances. Where the 16.5° angulation held more of a constant average max force across all tolerances. This would be largely based on the effects of loading on the screw due to the angulation. Through the testing even though the force is applied in compression (vertically) due to the angle of the screw it would cause some of the force to be directed down the shaft of the screw. This possibly shows that the VAST feature performs better when subjected to shear and compressive forces at the same time, possibly providing a stiffer VA screw/VAST interface.

The results that occurred during this testing method based on the failure type of the specimens is representative of what was seen in the Lenz et al. studies, where failure was often seen due to the screw head thread breaking out of the thread generated in the hole feature. The Lenz et al. studies however, did show that failure of the screw shaft could occur before the failure of the screw/hole interface, which was not evident in our study. Unfortunately, as mentioned there are not many studies to compare results to, but based on the comparison to the Lenz et al. study the design of the Austofix VAST technology can be improved. This is due to screw neck breakage being favourable over screw head pull out; this shows the material is the limiting factor not the design of the VAST feature.

*Table 12 ANOVA Analysis over view*

Dependent Variable: MaxForce

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared |
|---|---|---|---|---|---|---|
| Corrected Model | 61478.373[a] | 11 | 5588.943 | 5.961 | .000 | .582 |
| Intercept | 2200584.147 | 1 | 2200584.147 | 2347.047 | .000 | .980 |
| Tolerance | 48282.778 | 5 | 9656.556 | 10.299 | .000 | .523 |
| Angle | 135.597 | 1 | 135.597 | .145 | .705 | .003 |
| Tolerance * Angle | 11323.103 | 5 | 2264.621 | 2.415 | .050 | .204 |
| Error | 44067.054 | 47 | 937.597 | | | |
| Total | 2307729.982 | 59 | | | | |
| Corrected Total | 105545.427 | 58 | | | | |

*Table 13 Pairwise Comparison, Overall Effect of Angular Insertion*

Dependent Variable: Max Force

| Tolerance | (I) Angle | (J) Angle | Mean Difference (I-J) | Std. Error | Sig.[a] | 95% Confidence Interval for Difference[a] | |
|---|---|---|---|---|---|---|---|
| | | | | | | Lower Bound | Upper Bound |
| Nominal | 0 Degrees | 16.5 Degrees | 40.970 | 20.541 | .052 | -.353 | 82.292 |
| | 16.5 Degrees | 0 Degrees | -40.970 | 20.541 | .052 | -82.292 | .353 |
| -0.05 mm | 0 Degrees | 16.5 Degrees | 23.717 | 19.366 | .227 | -15.242 | 62.676 |
| | 16.5 Degrees | 0 Degrees | -23.717 | 19.366 | .227 | -62.676 | 15.242 |
| -0.1 mm | 0 Degrees | 16.5 Degrees | 24.377 | 19.366 | .214 | -14.582 | 63.336 |
| | 16.5 Degrees | 0 Degrees | -24.377 | 19.366 | .214 | -63.336 | 14.582 |
| -0.15 mm | 0 Degrees | 16.5 Degrees | -24.977 | 19.366 | .203 | -63.936 | 13.982 |
| | 16.5 Degrees | 0 Degrees | 24.977 | 19.366 | .203 | -13.982 | 63.936 |
| -0.2 mm | 0 Degrees | 16.5 Degrees | -12.047 | 19.366 | .537 | -51.007 | 26.912 |
| | 16.5 Degrees | 0 Degrees | 12.047 | 19.366 | .537 | -26.912 | 51.007 |
| -0.25 mm | 0 Degrees | 16.5 Degrees | -33.813 | 19.366 | .087 | -72.772 | 5.147 |
| | 16.5 Degrees | 0 Degrees | 33.813 | 19.366 | .087 | -5.147 | 72.772 |

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

*Table 14 Pairwise Comparison, Overall Effect of Tolerance*

Dependent Variable: Max Force

| (I) Tolerance | (J) Tolerance | Mean Difference (I-J) | Std. Error | Sig.[b] | 95% Confidence Interval for Difference[b] | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| Nominal | -0.05 mm | 6.965 | 14.115 | 1.000 | -36.689 | 50.618 |
| | -0.1 mm | 27.573 | 14.115 | .851 | -16.081 | 71.226 |
| | -0.15 mm | 76.041* | 14.115 | .000 | 32.388 | 119.695 |
| | -0.2 mm | 67.649* | 14.115 | .000 | 23.995 | 111.303 |
| | -0.25 mm | 50.263* | 14.115 | .013 | 6.609 | 93.916 |
| -0.05 mm | Nominal | -6.965 | 14.115 | 1.000 | -50.618 | 36.689 |
| | -0.1 mm | 20.608 | 13.694 | 1.000 | -21.742 | 62.958 |
| | -0.15 mm | 69.077* | 13.694 | .000 | 26.726 | 111.427 |
| | -0.2 mm | 60.684* | 13.694 | .001 | 18.334 | 103.035 |
| | -0.25 mm | 43.298* | 13.694 | .041 | .948 | 85.648 |
| -0.1 mm | Nominal | -27.573 | 14.115 | .851 | -71.226 | 16.081 |
| | -0.05 mm | -20.608 | 13.694 | 1.000 | -62.958 | 21.742 |
| | -0.15 mm | 48.469* | 13.694 | .014 | 6.118 | 90.819 |
| | -0.2 mm | 40.076 | 13.694 | .079 | -2.274 | 82.426 |
| | -0.25 mm | 22.690 | 13.694 | 1.000 | -19.660 | 65.040 |
| -0.15 mm | Nominal | -76.041* | 14.115 | .000 | -119.695 | -32.388 |
| | -0.05 mm | -69.077* | 13.694 | .000 | -111.427 | -26.726 |
| | -0.1 mm | -48.469* | 13.694 | .014 | -90.819 | -6.118 |
| | -0.2 mm | -8.392 | 13.694 | 1.000 | -50.743 | 33.958 |
| | -0.25 mm | -25.779 | 13.694 | .989 | -68.129 | 16.572 |
| -0.2 mm | Nominal | -67.649* | 14.115 | .000 | -111.303 | -23.995 |
| | -0.05 mm | -60.684* | 13.694 | .001 | -103.035 | -18.334 |
| | -0.1 mm | -40.076 | 13.694 | .079 | -82.426 | 2.274 |
| | -0.15 mm | 8.392 | 13.694 | 1.000 | -33.958 | 50.743 |
| | -0.25 mm | -17.386 | 13.694 | 1.000 | -59.737 | 24.964 |
| -0.25 mm | Nominal | -50.263* | 14.115 | .013 | -93.916 | -6.609 |
| | -0.05 mm | -43.298* | 13.694 | .041 | -85.648 | -.948 |
| | -0.1 mm | -22.690 | 13.694 | 1.000 | -65.040 | 19.660 |
| | -0.15 mm | 25.779 | 13.694 | .989 | -16.572 | 68.129 |
| | -0.2 mm | 17.386 | 13.694 | 1.000 | -24.964 | 59.737 |

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Note: Red Highlighted sections represent statistically significant results (p<0.05).

Due to the results being highly variable, a statistical analysis was performed to see whether the results affected each other or it was cause by other factors. As an overview, Table 12 shows that the overall effect of tolerance was significant ($p<0.001$), whereas the overall effect of angle was not ($p=0.705$). Considering the interaction between tolerance and angle, the analysis shown that the combination of these factors had a marginally significant effect ($p=0.05$).

Table 13 shows the effect of angular insertion, in terms of statistical analysis. As it can be seen there are no statically significant results, where all results are $p=0.052$ or over. It is unclear why these results have been effected and as such requires further investigation into why this occurred. One possible reason may be due to the differing loading direction from 0° compared to 16.5°. where at 0° the loading occurred perpendicular to the screw shaft and at 16.5° the loading is not perpendicular to the shaft.

Table 14 shows the effect of differing tolerances. The results show that half of the results are statistically significant, and half are not. When comparing the larger tolerances (nominal, -0.05 and -0.10) to the smaller tolerances (-0.15, -0.20 and -0.25) it can be seen from the table that there is statistical significance. Likewise, when the smaller tolerances are compared to each tolerance there is statistical significance with the larger tolerances. Other than the analysis of the -0.10mm tolerance the other tolerances have a similar trend based on the error of torque insertion that occurred in the torque test. This maybe the factor that caused only half of the results to be significant, and how the trend changes as we compare consecutive tolerances.

Overall this test method has provided some insight in the strengths of the specimens, as well as showing possible trends seen for different angulation and tolerances. This information will be later used to justify some of the tolerancing either for secondary testing or for final design aspects. Unfortunately, with the small sample size it is hard to obtain a large amount of information from the data, where additional testing would be important if this wasn't a preliminary testing method to obtain initial data. As this test was based off one of only a few tests that observe single screw and hole testing it is hard to compare results to other studies. The results seen in this test however are congruent with the previous study, which showed the majority of specimens failed due to failure of the screw/hole interface.

The testing method outlined in this report was performed to justify and observe the appropriate dimensioning of the VAST hole feature. Due to the sample size being small and some errors in the results obtained, more testing should be performed to provide more reliable results that are able to be manipulated for data analysis. Additionally, the basis of this report and testing was on the assumption that the VA screws were already of appropriate dimensioning and would not fail. However, this seems to not be the case, as can be seen in the results from the ramp loading test, which saw the failure of the construct, by failure of the thread of the screw head as well as the VAST hole feature. This will result in testing being required to test the VA screws to determine the best dimensioning required for the design and a revisit to these testing methods once a finalised design of the screws has been achieved. This testing has provided appropriate information to further the project and its designs, without which it would not have been known that the VA screw head thread was also a weak link of the construct. The testing has also shown ample information about the strength of these constructs where better dimensioned VA screws and VAST hole features should achieve higher loads before failure. Providing a basis to what would likely be expected for the final designs. This testing has also justified the initial aim of this testing

to show what the appropriate tolerance range for the final design may be. From the data obtained in the torque and ramp loading tests, there is enough information to justify a smaller tolerance range for additional testing, getting closer to the final design.

## 5.11 Conclusion

This testing has carried over some errors from the torque test which would have affected the results. This may be a result of some of the large variation seen in the testing specimens for the load vs displacement graphs as well as effected the significance of results. Additionally, due to the small sample size for each test, the data is not as reliable as what was originally expected for the type of testing. Although the results do show a trend of similar behaviour between the specimens, there is a large variation seen between the results. For more appropriate data this test should be repeated with fewer tolerance categories and larger sample sizes.

The information obtained from this testing has been useful and effected the direction of the project. It was a necessary process to find the maximum loads of the specimens, as this information was unknown for the designs. It was also important as the results suggest a failure of both VA screw thread and VAST hole feature mechanisms, not just the VAST feature which was initially predicted. If further use of this testing method occurs, a small rework to the testing jig may be necessary. This is to reduce the change over time of specimens and also to observe the overall stiffness of the jig.

# 6 Cyclic Loading Test

## 6.1 Background

There are many complex movements that occur with the movement of the upper extremities. Each of these movements cause different forces and moments to be applied to the muscles and bones in the extremity. This is evident in the use of proximal humeral plates and the forces seen in the shoulder. Unfortunately, due to the number of movements seen, even on a daily basis, with current modelling methods it is not possible to definitively say what forces occur in the shoulder. On top of not knowing the magnitude of forces, the number of cycles in which the forces are expressed are also unknown. These parameters are largely based on the individual, their activity, and situations like hobbies or working conditions. This shows that the number of cycles applied for one person may differ dramatically for the next and could differ between people for different working planes of muscles. This can be seen in the literature, where the number of cycles used for biomechanical testing of proximal humeral plates differs from 5 to 1,000,000 cycles. Even though there isn't a standard number of cycles for testing, it is very important to observe the fatigue of the construct.

In this testing method, the process of using cyclic testing will be explored. This method of testing was set to be part of the second iteration of button testing, but there was a change in direction for what Austofix required. Therefore, this testing method was finalised but has not been used to test specimens at this point in the project.

## 6.2 Aim

This testing method aimed to help determine the best tolerance range for the VAST hole feature. This method would observe the fatigue life of the VAST hole feature/screw constructs.

## 6.3 Testing Justification

The use of proximal humeral fixation plates in reduction and fixation of proximal humeral fractures is important for the recovery of many patients who have suffered these fractures. The goal of these fixation plates is to fixate bone fragments in there original anatomical location, as initially positioned by the surgeons, and to maintain the stable construct in the time required for the bone to perform self-repair.

The shoulder is a complex structure, made of 3 bones and over 20 muscles (47). Currently there is little consensus in the literature as to the exact forces that occur in the shoulder, this is likely due to the limitation of models of the shoulder to measure certain muscles; being either the force exerted, cross sectional area of a muscle, or the exact muscle insertion area (48). All this variation results in many biomechanical studies that test proximal humeral plates using a large variety of force parameters and characteristics. Some studies try to observe what forces occur in the shoulder during “daily activities”, however, what is considered daily activities differs from study to study, making it hard to justify one study over another (10,49,50).

Many of these studies however, reference a paper by Poppen and Walker which describes the contact forces in the glenohumeral joint (51). The fact that this paper has become one of the most widely referenced papers for forces in the shoulder shows that it is considered an acceptable model within the profession to be used when describing force in this location (49,51). Poppen and Walkers data has also been verified in more recent studies, one of which being by Karlsson et al. who instead of basing results on EMG results, uses anthropometric data of a young man weighing 75 kg. In their study, they found a maximum force of 600 N at 60-90 $^{o}$ elevation. This results in the contact forces in the glenohumeral joint coming to 0.8 times body weight, which is only slightly less than the 0.89 times body weight Poppen and Walkers recorded. The EMG results by Poppen and Walkers study are also supported by more modern 3D shoulder models designed by Van Der Helm et al. (52–54). Both Poppen and Karlsson showed that the majority of force was directed medially, which is supported by Van Der Helms 3D shoulder models (51,54). In many studies that report on the maximum force in the shoulder, even those studying daily activities, show that the largest force occurs around 90$^{o}$ abduction of the arm (47,50–52,54,55). Based on the information provided by these studies there is significant justification that the maximum contact force for the glenohumeral joint occurs at 90$^{o}$ abduction (10,50–52,55). The magnitude of the force varies in the literature, however, there is sufficient evidence to suggest that the 0.89 times body weight contact force, found by Poppen, is an acceptable measurement to use (9,10,51,56,57).

From the Anthropometric Reference Data for Children and Adults: United States, 2011 – 2014, the average weight of an Adult in the US is 80.4 kg (58). This will result in a total force of 80.4 x 9.81 x 0.89 = 702.1N. As the Button testing, will only be performed on a single screw construct and not a whole plate construct, the force will be divided by the number of screws that can be inserted into the head of the humerus. For this Austofix

proximal humeral plate design, there are 6 available screw positions in the humeral head, therefore the maximum force will be divided by 6. This will result in the maximum force for this test being 702.1/6 = 117.02 N, which will be rounded up to 120 N.

It is also important to subject the specimen to an appropriate number of cycles. This again varies greatly in the literature, as the amount of cycles for biomechanical testing of proximal humeral plates has been seen to vary from 5 to 1,000,000 cycles (43). In the studies reviewed, the most commonly seen number of cycles is 1000 cycles (13,56). A study performed by Wheeler et al. ran a cyclic torque load of 10,000 cycles and showed that inter-fragmentary movement of proximal humeral plates occurs within the first 1000 cycles (59). This information provides an insight into why 1000 cycles is a common value for plate testing, as the mechanism of failure in predicate devices shown occurs in other areas before plate/screw failure. Wheelers study has been used to justify the cycles used in other studies (56). In the studies by Lenz et al. the tests underwent 10,000 cycles, but were later revised to 5000 cycles (38,37). This was due to screws in the study failing by the screw shaft breaking at 5000 cycles rather than failure of the VA locking mechanism. Our testing will start with 10,000 cycles, which will allow observation of screw motion and if shaft failure occurs before the locking mechanism fails, as does in the Lenz study (38,60). In addition, a 5 Hz frequency will be used when loading the screws as seen in a study by Lenz et al. This will result in, 10,000 cycles at 5 Hz, generating a run time of 33.3 minutes per specimen.

Additionally, in our test, the use of a cyclic loading as a mechanism of loading will be used to observe fatigue of the VA screw/VAST hole feature interface. Unfortunately, most study papers do not provide a clear view on cyclic loading. Some studies, such as one by Lenz et al. did use a true sinusoidal cyclic loading (-100% to +100%)(38,44). Other studies have used sinusoidal positive only waves. Using +20 % minimum load to +100% maximum load cycles, as seen by Rose et al. which ran 40 N to 200 N cycle (61–63). Following this trend

another study was found that utilised a 30 % of max load as a minimum loading value (64). It seems acceptable by research to use a positive sinusoidal wave form; for testing, with the use of a +20 % minimum limit to +100% maximum limit. This will result in a pre-loaded +20% maximum force, then compressing the screw up to +100% maximum force, and cycling this loading system. Given the previous calculation of the maximum testing force on one screw, the loading range will be 24 – 120 N per cycle.

## 6.4 Testing Parameters

- Minimum load of 20% of max load = 24 N
- 120 N maximum load
- 24 – 120 N loading per cycle
- 10,000 loading cycle runout or until failure
- 5 Hz frequency of loading cycles
- Sinusoidal, half peak, positive loading waveform

## 6.5 Testing Equipment

The testing apparatus for this test will be a modified version of the testing apparatus found in Lenz et al. study. The equipment includes:

1. VAST Test jig
    a. VAST01 Rev 0
    b. VAST02 Rev 0
    c. VAST03 Rev 1 (x2)
    d. VAST04 Rev 0
    e. VAST05 Rev 0
    f. VAST06 Rev 0
    g. VAST07 Rev 1
    h. VAST08 Rev 0 (x2) (Modified Toolmaster Angle Plate – C.I. 112x88x75mm)
    i. VAST09 Rev 1
    j. THK SR 25TB 280mm bearing slider (x2)
    k. THK SR 25TB 120 mm bearing slider

Note: Drawings of testing jig components can be found in Appendix 1

2. Instron Material Testing Machine model 5969
    a. 50 kN load cell
3. Locating collar (0 $^{o}$ and 16.5 $^{o}$)
4. Norbar Torque Screwdriver Tester Series 2. (0.5 – 10 Nm)
5. Test Specimen
    a. 3.5 mm VA screw of 20 mm length
        - Manufactured without shaft threads (shaft diameter equal to major thread diameter, 3.5 mm)

b. Button disc plate 15 mm diameter by 4 mm thickness (containing a single, centred VAST hole feature)

## 6.6 Data Collection

Data collection will be included for each screw/button construct. The information that will be recorded for each test will include data obtained by measurements and results based on subjective observation. This information will be presented in the results section of this document.

All testing that is performed and a malfunction of any equipment occurs, will be recorded with appropriate information, including: a description of the malfunction, what test the malfunction occurred in, what specimen was being tested and how the malfunction may have effected results/measurements. If a problem was reported during the testing of a specimen, and deemed to effect results those results will be included but not utilised for the report. Similarly, if testing equipment issues occur depending on the impact on the failure of a specimen, they may be excluded from the report.

Data to be recorded:

- Button specimen number
- Insertion torque
- Insertion angle
- VA screw head distance from top face of button
- Load at failure
- Number of cycles performed
- Angular displacement from original position
- Failure mode

## 6.7 Sampling Technique

From the testing performed in the torque and ramp loading tests, it was found that a sample size of 5 for each test was too small for obtaining reliable data. From this information, it was deemed that the sample size should at minimum be doubled for each test. This will likely be increased further as there will be less tolerance ranges being tested using this method. Like seen in the torque test, specimens will be selected from a batch of around 100 specimens. The specimens chosen will be at random and only be used if the specimens are dimensioned as required within the tolerance range.

### 6.7.1 Sample Size

For this testing, a larger sample size than 5 will be used. Due to the poor reliability of the earlier testing method, the use of a sample size of 20 has been initially suggested. Much like the other testing the balance between obtaining reliable data and not overspending on specimens is key. The finalised sample size will be generated before this test method is used, and will incorporate all the information gained from testing up till that point to justify the number of specimens.

## 6.8 Testing Method

The equipment used for this testing method, including the Instron testing machine and VAST testing jig will remain the same as what was seen in the ramp loading test. This testing method is planned for the second iteration of button testing, which will require the insertion of a VA screw into a button. This will require the use of the locating collars to achieve the proper angle.

1. using the locating collars insert the appropriate number of specimens, being an equal number of specimens for both angles and tolerances. Using an insertion torque of 2.5 Nm
2. Insert the VA screw/button specimen into the VAST testing jig, by placing the specimen into VAST05
3. Align VAST05 with VAST06 and bolt the pieces together making sure that the specimen is clamped appropriately
4. Move the fixture up to the locating block VAST09, while making sure to slot the screw shaft of the specimen into the ball joint collar using the linear bearing slider.
5. This assembly is attached to the right angle VAST08, which is also attached to the base plate VAST07 using slots. This assembly slides up to contact the VAST09 stopper to provide the appropriate positioning of the specimen
6. As the specimen is moved to the stopper the ball joint housing will need to be adjusted in height so that the screw shaft of the specimen slides smoothly into the ball joint (VAST04), once in place the right angle (VAST08) will be securely tightened to the base
7. The VAST testing jig can now be placed in the bed of the testing machine, this is held in place using a locking pin
8. The Instron will be set up using the manual provided, including balancing the load cell before testing
9. The actuator is moved up to the VAST testing jig so that the pointer tool located in the loading hole of the testing jig. This should not introduce force, only locate the central axis for loading
10. The Actuator should load the specimen to 72 N as this in the mean force of the testing cycle

11. If all safety functions and limiters are set, the test can be run. The loading should first increase from 72 N up to the 120 N full force and then start cycling between 120 N and 24 N.
12. Run the test for 10,000 cycles or until failure of the specimen occurs
13. Once a specimen fails, remove the specimen from the testing jig and replace it with a new specimen.
14. Repeat the process above while keeping track of each specimen number

### 6.8.1 Failure Criteria

- Failure of the specimen by material fracture
- Visible screw loosening
- A displacement of the actuator of more than 7 mm from original position

Note: the test will be stopped if the specimen successfully reaches 10,000 cycles without failure.

## 6.9 Assumptions

- There is a removal of bending deformation on the screw shaft due to the protective sleeve of the ball joint
- The weight of the test jig is centred on the axis of the load cell
- There is minimal shear movement due to the testing jig only allowing 1 axis of freedom
- The test jig is centred on the load cell using x-y-axis bearing sliders, which also remove shear stress on the actuator

## 6.10 Discussion

This testing method was originally planned to be part of the initial testing of the VAST hole feature, to observe the fatigue life of the interface between the VAST hole feature and the VA screw. Due to the information gained from the torque and ramp loading tests, as well as a different direction chosen by Austofix, this testing method has been postponed.

Although this method has been cancelled for now it is still a valid form of testing and represents an important piece of knowledge that will need to be obtained. The idea behind the button testing was to maximise the performance of the VAST hole feature and VA screw, where the key part of this test method would be to observe the fatigue strength of the VAST design possibly including the effects of differing tolerances.

As the shoulder undergoes many cycles of loading during daily activities it is important to determine if the design can withstand what is deemed as an appropriate representation of this situation. Due to the difficulty in knowing the number of cycles and forces in the shoulder during daily activities, it is almost impossible to generate a test that would match real life loading. For this reason, the testing often uses generalised parameters. Testing the fatigue will be important to observe the deterioration of the material and its geometry over a number of cycles, so that failure can be prevented as much as possible.

Due to the nature of cyclic loading and how it damages material, it will also be an important method in observing the propagation of material fractures. This is key to observe if the material fails or if the VAST feature fails. For this type of testing it is preferred if the material fails, over the VAST feature. This is because if the material fails, then that's the limit of the standardised materials performance, where as if the VAST feature fails a redesign is required. In the study by Lenz et al. they stated that the majority of the cases in their study failed due to fracture propagation at the base of the screw head.

The fatigue test is most importantly useful for developing a S-N curve graph. A S-N graph shows the cyclic stress of the material against the number of cycles performed. This is helpful in determining fatigue life of the plate. Although fixation plates are designed to be removable it is important that they have a significant lifespan.

Depending on the direction Austofix decide to go with this project this testing may not be necessary, however a construct fatigue test for the final proximal humeral plate design will be needed. In the future works section of this document there will be a discussion on developing a construct fatigue test.

## 6.11 Conclusion

This testing method was postponed due to the findings of the ramp loading test, as well as altered requirements for testing. This testing method has been completed and is ready for implementation, however, may not be applicable depending on the new project direction. The use of cyclic loading to determine fatigue life, is an important parameter to test. This testing though may be held off until the design of the proximal humeral plate is finalised, in which a complete construct fatigue test will be implemented. This will depend on the requirements of Austofix and the direction they decide to go with for the rest of the project. In the future works chapter of this report there will be a discussion on construct fatigue of proximal humeral plates.

# 7 Future Works

Due to the period of the project as well as some of the limitations that affected the progress of the project, testing did not proceed as anticipated. Therefore, due to some of these limitations some of the testing methods that were being developed have not been finalised and will be required for future work on the project by Austofix. The testing methods that were not completed were, fret testing and a construct fatigue test for the finalised plate design. The construct fatigue test was a method that was identified from the start of this project as a necessary test to be performed. This was requested by Austofix as similar tests have been used previously, as well as construct fatigue tests for proximal humeral plates being a prominent testing method seen in literature. Fret testing was initially thought by the company to not be warranted, however due to some investigation in this project and through other project work it was decided that it was necessary. Fret testing however, is a standardised testing method, which makes it easier to design and test.

## 7.1 Fret Testing

### 7.1.1 Background

Fretting is the process of wear that occurs at contact surfaces, this can be mechanical or can be as a result of corrosion. In terms of proximal humeral plates, they are designed to have smooth finishes and made from materials that are considered to be of good biocompatibility (e.g. titanium). However, it has been seen that even some materials such as titanium can show negative reactions in the body, as this can be as a result of an allergy. These limited issues were made more significant with the inclusion of the variable angle technology. As the Austofix design uses two materials of differing hardness, where the screw (harder material) is used to generate a thread in the VAST hole material (softer material) there were concerns that there might be a significant amount of metal loss from this process. Additionally, metals are often anodised or otherwise treated for various reasons, where these processes also make the material less reactive. This is great for use in the body but the process only covers the surface of the material. This means that when a VA screw is used, the part of the treated surface is also removed from the VAST hole feature. This process could potentially result in a surface that is no longer anodised reacting within the body. The VA screw and VAST hole feature interface also will generate a high friction surface, which may cause greater material loss, being a site of micromotion. For these reasons, it is important to test the metal loss of the VA screws and the VAST hole features. This will help determine the level of material loss of the design and whether it is within acceptable safe limits for implantation. Luckily there are appropriate standards available for testing of metal loss and fretting corrosion.

## 7.1.2 Standard Test Method

### *7.1.2.1 Background*

ASTM F897 – Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws is one of the standards that suggests an appropriate method of fret testing (65). This standard provides a testing method to determine the amount of metal loss from plates and screws used in osteosynthesis, or bone fixation plates. This testing is based on the metal loss due to fretting corrosion at the interface between the screw head and the plate. This is performed by generating a relative motion between the plate and screws which simulates one type of motion. This generates a cyclic wear situation, which follows closely with the interest of this type of testing for use in this project. This testing method like others explored throughout this project and in the literature review, will provide a testing method that is not comparable to clinical situations. Unlike the bone plate standards, this fret testing however is easier to implement on the design for this project and is also more relevant.

This process is performed by using a linear plate with two holes in it. The plate is attached to two plastic rods using the bone screws. The plate, screws and rods are placed into a beaker filled with sterile solution and sealed with a rubber seal. This is mounted in a fretting apparatus which will cause a rocking motion (e.g. cyclic displacement) of the screw in relativity to the plate. The amount of fretting corrosion is determined at the end of the test by chemical analysis of the solution, and by weighing components.

### 7.1.2.2 Equipment

1. Specimen
    a. plate manufactured with two VAST hole features
    b. two VA screws for plate insertion
2. Plastic rod collars (x2)
3. Beaker
4. Thin rubber sheets
5. Solution – 0.9% NaCl in distilled water, with a pH between 6.5 to 7.5
6. Fretting apparatus
    a. Device able to use a slow rotating cam
    b. Device able to hold specimen in beaker
    c. Device able to cause slight movement of VA screw in relation to plate

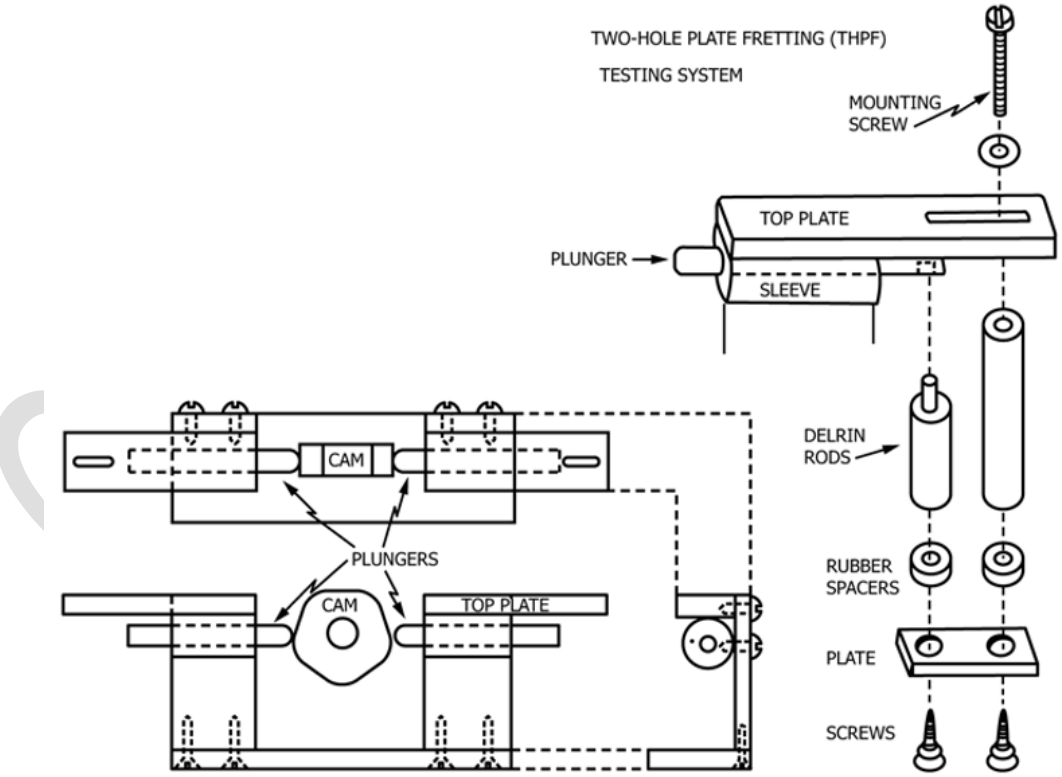


*Figure 45 ASTM F897 Two-hole plate fretting testing system example* (65)

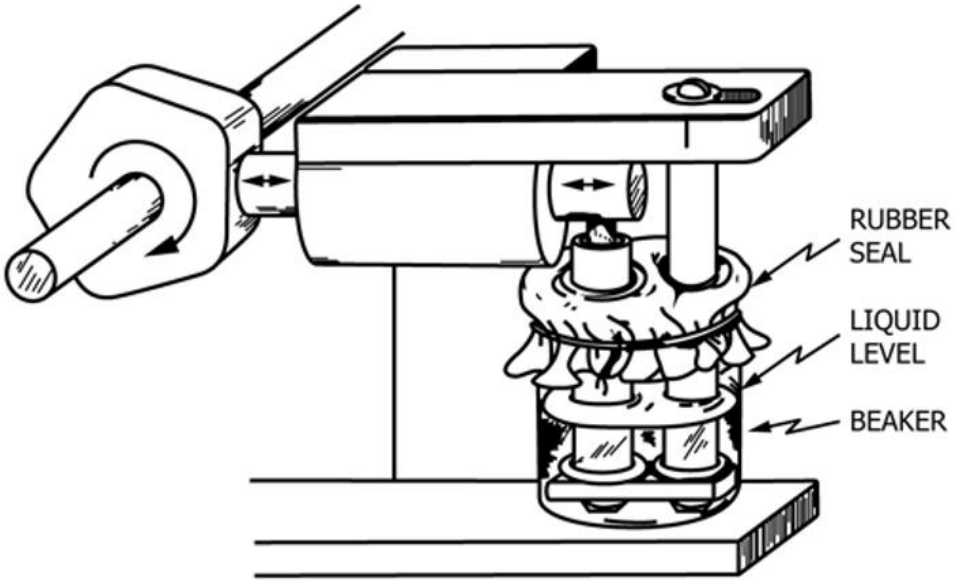


*Figure 46 ASTM F897 Example of test chamber with rubber seal* (65)

In Figures 45 and 46, the recommended set up of a fret testing device can be seen, as per the ASTM standard F897. This is a reasonably simple design, which would be easy to design and manufacture. The design largely consists of an appropriate cam and slow speed rotating shaft. The cam pushes on a slider which is connected to one of the screws of the specimen. This produces a cyclic angular displacement of that screw compared to the rest of the specimen which is secured by the frame of the test equipment.

#### 7.1.2.3 Test Specimen

Due to the type of specimen required for this test, being a plate with two holes and the use of two screw, custom specimens will have to be designed and manufactured. As the initial tests of this project used custom made single hole buttons, double hole plates should not be difficult to adapt from original designs. These will also utilise the VAST hole features.

The use of VA screws maybe slightly more difficult, as the aim would be to test at 16.5°, not just at 0° (perpendicular to the plate). This would require an adapter to allow testing of screws at 16.5°. Additionally, these tests occur over 7 – 14 days and therefore only a couple of specimens may be tested in a reasonable time without have multiple testing equipment setups.

#### 7.1.2.4 Procedure

This test required specimens to be cleaned before testing, which is important to not affect the rate of corrosion. The cleaning process should be performed using ultrasonics and detergent, being rinsed with distilled water after. The plate and the screws are all weighed separately and together before testing. The plate is then attached to the plastic posts using the rubber spacers and the VA screws. It is suggested that the screws be tightened to a point in which they generate a 400 ± 50 N axial force. This measurement can be found indirectly by calculation using screw torque. The specimen is then placed into the beaker with the solution and sealed using the rubber sheet. The plastic rods then can be attached to the slider and the equipment fixture for testing. This test is run over a number of days, where between 7-14 days fretting corrosion is measurable. After the test, the solution is placed into a screw cap container which is used for chemical analysis. The specimen is ultrasonically cleaned again, and dried. The specimen is weighed, as a whole, and then separately which will allow material loss to be calculated.

#### 7.1.2.5 Data Collection

In this testing method, a number of pieces of information are to be collected and calculated. The change in weight can be calculated for the plate and the screws separately and as the total weight. This should be recorded as loss of weight of each component, loss of weight of the total device and the amount of corrosion products in the solution after testing. Results from the solution should also include the change in pH. The damage caused by corrosion should also be described with appropriate imaging if possible.

### 7.1.3 Considerations

From the testing method and equipment described in the standards there are some considerations that need to be made if it is going to be adapted to this project. The incorporation of VA screws always adds difficulty in testing, where for this test the equipment and specimens will have to be designed so that the maximum insertion angle can also be tested. For this project testing should occur at 0° and at the maximum angle (plus safety factor) of 16.5°.

As biomechanical testing can't be directly compared to clinical behaviour, this test can't be used to directly predict the behaviour of the design. This is increasingly evident as this test only allows motion in one direction. This limitation in motion won't represent the complex motions that are seen in the shoulder, and is highly likely that the motion seen in the shoulder will cause greater fretting corrosion than this test.

The time period for these test is extreme, being 7 – 14 days. This is a necessary testing method for this project so this time period for testing will have to be incorporated in the timeline of the project. However, due to how long the tests take only a couple of specimens may be performed, unless multiple equipment set ups are made. There should be a minimum 3 specimens tested at 0° and 3 specimens tested at 16.5°, which is the minimum requirement for sample size. However, more specimens should be considered.

### 7.1.4 Conclusion

Through previous testing and literature, it was found that fret testing is an important method of testing that needs to be explored for this project. An outline of the ASTM F897 standard for fret testing and corrosion fretting has been presented, and has shown to have many of the same aims as what the project requires. Through investigating the method and equipment there are some considerations that need to be considered. Most of these considerations or aspects that need to be adapted for this project are due to limitations of the project including the use of VA screws. This test will be required to observe the metal loss from fretting over a number of cycles to provide an estimate on what would likely occur in a clinical setting and to calculate if the amount of material loss is within acceptable limits for use in the body.

## 7.2 Construct Fatigue

### 7.2.1 Background

Construct fatigue is fatigue testing that is performed on a particular construct. In this case, the ‘construct’ is the finalised design of a proximal humeral fixation plate, including the VA screws. The process of fatigue is the slow failure of the material due to cyclic loads. Cyclic loading is one of the most common forms of biomechanical testing for proximal humeral plates, and an important test for determining key performance criteria for these plates. This test was investigated due to the request by Austofix as well as its inherent importance seen in literature. As the shoulder is a source of complex loading and cyclic motion, it is important to observe the effect of cyclic loading on the fatigue life of the plate.

As like many of the biomechanical testing in this field, there are no standardised testing method. Therefore, heavy justification on parameters of the testing have to be performed. Most of the justification of this testing method follows literature and other testing methods used in studies. The justification for this testing method included the use of studies that performed similar tests. As cyclic fatigue loading is a common test there are many available, to investigate. Most of the justification and choice in parameters for this test, came from the requests of Austofix or following reliable studies.

The following chapter shows the justification of the parameters that were ultimately chosen for this testing. The chapter will also have a discussion on equipment, specimens, and data to be collected. As this testing method will be a part of the future testing to be performed by Austofix, the aspects outlined in this report will be subject to change.

### 7.2.2 Justification

Testing of proximal humeral plates is an important step in showing the relevant mechanical properties of designs and how these properties affect performance. Most commonly seen in the literature is the use of cadaveric specimens for plate testing (43). This is to use the best basis for comparison between biomechanical testing and clinical behaviour. However, the use of cadaveric specimens is often expensive. Additionally, for tests that are looking at the pure mechanical properties of a plate cadaveric specimens are not needed. In these situations, the use of synthetic saw bones is used. Being cheaper and having an identical structure, making them highly repeatable for use in mechanical testing. The identical structure causes the trends seen in results to not be effected by the material of the specimen, allowing for better insight into the behaviour of the fixation plate. Effectively removing one sources of variance of the results. Therefore, the cost benefits and repeatability of mechanical testing show that synthetic bone is the appropriate material to use for this testing method.

The use of 2 part fractures as a synthetic proximal humeral fracture for testing is largely popular(43). This is due to the ease of making repeatable synthetic 2-part fractures versus fractures seen for 3 and 4 part fractures. This is a situation where repeatability outweighs clinical evidence. Three part fractures have been shown to be the most common type of proximal humeral fracture seen in patients, whereas, 2 part fractures are still the most commonly tested biomechanically (43). 2-part fractures are made at the neck of the humerus using some form of saw, making them easy to produce and repeat.

Fatigue loading of proximal humeral plates in biomechanical testing is quite common, with different variations being seen between studies. These fatigue loads are usually of torsional or axial loading types, with a cyclic load (43). This test will use cyclic loading to observe the failure of the plate construct which removes the need to use other loading methods, such as failure loading. For the preliminary testing for this project the use of a maximum 120 N for a single VA screw/button construct was used. This is based on a variety of literature that supports the findings of Poppen and Walker who calculated the contact force in the glenohumeral joint at 90$^{o}$ abduction, to be 0.89 times body weight (51). Based on the same information provided by Anthropometric Reference Data for Children and Adults: United States, 2011 – 2014, which states the average weight of an adult in the US as 80.4 kg (58), this will result in a total force of 80.4 x 9.81 x 0.89 = 702.1N. This value of 702.1N will be increased to a rounded value of 710 N for testing (51).

In some of the studies It was not clear at what angle the forces were applied, but there is significant literature that supports that the force should be applied at 20$^{o}$ (62–64,66–70). In many of these studies the humerus is potted at this angle or otherwise supported at this angle. This is done to match contact forces that would be seen in the body. Based off this evidence the 710 N force found will be applied at an angle of 20$^{o}$. The force in all the studies that use 20$^{o}$ apply the load in a vertical axis and angle the specimen so that it contacts at the prescribed angle. This seems much easier to perform then applying the force at an angle, this way the use of linear axial loading machines can be utilized.

From the literature, there is a large variation of frequencies used for biomechanical testing of plates. Following the preliminary testing the use of 5 Hz frequency would be appropriate. This is supported by the ASTM standards for bone plate testing suggesting 5 Hz as an appropriate frequency (34). This frequency reduces strain sensitivity of the material as well as allowing testing to be completed in a reasonable time (34). Also as the original testing

using buttons was based on Lenz et al. study which used 5 Hz, this makes it appropriate to keep the same frequency for comparison (38).

Lastly, the preliminary tests based the number of cycles used off the study by Lenz et al.. For the construct fatigue test, it is reasonable to hold the same number of cycles for appropriate comparison. Additionally, in the observed literature the use of 10,000 cycles was the most common (38,45,60,69,71), followed by 5,000 cycles. A study did observe loosening of plate constructs at as low as 1,000 cycles, however, complete failure did not occur at this time. The use of 10,000 cycles will allow the observation of any loosening and the complete failure of the construct, which is the aim for this test. Additionally, the use of a uniform wave from 20% of maximum force to 100% is also appropriate for comparison with preliminary tests, which in the justification of the cyclic loading test was found to be an appropriate loading method.

### 7.2.3 Testing Parameters

- Cyclic loading waveform
- 10,000 cycle runout
- 5 Hz frequency
- 20% - 100% loading cycle
    - 100% load = 720 N
    - 20% load = 144 N
- Specimen mounted at 20°

### 7.2.4 Testing Equipment

This testing method would likely use an Instron Material Testing Machine, or similar uniaxial testing machine. As the Instron was the available testing machine for this project it is highly likely that it will be the testing machine used in future testing for the Austofix project.

The specimens for this test will be based on the completed design of the Austofix proximal humeral fixation plates, and their associated bone screws. The specimens will be attached to synthetic bone for testing. The saw bone is used to generate a synthetic fracture for testing, and mimic clinical scenario as much as possible. As mentioned in the justification the use of 2-part fractures are the most commonly used for this testing, and will be used for the construct fatigue tests. This will involve using a saw to make a 1 cm cut through the neck of the synthetic bone. The synthetic specimen will be cut at 20 cm, so that they are all equal length with a flat end, this allows for easy potting and adjustment. By potting the specimen, the 20° incline can also be more easily obtained, where the pot of the specimen is held at this angle.

To obtain this mounting angle some equipment will have to be made. This will involve a stiff material that can be mounted to the testing bed of the machine, as well as hold the potted specimen at 20°. The most likely option for this, is making the equipment out of some angled steel, to provide a strong base. The testing machine tool will most likely be a cup design, similar to what is seen in many biomechanical tests. these are usually a couple of cm in diameter and provide a small semi-circle cut out of the material so that the head of the humerus fits to allow appropriate loading.

### 7.2.5 Sample Size

By this point of the project there will be more information available on the design and its performance, this will likely effect the number of specimens that will be required for this testing. As this will be outside the period of this thesis project it is hard to determine some of the specifics that will occur for these tests. Based on the information available so far, and that found in the literature, an appropriate sample size of 10 specimens seems likely. This is a result that all the specimens would be tested in the same way, with no differing angles of screw insertion or tolerancing. Depending on what is decided for the number of screws used in these tests, there could be upwards of 100 screws used across the 10 tests, which needs to be considered. Manufacturing cost for testing specimens for these tests needs to be managed, as these tests will result in failure of specimens, ultimately the manufacturing cost will be for the information gained for the testing.

### 7.2.6 Testing Method

The testing method for this construct fatigue test will have to be finalised closer to the use of this method. As this test will be one of the final methods used, there will be a considerable amount of knowledge that will be obtained from the current point of the project to when this testing is used. This information will largely define what is required by this testing method and will ultimately define the parameters and process of testing. The parameters so far are those that have been found and justified through literature for a test method that would produce the required testing as requested by Austofix.

The testing method for this test will however have to explain the relative steps for setting up testing specimens, in terms of potting the specimen, generating a synthetic fracture and how many/what positions utilise bone screws for the fixation of the plate. Potting and generating a fracture have been seen in literature as it is common to use cadaveric

specimens with synthetic 2-part fractures for biomechanical testing. These studies will provide a basis on the likely method of preparing specimens for this test. Commonly PMMA (polymethylmethacrylate) is used to pot specimens that have been cut to be 20 cm long or two thirds in length. Synthetic fractures are usually generated by using a circular saw, where a 1 cm cut is usually the most practical. A 1 cm fracture is commonly seen as this is the smallest displacement of bone fragments of a fracture, in which surgical fixation is required. Therefore, it is likely that the method for this test will follow a similar procedure, as this a justified method of specimen preparation.

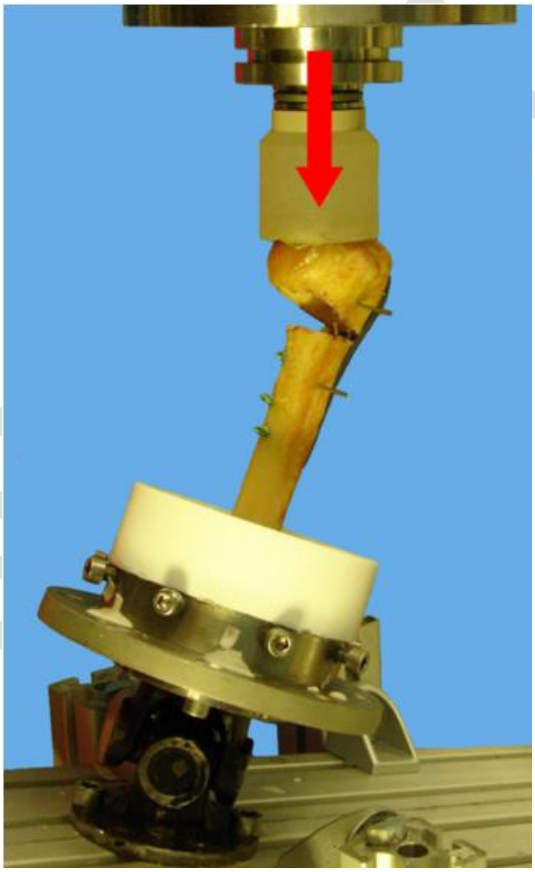

*Figure 47 Example of currently used construct fatigue setups* (64)

Figure 47 shows a likely setup for the construct fatigue test. Most studies that observed the use of the 20° angulation, have similar setup to this. This setup should provide significant stiffness of the construct, while also allowing for a loading direction as seen in relevant models of the shoulder.

### 7.2.7 Data Collection

The data recorded will be subjected to the finalised testing method, and therefore currently it can only be speculated on to what likely data will be obtained. On the basis of the type of testing to be used, cyclic loading, data such as time, number of cycles, force, and displacement are likely to be recorded. As the test is set to be a force controlled test it will be important to monitor the displacement, as this will most likely be a part of the failure criteria. Additionally, for the current parameters the specimens should fail, therefore data should be recorded in terms of the failure seen and if any loosening occurred.

As a result of the test being a cyclic loading and aimed at observing fatigue, the use of the data to generate a plot such as Stress-Cycle Curve should be considered. Therefore, it may be important to monitor stresses and even strains during the testing, or at least parameters that can be used to generate stress results. Unfortunately, as these factors can be influenced by temperature among other factors this might not provide useful information for trying to predict clinical results.

### 7.2.8 Assumptions

- The use of 20° angulation is used to mimic the direction of contact forces on the humeral head. This follows the force calculations presented by Poppen et al. study on glenohumeral joint contact forces, and follows what has been seen in a range of biomechanical testing studies.

### 7.2.9 Conclusion

This construct fatigue test will be an important part of testing the final design of this project. Unfortunately, due to limitations of the project and the time of the thesis, this testing method was not finalised and will represent future works to be performed by Austofix. This test will provide some key information about the fatigue failure of the design which will be used to justify the designs performance. Information from this test will also be used when designing surgical techniques for the device. This will be specifically important for controlling the number of VA screws used and how many can be inserted at an angle other than 0° (perpendicular to the plate). The testing method will be finalised later in the Austofix project, when designs such as the VAST hole feature and preliminary testings are completed.

# 8 Project Limitations

Due to the time constraints of this project as well as some setbacks that occurred during the project, the use of all testing methods was not able to be conducted. These test methods were still explored so that they could be used in future works by Austofix.

There were a number of limitations that resulted in setbacks, being: time taken to get inducted on testing machines, issues with data acquisition of instruments, time taken for manufacturing of specimens and equipment, and change of requirements during the project.

Due to scheduling and use of testing equipment, it was difficult to set aside time where instructors were free to provide appropriate training on use and safety of testing equipment. Induction was performed on two different Instron material testing machines as issues arose with the use of the initial Instron testing machine planned.

Initially the use of a Instron material testing machine for biomechanical testing was desired for use. After training occurred and testing had begun on this machine, it was found that there was significant noise interference of the data acquisition system. After testing, it was found that this interference was coming from the motors of a 6 degree of freedom hexapod testing machine, in the same room. Unfortunately, this machine has a large waiting time and is almost always in use, which made it impractical to perform testing in the lab. It was explored if data could be recorded when the motors were not loading a specimen, but there was still a reasonable amount of interference. As the project in the end did not require the use of biological specimens, there was the opportunity to use a newer version Instron testing machine in a mechanical testing laboratory. This Instron provided better data acquisition. However, induction to this testing machine was required, which extended the

induction period. This Instron in the mechanical lab was the machine used for testing in this project

After the initial testing of this project, requirements for testing had changed based on the information obtained by these tests. This was also effected by an alteration in testing priority as requested by Austofix. Unfortunately, this resulted in postponing some of the testing methods, pushing the tests outside of the thesis project timeline. These testing methods have been completed to an appropriate level based on the information so far presented by testing results. However, these testing methods will ultimately be performed by Austofix after the completion of this thesis project. These testing methods include the cyclic loading test, fret test and construct fatigue test. The methods of these tests will also be subjected to change based on information obtained up to the point of the methods use.

A limitation that was not considered originally is the length of time it would take for manufacturing of specimens and testing equipment to occur. Ultimately this set back testing a number of weeks, as it was not originally expressed that specimens would also need to be anodised. This on top of the number of specimens manufactured resulted in the long manufacturing time.

In terms of testing there were some limitations. In the torque test, the method is very simple and is easily repeatable however, the use of a T-bar driver, was not the most appropriate tool for inserting the screw. For this testing, a range of torques were needed but doing this by hand was factor that would affect the accuracy of the results. For further testing a torque range should be excluded and focus on using a torque limiting driver, as seen in surgery, as the insertion device. This would help standardise the test and provide more reliable screw insertion.

The ramp loading test has a few considerations that need to be addressed. Due to the set up followed and the design used in this project, results were only able to be recorded in compression (vertical axis) as there was only one load cell used. This limits the results available as well as limits the understanding of what forces may be directs in other axis, which occur when the screw angle changes. This needs to be also considered in terms of different angled specimens. As loading occurred only in compression the angle of load application was different for the different orientations of screws. This may affect the ability to compare the results of different angled screws. Future testing of this type should include multiple load cells specifically in compression and along the axis of the screw, so that forces generated through the screw can also be observed. To overcome the obstacle of the screws being inserted at different angles, the angle of the button could be modified during testing. Currently the button stayed in the same orientation for all specimens, however, the testing may benefit from maintaining the same orientation of the screw compared to the actuator instead. By holding the screw always at a perpendicular angle to the actuator the loading of each specimen regardless of angle of insertion would remain the same.

As mentioned reliability of the results was effected due to an error in the torque test, this was as a result of multiple people performing the test. As the method was altered before the test, not everyone understood the new methods which caused the error to arise. This can be prevented easily by finalising a method and properly informing everyone involved. Additionally, a single testing operator would be preferable.

The recorded results are not as reliable as initially thought, this was due to a limitation in the equipment available. The original Instron testing machine that was to be used, had an acceptable load cell for what was required for this testing, however, due to the change in testing machine the Instron used for this testing had a less than preferable load cell. The

test ended up utilising a 50 kN load cell, which is not appropriate for the 330 N max loads that were being seen in testing.

Overall there has been some delays in the schedule of the project. Some of these setbacks have been overcome in the most optimal way possible, as in the case of finding other available testing machines. Other limitations have caused alterations in the direction of the project, due to the knowledge gained from the testing in this project. This is largely due to this project being a new project for Austofix, however without the testing performed in this project there would not have been enough information available to determine the next steps to take.

# 9 Conclusion

This thesis project was to help the local company Austofix develop a new proximal humeral plate. The project has aimed to test the VAST hole feature design as well as the design of the VA screws for the Austofix proximal humeral plate. Although simplistic in design, this is a complex mechanism to test and fundamental to the performance of the proximal humeral plate. This project has designed testing to observe the performance of the VAST hole feature and VA screw interface. These tests represented the preliminary testing for the project and provided the initial information gained through testing for the design. The tests were justified by literature and based on the requirements by the company and the restrictions based on the testing machines available. The information gained from the tests in turn altered the design of the plate, specifically the VAST features. This progressed the development of the device as well as the direction of testing. Due to some limitations encountered during the project not all testing that was designed was used, instead this became future work for the Austofix project. Overall the work outlined in this project has assisted Austofix in furthering the development of their proximal humeral plate design. Where the information obtained from the results of testing as well as research throughout this project has assisted in this progression.

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# Appendix 1

## Appendix 1A

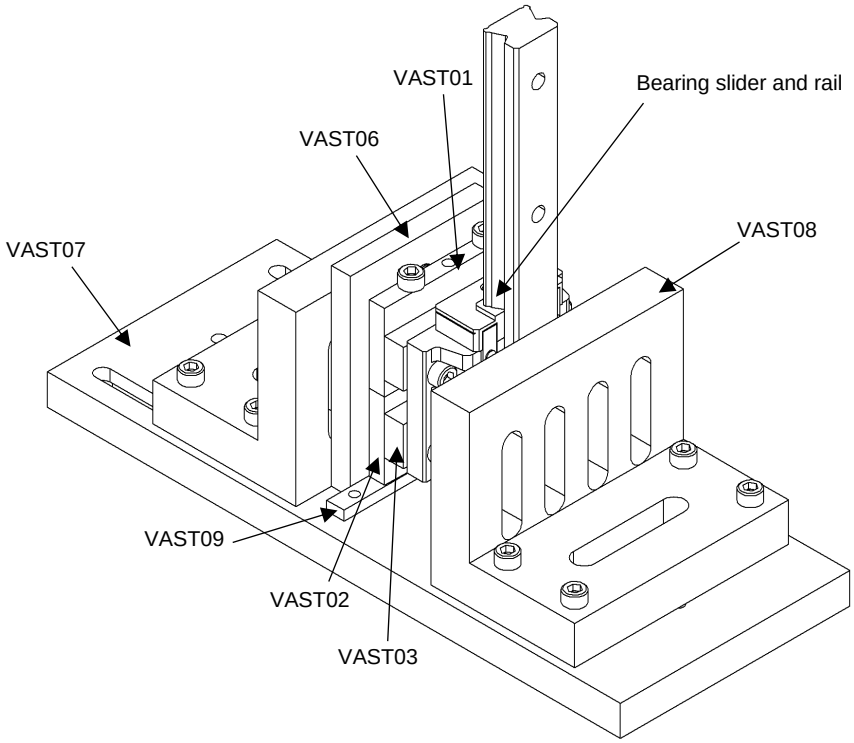
| PART NUMBER | QTY. | REV |
|---|---|---|
| VAST01 Rev 0 | 1 | 0 |
| VAST02 Rev 0 | 1 | 0 |
| VAST03 Rev 1 | 2 | 1 |
| VAST04 Rev 0 | 1 | 0 |
| VAST05 Rev 0 | 1 | 0 |
| VAST06 Rev 0 | 1 | 0 |
| VAST07 Rev 1 | 1 | 1 |
| VAST08 Rev 0 | 2 | 0 |
| VAST09 Rev 2 | 1 | 2 |

| FASTENER | QTY. |
|---|---|
| B18.3.5M - 6 x 1.0 x 20 Socket FCHS -- 20N | 2 |
| B18.3.5M - 6 x 1.0 x 16 Socket FCHS -- 16N | 4 |
| B18.3.1M - 6 x 1.0 x 16 Hex SHCS -- 16NHX | 2 |
| B18.3.1M - 6 x 1.0 x 35 Hex SHCS -- 24NHX | 4 |
| B18.3.1M - 4 x 0.7 x 12 Hex SHCS -- 12NHX | 2 |
| B18.3.1M - 6 x 1.0 x 55 Hex SHCS -- 24NHX | 2 |
| B18.3.1M - 6 x 1.0 x 30 Hex SHCS -- 30NHX | 8 |
| B18.2.4.1M - Hex nut, Style 1, M6 x 1 --D-N | 4 |

| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.04
Angular: 0 +/- 1°

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:
Authorised By and Date:

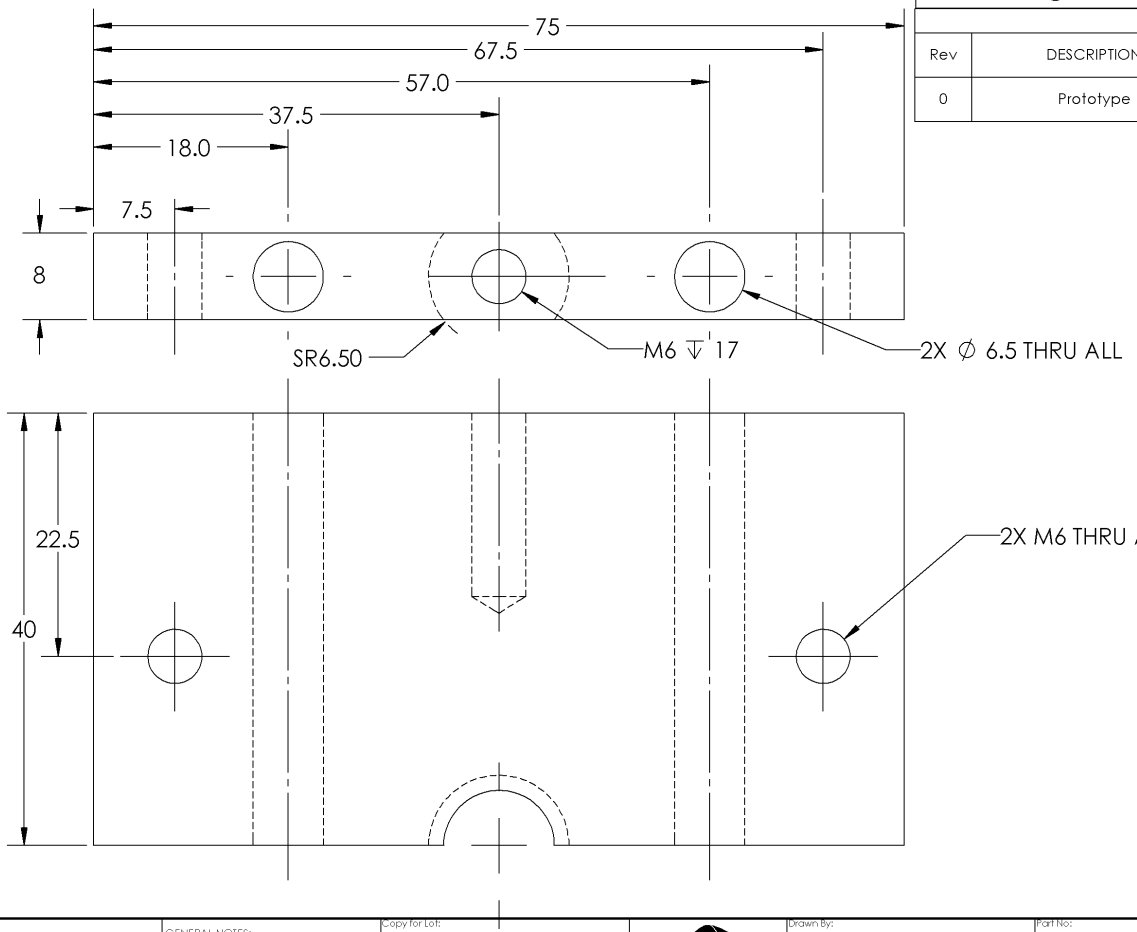
austofix



Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

Part No: VAST Assembly
Title: VAST Test Jig
Dwg #: VAST Assembly
MATERIAL: N/A
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 1:5
SHEET 1 OF 1

# Appendix 1B




| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:
Authorised By and Date:

austofix



Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

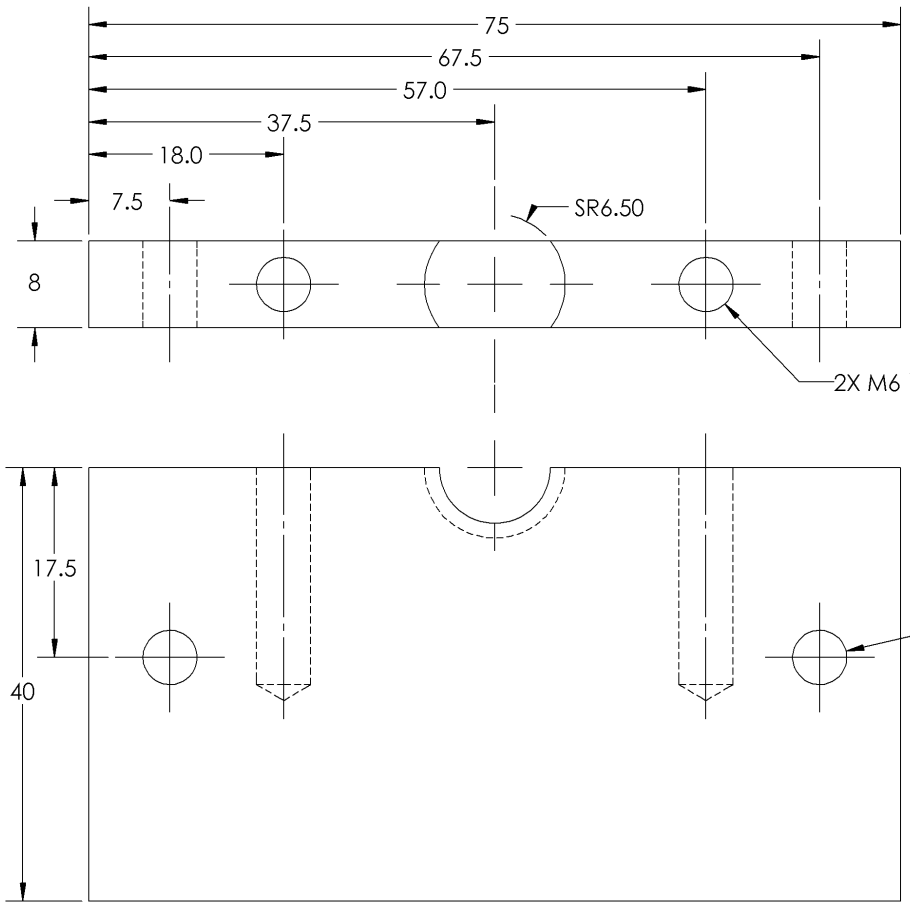
| Part No: | Title: |
|---|---|
| VAST01 | VAST Test Jig |

Dwg #: VAST01 Rev 0

| MATERIAL: | FINISH: | H.T. |
|---|---|---|
| Steel | AS MACHINED | N/A |

DO NOT SCALE DRAWING | SCALE: 2:1 | SHEET 1 OF 1

# Appendix 1C




| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:
Authorised By and Date:

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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

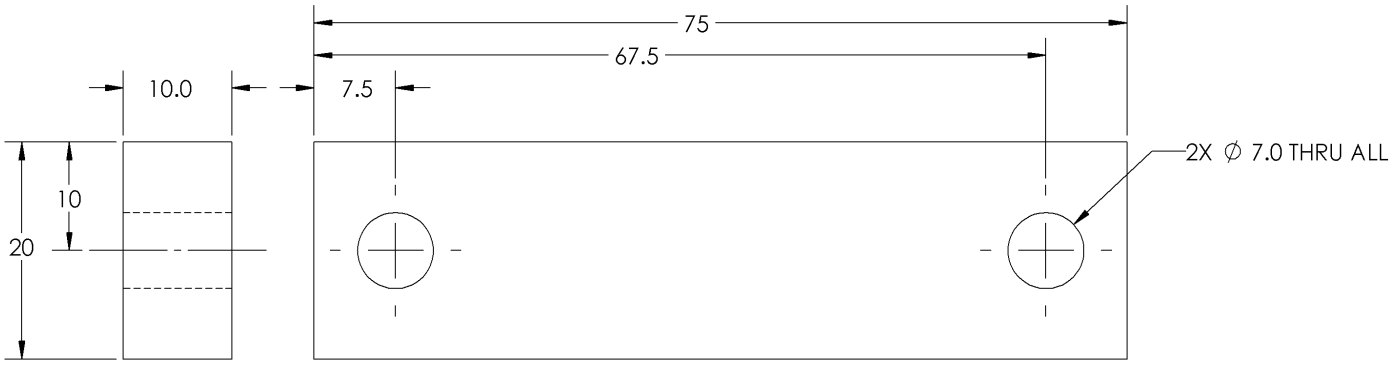
Part No: VAST02
Title: VAST Test Jig
Dwg #: VAST02 Rev 0
MATERIAL: Steel
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 2:1
SHEET 1 OF 1

# Appendix 1D

| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |
| 1 | Added Thickness Dimension | N/A | Ryan Spry | 21/02/2017 |




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:

Authorised By and Date:

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Drawn By: Ryan Spry 19/01.2017
Checked By:
Approved By:

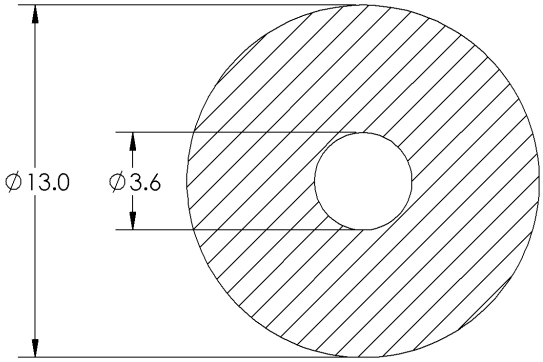
Part No: VAST03
Title: VAST Test Jig
Dwg #: VAST03 Rev 1
MATERIAL: Steel
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 2:1
SHEET 1 OF 1

# Appendix 1E

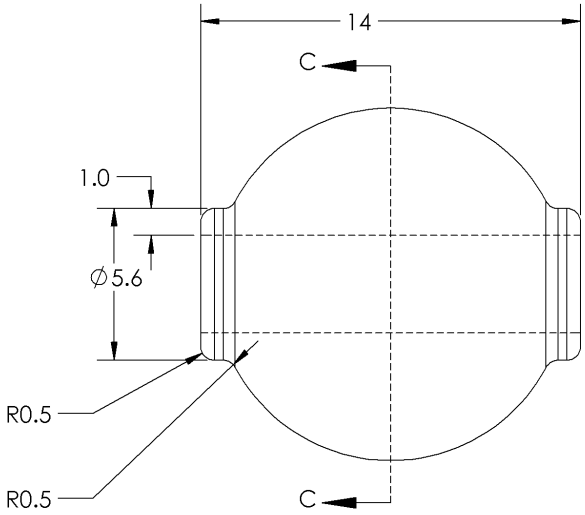
| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |




SECTION C-C




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:

Authorised By and Date:

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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

| Part No: | Title: |
|---|---|
| VAST04 | VAST Test Jig |

Dwg #: VAST04 Rev 0

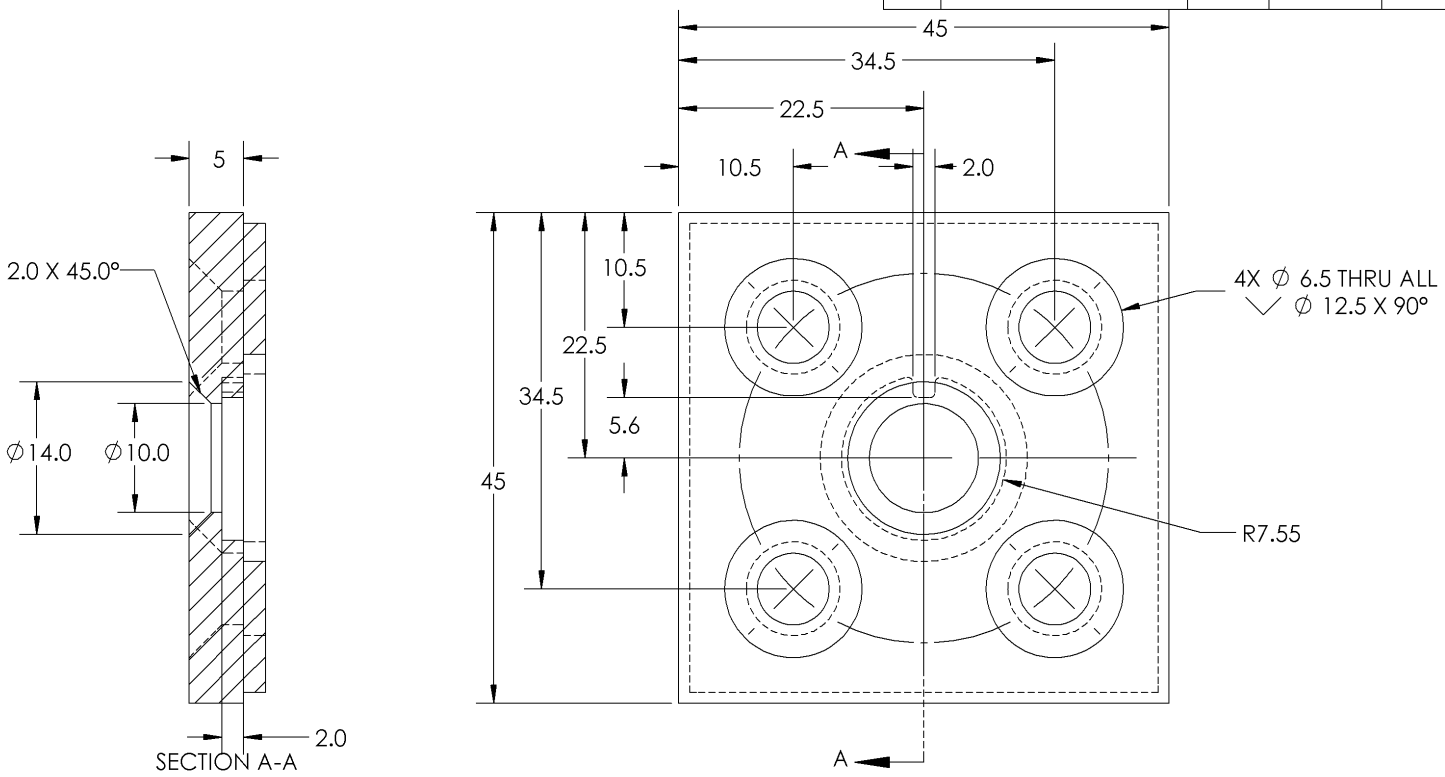
| MATERIAL: | FINISH: | H.T. |
|---|---|---|
| Steel | AS MACHINED | N/A |
| DO NOT SCALE DRAWING | SCALE: 5:1 | SHEET 1 OF 1 |

## Appendix 1F

| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK
SHARP EDGES
Inspection dimension

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Authorised By and Date:

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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

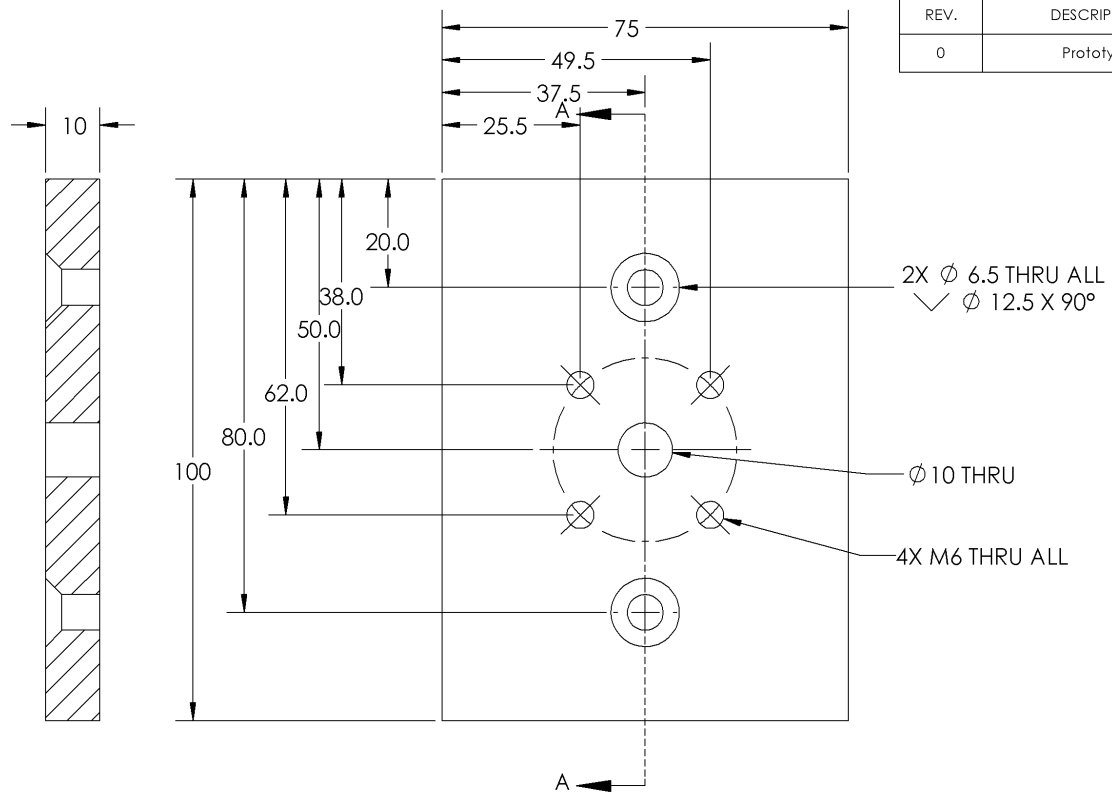
Part No: VAST05
Title: VAST Test Jig
Dwg #: VAST05 Rev 0
MATERIAL: Steel
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 2:1
SHEET 1 OF 1

# Appendix 1G

| Drawing Status | Prototype |
|---|---|

REVISIONS

| REV. | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |




SECTION A-A
SCALE 1 : 1

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.04
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:

Authorised By and Date:

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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

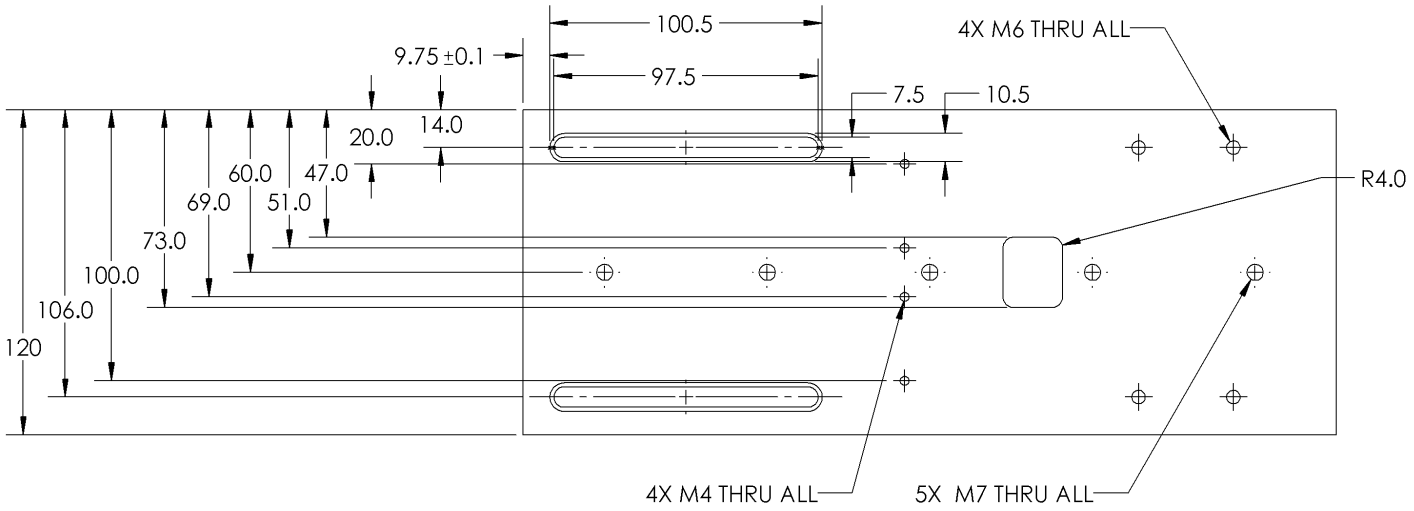
Part No: VAST06
Title: VAST Test Jig
Dwg #: VAST06 Rev 0
MATERIAL: Steel
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 1:2
SHEET 1 OF 1

# Appendix 1H

| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |
| 1 | Increased thickness of plate to 16 mm. Removed 4x mounting holes/replaced by 5x M7 holes running along axis. Added additonal holes for locating block. Added cut out for alternate slider. Increased edge cut out depth of slot to 10mm. | N/A | Ryan Spry | 21/02/2017 |




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

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Authorised By and Date:

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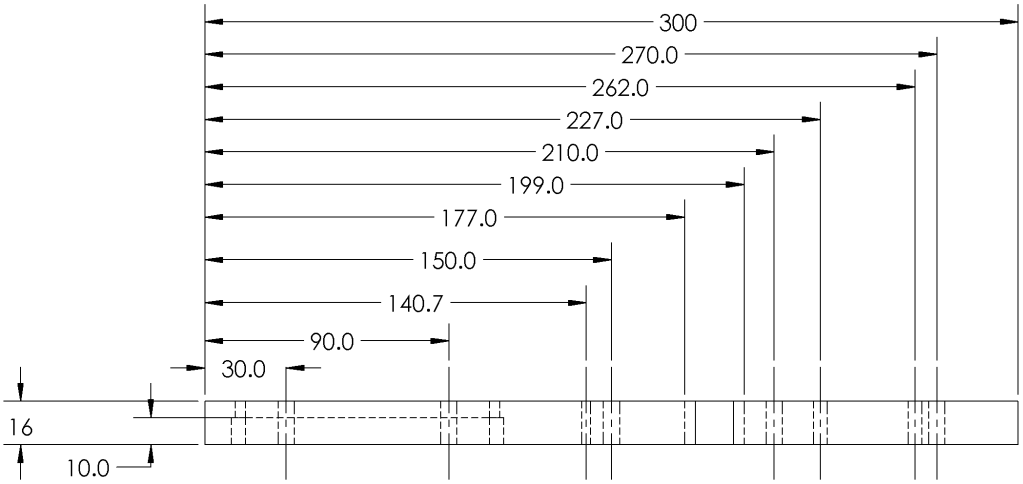
Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

Part No: VAST07
Title: VAST Test Jig
Dwg #: VAST07 Rev 1
MATERIAL: Steel
FINISH: AS MACHINED
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 1:2
SHEET 1 OF 2

# Appendix 1I

| Drawing Status | Prototype |
|---|---|




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/- 1°

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:

Authorised By and Date:

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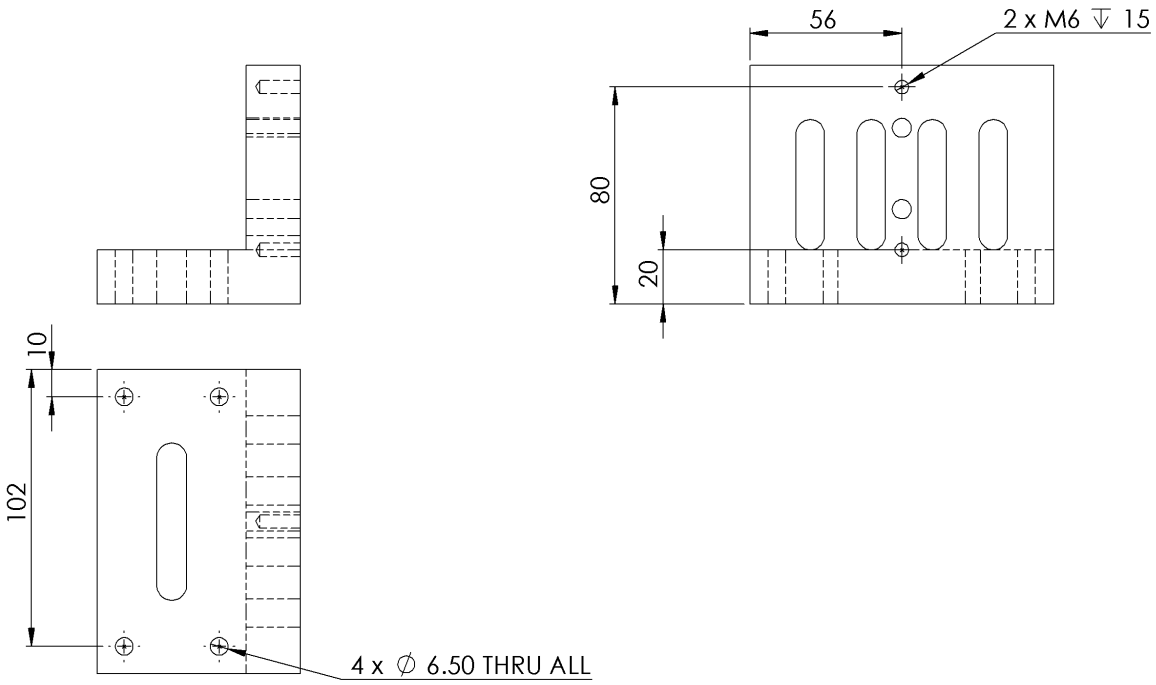
Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

| Part No: | Title: |
|---|---|
| VAST07 | VAST Test Jig |
| Dwg # | VAST07 Rev 1 |
| MATERIAL: Steel | FINISH: AS MACHINED |
| H.T.: N/A | |
| DO NOT SCALE DRAWING | SCALE: 1:2 |
| SHEET 2 OF 2 | |

## Appendix 1J

| Drawing Status | Prototype |
|---|---|




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.02
Angular: 0 +/- 1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

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Authorised By and Date:

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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

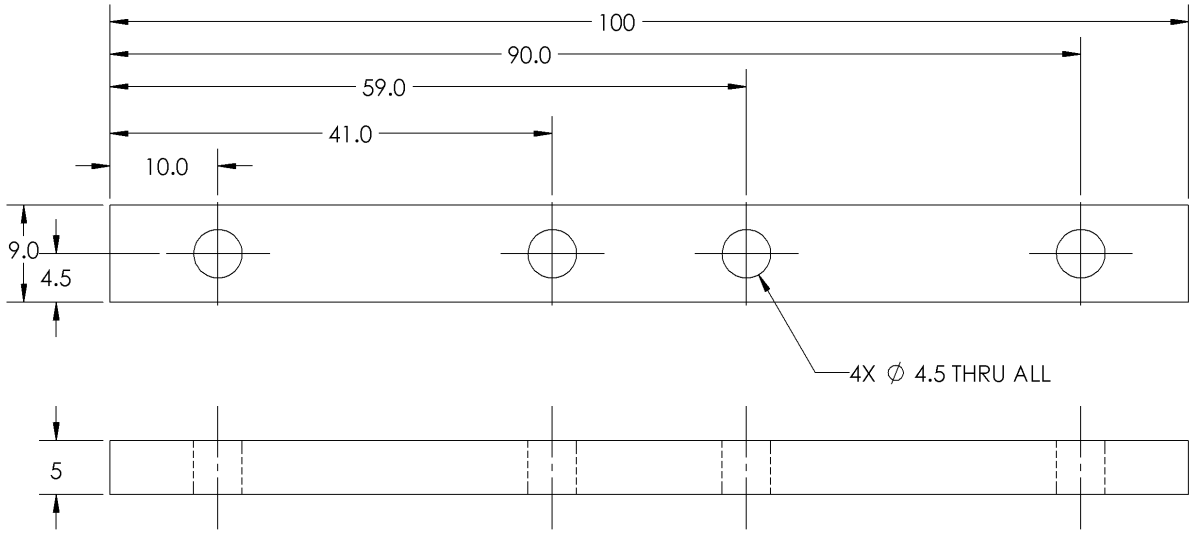
Part No: VAST08
Title: VAST Test Jig
Dwg #: VAST08 Rev 0
MATERIAL: N/A
FINISH: N/A
H.T.: N/A
DO NOT SCALE DRAWING
SCALE: 1:2
SHEET 1 OF 1

# Appendix 1K

| Drawing Status | Prototype |
|---|---|

REVISIONS

| Rev | DESCRIPTION | CC/ref | Rev By | Rev DATE |
|---|---|---|---|---|
| 0 | Prototype | N/A | Ryan Spry | 19/01/2017 |
| 1 | Extended Length. Added 2X additional holes | N/A | Ryan Spry | 21/02/2017 |
| 2 | Increased thickness | N/A | Ryan Spry | 22/03/2017 |




UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH: 1.6Ra
GENERAL TOLERANCES:
Linear: 0 +/- 0.5
0.1 +/- 0.1
0.01 +/- 0.002
Angular: 0 +/-1 °

GENERAL NOTES:
DEBUR AND BREAK SHARP EDGES
Inspection dimension

Copy for Lot:
Authorised By and Date:



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Drawn By: Ryan Spry 19/01/2017
Checked By:
Approved By:

Part No: VAST09
Title: VAST Test Jig
Dwg #: VAST09 Rev 2
MATERIAL: Steel
FINISH: AS MACHINED
H. T.: N/A
DO NOT SCALE DRAWING
SCALE: 5:1
SHEET 1 OF 1