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Assessment of Surgeon Performance of Total Shoulder Arthroplasty Insertion and the Resulting Affects on Projected Patient Outcomes

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Supervisor: Johnson, James A., The University of Western Ontario A thesis submitted in partial fulfillment of the requirements for the Master of Engineering Science degree in Mechanical and Materials Engineering © Nicholas Van Osch 2021

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Abstract

Replacement of the human shoulder with implants is a commonly employed procedure in orthopedics to alleviate patient discomfort and pain. The alignment of the implant relative to bone, which is often dictated by the initial cut plane, is an important parameter when considering the stability and long-term fixation of the implant. This thesis explored the effect of the selection of the cut plane by four different surgeons in a series of glenoid models, and subsequently evaluated the variation of the cut planes on load transfer from implant to bone using finite element modelling. The findings indicated that there is a wide variation in the selection of the cut plane amongst the surgeons based on a target alignment. Using the variation that was determined in this study, it was shown that the stresses and implant stability (*viz.* micromotion) were highly variable amongst these various different combinations of cut planes. It is concluded that with current approaches to the selection of cut planes, there is a wide variation in the load transfer mechanics, even for the same bone model. This has implications with regard to surgical outcomes and biomechanical modelling predictions.

Lay Summary

Shoulder replacement surgery is becoming a more popular procedure in North America. A key component of shoulder implant performance is alignment of the implant. As such, this thesis examined the link between surgeon performance at inserting the glenoid implant and the expected implant performance. Using observed surgeon variability in implant insertion, the impact of glenoid implant misalignment was simulated using three-dimensional computer models. The results of these studies indicated that typical surgeon performance can lead to drastically different implant performance. These results stress the importance of considering surgeon performance when performing biomechanical predictions for new implant designs.

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Chapter 1

1. Introduction

This chapter aims to provide all of the necessary background information regarding anatomy and motion of the shoulder joint, benefits and challenges of total shoulder arthroplasty, and a summary of the available literature on the impact of implant alignment. Included in this chapter are the objectives, hypotheses and rationale for this thesis.

1.1 The Shoulder

The shoulder has a unique joint structure that includes many structural and functional advantages. The ball and socket joint structure allows the humerus to achieve orientation in a space larger than a hemisphere, the largest range of motion in the human body [1]. For the shoulder to maintain its stability through such a large range of motion, various soft tissues including muscles, tendons and ligaments keep the bones in joint. Maintaining proper interaction between these hard and soft tissues is vital for both preventing trauma, such as dislocation, and performing everyday tasks [2].

In order to provide sufficient background for exploring the glenohumeral joint in the shoulder, aspects of the entire shoulder's structure should be introduced. There are three main structural components of the shoulder: osseous anatomy, passive soft tissues and active soft tissues. These categories are explored in in the following sections.

1.1.1 Shoulder Anatomy

The three bones that make up the shoulder include; the humerus, scapula and clavicle (**[Figure 1-](#page-11-0) [1](#page-11-0)**). Since the main focus will be on the glenohumeral joint, a basic understanding of the scapula and its motion is beneficial since it serves as the main anchor for the shoulder. The scapula is the main attachment point for multiple active and passive structures between both the scapula and humerus as well as the scapula and the torso. These structures result in the scapula acting as a means of force transmission between the torso and the upper limb.

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Figure 1-1: The shoulder joint

The complete bony structure of the shoulder is illustrated here while highlighting the glenohumeral, acromioclavicular and scapulothoracic joints.

For the scapula, there are three main structures of interest. The glenoid is the concave, pear-shaped region and serves as the main articulating surface between the humerus and the scapula [\(Figure 1-](#page-13-0) [2\)](#page-13-0). The acromion extends from the spine of the scapula and takes the shape of a curve that matches the humeral head. Through articulation with the clavicle, the acromion is integral for scapulothoracic rotation. Opposite the acromion on the anterior side is the coracoid process that also extends from the spine of the scapula. The coracoid process serves as the attachment site for many muscles and ligaments that assist with the stabilization of the shoulder.

The humerus is a long bone that enables gross movement of the upper limb [\(Figure 1-3\)](#page-14-0). At the proximal end of the humerus is the humeral head, a convex hemisphere that matches the curve of the glenoid. Within the shoulder, the humeral head articulates with the glenoid to form the glenohumeral joint. In terms of orientation, the humeral head is aligned at a slight angle off of the flexion-extension axis of the elbow, in a superior-medial-posterior direction relative to the elbow [3]. This orientation helps the humeral head to remain centered in the glenoid while the elbow is in a resting position within the sagittal plane at the side of the torso. While the humeral head is centered in the glenoid, it creates the ideal conditions for load transfer, range of motion and stability [4]. The humeral head is covered in cartilage to form part of a synovial joint.

Anterior view of the osseous anatomy of a right scapula and clavicle.

Figure 1-3: Humerus

Anatomy of a right humerus highlighting the osseous anatomy.

1.1.2 Articulations

The articulations between the bones of the shoulder enable the relative motion of structures. They provide stability, dictate range of motion and can cause impingement depending on their geometry. Motion of the shoulder is achieved by four joints, the glenohumeral joint enables relative motion between the humerus and scapula while the sternoclavicular, acromioclavicular and scapulothoracic joints enable rotation of the scapula relative to the torso [1]. This relative motion between the scapula and the torso occurs simultaneously with the glenohumeral motion to achieve a greater range of motion in the shoulder than would be possible with only a ball and socket style joint. With the scapula moving relative to the torso, this helps the shoulder to maintain joint stability by adjusting the contact loading conditions to limit shear forces that could overcome the limits of the soft tissues [5]. Impingement occurs when the soft tissue of the rotator cuff becomes pinched between the acromion and humerus, from either a change in bony anatomy or swelling of soft tissues. This impingement leads to general pain and stiffness in the shoulder.

The glenohumeral joint is of particular significance because it sacrifices joint stability to be able to make the largest contribution to the range of motion of the shoulder [5]. To help maintain the stability and improve conformity of the glenohumeral joint, the glenoid is coated with hyaline cartilage [6]. This effect is further enhanced by the glenoid labrum which increases the contact area between the humeral head and glenoid [Figure 1-4.](#page-16-0) The increase in contact area between the glenoid and the humeral head as a result of the labrum helps to reduce contact stress [4]. As a result of the soft structure for the glenoid labrum, it is not as stable as hard constraints but is still able to permit the large ranges of motion for the shoulder.

1.1.3 Passive Soft Tissues

Within the shoulder are passive soft tissues, including ligaments and joint capsules, that contribute to stabilization of the shoulder when experiencing tension from glenohumeral motion and loading. The joint capsule serves as a connection between the glenoid labrum and humeral head. The joint capsule is reinforced by the glenohumeral ligaments which become tensioned along the superior, anterior and inferior aspects of the joint during certain motion configurations [7]. An advantage of the glenohumeral joint capsule [\(Figure 1-4\)](#page-16-0) is that it does not impede the range of motion of the joint until it becomes sufficiently tensioned near the limits of the joint and then is able to passively restrict mobility of the joint [1].

Figure 1-4: Glenohumeral joint

This medial view of the right side shows the soft tissue structures of the glenohumeral joint including the tendons and where they attach to bone.

1.1.4 Musculature

Similarly to the passive soft tissues, active soft tissues, or muscles, help to maintain stability in the shoulder while enabling motion of the shoulder. Muscles within the shoulder can be defined by three main groups; the humerothoracic, scapulohumeral and scapulothoracic. These muscles stabilize the shoulder by holding the articulating surfaces in joint and resisting motion at the extreme angles of the shoulders range of motion. Through activation of coordinated muscle groups, the shoulder can achieve motion of the upper limb.

The muscles that are grouped into the scapulohumeral muscles include: the deltoid, subscapularis, teres minor, supraspinatus, infraspinatus, and the coracobrachialis (Figure 1-**[5](#page-18-0)**). The deltoid is a major contributor to stabilization of the glenohumeral joint and to achieving humeral abduction, generating approximately half of the moment required for motion [8]. There are 3 main independent bodies of the deltoid: anterior, middle, and posterior deltoids. As a result of the anterior and posterior deltoids having lines of action that have some opposition to each other, the deltoid can aid with rotation of the humerus in both the flexion-extension and the internal-external planes [9].

The rotator cuff is a structure composed of the subscapularis, teres minor, supraspinatus, and infraspinatus and aids in the stabilization of the glenohumeral joint. To provide additional stabilization during upper limb motion, the rotator cuff surrounds the glenohumeral joint anteriorly, superiorly, and posteriorly (**[Figure 1-4](#page-16-0)**) [1], [10]. With the various lines of action from the rotator cuff muscles, they are able to work with the joint capsule to achieve stable motion [11].

Lastly, the humerothoracic muscles are comprised of the pectoralis major and latissimus dorsi, which both originate in the torso. These muscles serve to primarily abduct the humerus but also provide flexion-extension and internal-external rotation with the pectoralis major being positioned anteriorly while the latissimus dorsi being positioned posteriorly [9].

5: Deltoid and rotator cuff muscles

The left image shows the anterior view of a right shoulder while the right image illustrates the posterior view. The line of action for the pectoralis major and latissimus dorsi is also shown in the left image.

1.1.5 Motion of the Shoulder

Since the upper arm can move in a variety of directions, there are four commonly used terms to describe the motion of the shoulder. These motions are achieved thanks to the interactions of the humerus and scapula and are called: axial rotation, abduction, forward flexion and horizontal flexion-extension (**[Figure 1-6](#page-20-0)**). Axial rotation involves the motion of the humerus about its diaphyseal axis and can be described as either external or internal. Abduction, or extension, refers to the lateral movement of the upper limb away from the torso while adduction is the motion towards the torso. Forward flexion is another form of elevation, similar to abduction, however it occurs while the humerus moves away from the body in an anterior direction. Lastly, horizontal flexion-extension is the anterior-posterior motion of the humerus exclusively in the horizontal plane.

To allow for the placement of the hand within such a large range, the scapula also rotates with the humerus in elevation, staying in line with torso and along an arc away from the midline of the body (**[Figure 1-7](#page-21-0)**). This interaction is called the scapulohumeral rhythm and follows an approximate relative rotation of 2:1 (glenohumeral to scapulothoracic) during abduction of the shoulder [12]. For an average individual, the expected range of motion in abduction-adduction is just under 180º and is determined by the bony structures and laxity of the joint [4]. Any changes to the bony structures or laxity of the joint can directly impact the range of motion of the shoulder.

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Figure 1-6: Common shoulder movements

The motions of the shoulder can most easily be broken down by establishing the above four basic movements: axial internal-external rotation, abduction-adduction, forward flexion-extension, and horizontal flexion-extension.

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Figure 1-7: Scapular rotation during humeral elevation

The arm at side position is shown in solid while the arm in abduction is overlaid. Note the change in alignment of the glenoid during abduction to help limit the shear stress on the joint.

1.2 Total Shoulder Arthroplasty

If an individual loses function or stability in their shoulder, implant replacement is a surgical option. In this case, loss of function refers to inability to perform regular activities of daily living because of pain, lack of strength, or being unable to achieve the necessary range of motion.Total shoulder arthroplasty (TSA) is a surgical procedure that replaces the diseased or damaged bony tissues with an implant that is engineered to restore the shoulders structure. These engineered implants aim to improve shoulder stability, range of motion and alleviate pain by forming a new articulation that mimics the behaviour of the glenohumeral joint. The traditional TSA follows an anatomic approach where the glenoid surface is replaced with a concave dish component and the humeral head is resected and replaced with a hemispherical implant [13]. Alternatively, a more recent development for TSA procedures has been a reverse total shoulder arthroplasty (RTSA) which is able to improve the contribution of the deltoid for abducting the arm (**[Figure 1-8](#page-23-0)**). For RTSA, the traditional anatomy of the shoulder becomes reversed by inserting a concave disc into the humeral head and a hemispherical component into the glenoid, thus swapping the structures that act as the ball and socket [13].

There are a variety of means by which the range of motion of the shoulder can become compromised, including end-stage rotator cuff tear arthropathy, or trauma to the gleno-humaral joint. In the event of these injuries, RTSA is an accepted method of treatment to restore stability and function to the shoulder [14]. As such, in a sample of 100 hospitals in 2012, half of the 3119 total shoulder arthroplasty cases completed were an RTSA procedure [15]. In addition, RTSA is an effective revision procedure for failed anatomic TSA replacements, with improvements to a patients range of motion and perceived health [14].

Figure 1-8: Different total shoulder arthroplasty techniques

The above shows the intact shoulder (top-center) and compares it to the shoulder structure for anatomic total shoulder arthroplasty (bottom-left) and reverse total shoulder arthroplasty (bottom-right).

1.2.1 Implant Performance and Complications

Compared to anatomic TSA, RTSA is still a new procedure and while it has some clear advantages over anatomic, there are some complications too. Following shoulder revision procedures, range of motion and pain are two common outcome measures, and RTSA has been shown to be effective at improving both with drastic improvements in forward flexion and abduction (averages improved from 53º to 134º and 49º to 125º respectively) [16]. Unfortunately, there are some high rates of complications with RTSA procedures as a 2011 meta-analysis of 782 cases between 1995 and 2008 found that 24% had complications, 3.3% required reoperation, and 10.1% required revisions [17]. It is worth noting that the numbers for patients receiving their first arthroplasty procedure had lower complication and revision rates at 13.4% and 6.4% respectively [17].

Figure 1-9: Reverse total shoulder arthroplasty components

The main RTSA components are the baseplate, glenosphere, humeral stem and humeral cup.

Figure 1-10: Anatomic total shoulder arthroplasty components

The main components for anatomic total shoulder arthroplasty are the glenoid baseplate, humeral head implant and the humeral stem.

1.2.2 Surgical Implant Alignment for Total Shoulder Arthroplasty

Identifying the optimal position and orientation of the glenoid component is typically done in advance via a preoperative planning software. For RTSA procedures, the glenoid baseplate is commonly planned to be inserted in the inferior third of the glenoid, centered anteriorly-posteriorly to match the profile of the glenoid (**[Figure 1-11](#page-28-0)**). The surgeon then follows this plan to insert a guidewire for reaming the surface of the glenoid. This guidewire is commonly inserted either freehand or with a patient specific guide. The position of this guidewire dictates the final position of the implant. For anatomic TSA procedures, the glenoid baseplate is commonly planned to be inserted in a neutral position that maintains maximum contact between the glenoid and the backside of the glenoid baseplate implant (**[Figure 1-12](#page-29-0)**).

Figure 1-11: Positioning of the glenoid baseplate for RTSA

The glenoid baseplate for the RTSA implant is the disk with 4 holes shown positioned in the inferior third of the glenoid face and centrally in terms of anterior-posterior alignment. This planned case is taken from BluePrint software which is a common program for preoperatively planning the surgery.

Figure 1-12: Positioning of the glenoid baseplate for anatomic TSA

The glenoid baseplate for the anatomic TSA implant is the disk shown positioned centrally on the glenoid face. On the backside of the baseplate, the cut plane is lined up to ensure maximum contact between the baseplate and the glenoid.

1.3 Impact of Implant Alignment

With respect to the effect of implant position and orientation on implant load transfer, little is known. This important implications with regard to the stability and fixation of the implant, and also load transfer mechanics at the articulation. There have been findings suggesting that the positioning of the implant can affect the implant performance in terms of impingement. From the perspective of impingement, orientation of the implant has a very minimal effect on completing activities of daily living so long as it is positioned in the bottom third of the glenoid [18]. However, there is limited research completed examining the long term affects of the implant orientation.

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In a previous clinical study conducted by Cuff et al., the impact on longer term outcomes of following an alternate implant orientation for shoulders with glenoid bone loss was conducted. In this study, the glenoid baseplate was oriented at an angle of approximately 10-15° anteriorly and 10° inferiorly to align the stem with the more dense pillar of bone in the shoulder [19]. After follow-ups with the patients over periods of two years and five years, it was shown that the alternative orientation for the RSA implant performed better than a traditional neutral alignment while not increasing the risk of shoulder notching or negatively impacting range of motion. However, there were some key drawbacks of this study including using an implant that was only two thirds of a hemisphere which would decrease the risk of shoulder notching compared to a conventional full hemisphere glenoid and there was no control group of a traditional baseplate orientation included alongside the alternative orientation to compare outcomes with.

1.4 Theis Rationale

Maintaining shoulder function and stability for individuals as they age or after suffering trauma is of great importance for independence and quality of life. While TSA can have a great impact on individuals suffering from negative shoulder conditions, TSA still has room to improve its risk of complications during surgery and future revisions. Understanding the variability that exists between surgeons and the impact it has from both a biomechanics and structural standpoint can help to improve surgical techniques to limit complications and revisions.

There are many factors contributing to the increased number of shoulder procedures and while TSA is still newer and not fully understood, the rate of TSA procedures compared to other shoulder procedures continues to increase. With many surgeons not being as experienced with TSA

procedures compared to other techniques, the variability of the surgeon in terms of placement for the glenoid baseplate could further impact the risk of complications during surgery and the need for revision surgeries later. With the common TSA concerns including screw fixation, baseplate loosening and scapular notching, knowing how large of an impact baseplate insertion variability would be beneficial for identifying areas of improvement.

It is important to also note that the vast majority of biomechanical studies, whether experimental or computational, do not account for the potential variations in implant alignment that may occur due to variations in surgical technique and surgeon selection of landmarks and positioning. Hence, an understanding of the effect of this potential variation of implant alignment on implant load transfer may well be very significant. In view of the foregoing, this thesis addresses this important question by (1) identifying the variation that can occur amongst clinicians and (2) address the effect of this variation on implant load transfer using finite element analyses.

1.5 Objectives and Hypotheses

There are 2 studies within this thesis as given in Chapters 2 and 3. The objectives and hypothesis of each chapter are:

Chapter 2:

Objective: To establish and quantify the variability that exists between surgeons. Surgeons will be testing on 3D models of the same glenoid, with the same plan to insert a guidewire for TSA. The surgeons will also vary in terms of their experience. Variability between each of the surgeon's insertion of the guidewire will be measured in terms of orientation (or angle) of the guidewire and location of the insertion.

Hypothesis: There will be location and orientation variability across all surgeon skill levels.

Chapter 3:

Objective: To quantify the variability (assessed in Chapter 2) in implant load transfer at the interface. This will be completed *in-silica* using finite element analysis to simulate the potential surgeon variations and how the implant will behave under loading conditions.

Hypothesis: The variables that are used for predicting implant performance will be highly dependent on the orientation of the implant.

1.6 Thesis Overview

The goal of Chapter 2 is to examine surgeon performance for achieving a target implant location and orientation when completing a total shoulder arthroplasty procedure. This will be achieved using replica glenoids and creating an accurate simulation of a surgical setting. Surgeons of various levels of experience will be tasked with inserting a guide pin into the glenoids to match the preoperatively planned target and the difference between the achieved and the target will be analyzed to determine surgeon performance. Next, Chapter 3 will use the surgeon performance data defined in Chapter 2 to examine the impact common surgeon performance has on implant contact load conditions, a common predictor of implant performance for TSA procedures. These implant contact load conditions will be modelled using finite element analysis models representing the glenoids tested on in Chapter 2 and joint loads that can be expected following a TSA procedure. Furthermore, the glenoid models will be modified to represent nine unique glenoid cut plane orientations: one case to match the preoperatively planned case, four cases to model the maximum surgeon orientation error in each of the anatomic directions (inferior, superior, anterior and posterior), and four cases to model one standard deviation of error that was observed from the surgeon orientation error in Chapter 2. Finally, Chapter 4 will summarize the results from the previous chapters. Following the summary, potential links between chapters will be discussed alongside the strengths and limitations of each study. Lastly, suggestions for future directions based on the successes and shortcomings of this thesis will be discussed.

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Chapter 2

2. Quantifying Surgeon Variability for Implant Location and Orientation While Completing Total Shoulder Arthroplasty

One of the earliest steps for completing a total shoulder arthroplasty (TSA) procedure is defining the glenoid cut plane that will be used for determining glenoid implant location and orientation. In TSA procedures, this is typically achieved using a guide wire inserted into the glenoid that will *later be used for aligning glenoid reaming tools. It has been documented for what is typically considered the optimal implant location and orientation, however, the range of surgeon variability for TSA procedures requires further investigation. The purpose of this study was to create a means for testing surgeon variability in TSA implant location and orientation by having orthopedic surgeons of different experience levels complete a simulated TSA procedure on glenoid models that were then analyzed for the surgeon's ability to hit the pre-planned target (A version of this work is in submission for the Canadian Orthopaedic Research Society, Quebec City, June, 2022).*

2.1 Introduction

Total shoulder arthroplasty (TSA) has become a common and effective treatment to improve range of motion and ability to perform everyday tasks for patients that suffer from shoulder instability or pain issues. Planning for the optimal alignment of implants, as was noted in Chapter 1, is an important aspect of the surgical procedure but this can be difficult to achieve. This can primarily be attributed to the variability in the selection of anatomical landmarks to establish reference axes and/or coordinate systems of the bone of interest. To further illustrate the difficulty in consistently identifying anatomic landmarks, a study completed by Bokor et al. showed that the measured value for glenoid version can vary by as much as 10° on the same glenoid with only minor rotations of the scapula [1].

With regards to implant orientation and location, there is limited research quantifying the variation in TSA implant malalignment. Brownhill and colleagues reported that the variability on the selection of the flexion-extension axis of the elbow would achieve an average error of approximately $1.5 \pm 3.0^{\circ}$ and over a range of -6.3° to 9.6° [2]. This study was conducted by experienced surgeons and with elbow landmarks that are easier to identify than glenoid landmarks so there is the potential for glenoid implant malalignment to have a margin of error with greater
variability. In a study by Hopkins et al., it was shown that the angle for TSA implants can have a direct impact on the outcome performance of the shoulder implant [3]. It was shown that TSA implant failure as a result of stress magnitudes in cemented implants becomes a greater risk if implant orientation is off by 10° in any direction. As such, obtaining a neutral implant orientation with respect to the glenoid is generally considered ideal for implant performance. Furthermore, Favre et al. were able to show that a difference in implant location of 5mm or greater superiorly would result in a loss of at least 5° glenohumeral elevation angle and that implant orientation beyond 20° superiorly of neutral would completely prevent glenohumeral elevation [4].

As a result of the difficulty associated with achieving the planned position and orientation, a number of methods have been employed to improve bone cutting and hence, implant alignment and positioning. Most notably, computer-assisted approaches for preoperative planning in orthopedic surgery have become increasingly popular as an approach to improve implant alignment. As an example, three-dimensional (3D) preoperative computer planning provides presurgical visualization and conceptualization to assist the surgical team for implant placement and alignment. This then makes it easier for surgeons to visualize potential alignment options and identify the anatomical landmarks they will use as reference in advance. Another method for improving surgeon performance is using patient specific guides that are designed to match the patient's anatomy and create an explicit guide for surgeons to use for aligning the implant location, which can help surgeons achieve an average error of approximately 3.4mm from the planned case [5].

The purpose of this study was to determine the variability amongst four orthopedic surgeons, two senior surgeons and two fellows, when inserting a guide pin that matches the pre-operative plan for a range of glenoids of various morphological characteristics. It was hypothesized that even with the use of advanced pre-operative software, the insertion of the guide pin in terms of both the angular orientation and translational position would be highly variable.

2.2 Materials & Methods

2.2.1 Bone Model Generation and Testing Setup

Institutional ethics review board approval was obtained for the use of eight total patient shoulder computer-tomography (CT) scans. For this study, four left and four right shoulders (age: 71 ± 10 years) that had various cases of glenoid erosion were selected. The glenoid erosion criteria developed by Favard and Walch was employed and included: two E2s, two E3s, one B3, one E3, one C and one D glenoid case [6], [7]. Once the glenoids were selected, the preoperative plan for each glenoid was completed by a senior surgeon, G. S. Athwal, in BluePrint planning software $(BluePrintTM, Wright Medical, Bloomington, MN).$

These glenoid models were exported as .stl files from BluePrint with the planned guide pin inserted into the glenoid model and imported into Solidworks (assault Systèmes SolidWorks Corporation, Waltham, MA, USA, Version 28.3.0.0086). Using these models, the glenoid coordinate system was established, and the relative orientation and insertion of the guide pin with respect to the glenoid was quantified. Then, custom landmarks for digitization were added as well as cuts to isolate the glenoid, acromion and coracoid for the purpose of generating four duplicate, physical 3D specimen models for each patient. Using an additive manufacturing 3D printer (Prusa i3Mk3S, Prusa Research, Prague, Czech Republic), the 32 physical glenoid models were generated (**[Figure](#page-38-0) [2-1](#page-38-0)**). To print the models, thermoplastic material used was polylactic acid (PLA), with a setting of 2 shells, 25% infill and a 3D gyroid infill pattern to simulate a natural glenoid with differences in density between cortical and cancellous bone.

For the testing setup, the shoulder was recreated using the glenoid models mounted to baseplates that had a matching acromion and coracoid that the participants could use for reference. These models were then mounted to a workbench fixture and covered with a soft tissue shoulder model to replicate an anterior opening for a deltopectoral surgical approach (**[Figure 2-1](#page-38-0)**). This soft tissue model would then be retracted by an assistant to as closely as possible match the glenoid exposure a surgeon would have during arthroplasty.

Figure 2-1: The experimental set up with the 3D printed models and the soft tissue shoulder model *For testing, the 3D printed glenoid, acromion and coracoid were first mounted (A), then the soft tissue shoulder model was placed over top (B) and an assistant would retract the soft tissue to simulate surgery (C).*

2.2.2 Surgeon Testers

For testing, four surgeon testers participated in this study including two senior surgeons and two fellows. Each surgeon tester was required to insert one guide pin in each unique glenoid model. The nature of the study was explained and written consent was received from each participant.

2.2.3 Surgical Pre-planning and Testing

As was mentioned previously, the eight erosion case glenoids were all planned in advance by a senior surgeon, Dr. George Athwal, using the presurgical software planning program BluePrint $(B\text{luePrint}^{TM}, \text{Wright Medical}, \text{Bloomington}, \text{MN}).$ Each of the glenoids were planned with a TSA implant to match the ideal insertion location and orientation criteria of neutral version and inclination while being centered on the glenoid with the location being adjusted only to maximize implant seating on the glenoid if necessary (**[Figure 2-2](#page-40-0)**). The planned cases for these eight shoulder specimens served as the control case, with all surgeons being asked to replicate both the insertion location and relative orientation of the guide pin as accurately as possible during testing.

For testing, the order of the eight specimens was randomized for each surgeon and all eight specimens were completed by a surgeon in one sitting. Each surgeon was permitted to examine the planned case on a computer screen for as long as desired and could return to examine the plan for further inspection at any point. Each surgeon then inserted the 2.5mm diameter guide pin using a drill such that the orientation and location of the guide pin matched the planned case as closely as possible and was deep enough to achieve stable fixation for digitization following testing. These pins were then left in the glenoid models until digitization was completed.

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Figure 2-2: Pre-planned TSA glenoids

On the left is the pre-planned TSA model with a reverse glenoid implant centered in the middle of the glenoid and orientated with neutral version (A). On the right is the same glenoid and implant showing the implant oriented with neutral inclination (B).

2.2.4 Outcome Variables and Digitization Technique

Outcome measures of this study included the guide pin insertion location compared to the preplanned control and the guide pin orientation compared to the control.

To begin, key landmarks on the preoperatively planned 3D glenoid models were defined so that the planned guide pin insertion location and orientation could be quantified and treated as the control, or targets, that the surgeons will be measured against. The same 3D digital models that were originally planned in BluePrint and then additively printed for testing were imported into SolidWorks 2020 software (Dassault Systèmes SolidWorks Corporation, Waltham, MA, USA, Version 28.3.0.0086). For each model, the relative position of the guide pin insertion point and the orientation of the guide pin with respect to the glenoid coordinate system were measured (**[Figure](#page-42-0) [2-3](#page-42-0)**).

Figure 2-3: Digital 3D model of a glenoid and the glenoid coordinate system

The glenoid coordinate system was established using the inferior and superior mounting holes to define the inferior-superior axis and the posterior and anterior mounting holes to define the posterior-anterior axis. The center of each mounting hole, the insertion point of the planned guide pin and the distal point of the guide pin were all recorded for establishing the control targets for implant location and orientation. Inclination is defined as rotation about the anterior-posterior axis while version is defined as rotation about the inferior-superior axis.

To complete an analysis of the deviation between the control and the surgeon-selected pin trajectories, digitization of the guide pin and glenoid was required. Using active optical tracking tools (Optotrak Certus Position Sensor Full, Northern Digital Inc., Waterloo, ON, Canada) and First Principles software (Northern Digital Inc., Waterloo, On, Canada, Version 1.2.4), a marker was rigidly affixed to the glenoid specimen with the guide pin that was inserted by the surgeon. Once the marker was rigidly affixed to the glenoid, key landmarks were probed with a stylus to determine the relative position of each point and a trace of the guide pin itself was completed to capture multiple points along the guide pin (**[Figure 2-4](#page-44-0)**). The key landmarks that were digitized included the glenoid mounting points, the insertion point, both ends of the guide pin, and three unique stylus holes previously added to the glenoid model for calibration purposes.

Figure 2-4: Glenoid digitization setup

For the digitization of the completed glenoid model, each glenoid was rigidly fixed to a marker and then the key landmarks were probed using a stylus. The same rigid body setup was used for each glenoid.

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Upon collection of all the data from the pre-planned controls and the executed models completed by the participants, analysis was run in MATLAB (The MathWorks, Inc., Natick, MA, USA, Version 9.7.0.1190202). The location of the target insertion point was defined for each specimen with respect to the superior mounting hole and the target orientation of the planned guide pin was defined using two angles, the angle of the guide pin with respect to rotation about the inferiorsuperior axis (version) and the angle of the guide pin with respect to rotation about the anteriorposterior axis (inclination). For determining the vector that represents the guide pin insertion, a cylinder fit via a trace around the circumference of the pin was applied at both ends and the resulting vector was used.

2.3 Results

When comparing the guide pin insertion location (**[Figure 2-5](#page-46-0)**) of the senior surgeons and fellows, the standard deviation for the error in the anterior-posterior direction was 1.71mm for fellows and 2.64mm for senior surgeons. In the inferior-superior direction, standard deviation for fellows was observed to be 2.41mm and 2.24mm for senior surgeons.

However, with respect to the orientation of the inserted guide pins (**[Figure 2-6](#page-46-1)**), there was a larger standard deviation. For the senior surgeons and fellows, the standard deviation for the error in the version plane (anterior-posterior) was 13.16° for fellows and 11.64° for senior surgeons. In the inclination plane (inferior-superior), standard deviation for fellows was observed to be 7.21° and 9.71° for senior surgeons.

Figure 2-5: Guide pin insertion location across all specimens

The graph showing the guide pin insertion location for each specimen completed by fellows F(a) and F(b) on the left and the specimens completed by senior surgeons S(a) and S(b) on the right.

All participants had a similar average error of orientation, with more error occurring for the version of the guide pin compared to the inclination.

Tester	Anterior-Posterior	Inferior-Superior		Version Inclination
Fellows (F)	1.71 mm	2.41 mm	13.16°	7.21°
Senior Surgeons (S)	2.64 mm	2.24 mm	11.64°	971°

Table 2-1: Summary of a single standard deviation for each recorded parameter

Table 2-2: Summary of the absolute maximum observed values for each parameter

Tester	Anterior-Posterior	Inferior-Superior	Version	Inclination
Fellows (F)	4.35 mm	7.29 mm	20.33°	12.22°
Senior Surgeons (S)	6.69 mm	4.47 mm	29.25°	15.86°

[Table 2-1](#page-47-0) summarizes the standard deviations of each group in terms of guide pin insertion location and orientation. **[Table 2-2](#page-47-1)** summarizes the observed maximum values for guide pin insertion location and orientation.

2.4 Discussion

In this study, it was observed that there were relatively large errors in terms of both the guide pin insertion location and orientation, as well as in the standard deviations of this error.

There are multiple factors that could have contributed to these errors. First, participants were required to navigate around the soft tissue shoulder model that, like in surgery, would obscure some of the landmarks. In surgery, the soft tissue that surrounds the glenoid can also obstruct the view even with an assistant attempting the expose the glenoid, hence identification of anatomy is a challenge. Second, each specimen modeled a unique glenoid erosion case, and this could also have made it more difficult for participants having to recognize unique glenoid anatomy that differed from the morphology of healthy glenoid anatomy. However, the unique glenoid cases used for testing in this study are generally representative of the shoulders a surgeon could be expected to perform a TSA procedure on to restore normal shoulder function. Third, transposing the on-screen guide point may have produced additional error. The largest challenge to overcome for the surgeon in surgery is the portability of the pre-operative plan. Having the pre-operative plan for the surgery on the computer means it is not possible to have the plan in the same view as the physical glenoid and it becomes very difficult to maintain a consistent orientation and location from the landmarks while the surgeon turns their body back to the surgical site. It is worth noting that all of these potential challenges that were present in the study do mirror similar challenges surgeons experience in the operating room for performing TSA procedures.

The variation in implant alignment may well have significant implications with regard to the biomechanics of the implant and in particular load transfer from the articulation to bone. As was mentioned earlier, the postoperative range of motion for the shoulder can be heavily impacted by incorrect implant insertion, resulting in a complete lack of shoulder elevation in some extreme cases [4]. At the implant-bone interface, the implant insertion is of significance because impingement of the shoulders range of motion is a common consequence of incorrect implant insertion location and results in eccentric loading, which has been shown to cause implant loosening [8], [9]. Also, scapular notching is another common issue with TSA patients and has been shown to be more likely to occur if the glenoid baseplate is positioned more superiorly or oriented more superiorly [6].

Another interesting result from this study was that the level of error between fellows and senior surgeons was comparable. This could either be that experience between fellows and senior surgeons has minimal impact on performance or could be an indication that while there is still a noticeably large range of surgeon error, using a preoperative plan helps surgeons of different experience levels achieve a similar baseline in terms of performance for implant insertion. Further research would be required to determine how comparable surgeon performance is across different experience levels without the aid of a preoperative planning tool.

With regard to the clinical relevance of these findings, it is logical to postulate that there will be a wide variation in the final location and orientation of the implant using these methods. While it has been shown that achieving the planned target for the guide pin insertion is likely key for long term implant performance [3], it is still unknown if these observed standard deviations in the surgeon error are acceptable in terms of their impact on surgical outcomes or if they would start to negatively affect implant performance. It would seem that the optimal approach to achieve the target trajectory of the guide pin would be to employ advanced computer-assisted that could provide feedback on surgeon performance or patient specific guides to effectively register the preplan to the host anatomy. Although this would certainly reduce the errors measured herein, there is of course the potential variation on the landmark selection between surgeons using the preoperative software. While this was not assessed in this study, this again would be another variable potentially promoting implant alignment variability.

2.5 Conclusion

In conclusion, even with senior surgeons using the tools that are commonly used in current TSA procedures, it is very difficult to achieve repeatable results with minimal deviation from the planned case. With respect to the hypothesis, it was an accurate prediction that there would be significant variability in implant position and orientation. There are some limitations of the existing tools for improving on these results so further advancement into tools that can provide accurate feedback to surgeons completing TSA procedures on the current guide location and orientation could be extremely beneficial to mitigating variability. However, it is not yet known how large of an impact the surgeon variability has on the implant performance outcomes. Chapter 3 quantifies the impact of surgeon variability on implant performance through a finite element

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analysis using the results and specimens from this study and examining implant-bone contact and loading interactions.

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2.6 References

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Chapter 3

3. The Effect of Surgeon Cut Plane Variability on Total Shoulder Arthroplasty Implant Loading Conditions using Finite Element Analysis

When a surgeon completes a total shoulder arthroplasty (TSA) operation, there exists variability in the glenoid resection plane that the surgeon creates for inserting the glenoid baseplate. In TSA procedures, the effect of implant geometry on the loading conditions has been documented, however, the effect of the resection plane angle falling within a variable range that is representative of surgeon error in the operating room requires further investigation. The purpose of this study was to use finite element analysis to simulate nine different glenoid resection plane angles across six unique specimens and to compare their effects on implant loading conditions (A version of this work is in submission for the Canadian Orthopaedic Research Society, Quebec City, June, 2022).

3.1 Introduction

As discussed in Chapters 1 and 2, total shoulder arthroplasty (TSA) is a common and effective method of treatment for patients that suffer from a loss of shoulder function. Typically, in both anatomic and reverse TSA procedures, the first step is to prepare a slot, or vector, that will be followed for reaming the glenoid to receive the implant. Any variation in the orientation of this initial vector will lead to a change in alignment for the glenoid cut plane and will also alter the anatomical geometry of the shoulder from the planned state. Orientation of the glenoid cut plane is commonly reffered to as inclination and version to define the rotation. As described in Chapter 2, inclination is a rotation of the cut plane about the anterior-posterior axis whereas version is a rotation of the cut plane about the inferior-superior axis (**[Figure 3-1](#page-53-0)**). While there are tools such as preoperative planning and patient specific guides, there is still a range of surgeon error present in terms of implant orientation and location as was shown in Chapter 2.

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Figure 3-1: Illustration of inclination and version directions for a left glenoid

In the above image on the left from the anterior perspective, the arrow indicates inclination in the superior direction, where inclination in the inferior direction would be opposite the direction of the arrow. Similarily, for the image on the right from the superior perspective, the arrow indicates version in the posterior direction, where version in the anterior direction would be rotation in the direction opposite the arrow.

When studying the long-term performance of TSA implants, there are a couple of key factors that can be measured to predict surgical outcomes. Major factors that can negatively impact implant performance are implant loosening and bone resorption, both issues that are frequently present in TSA procedures [1], [2]. One method identified by Hopkins et al. for mitigating the risk of implant loosening is by keeping micromotion of the implant under 50µm [3]. Bone resorption around the implant is highly dependent upon the stress experienced by the by the bone, as per Wolff's Law. The natural bone will respond to the stress it experiences and modify via cellular activity the osseus structure to handle the stress change. Further, it has been shown that following a hip or humeral head arthroplasty, that the bone will undergo a change in strain energy density, a measure of the internal energy that is stored within an object as it is distorted under stress, and this change in strain energy density can be used to approximate how the native bone will respond to the implant [4], [5].

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While there have not been many studies completed to quantify the effect of implant alignment for TSA procedures, particularly for alignment that matches surgeon selection approaches, there have been similar studies completed for other arthroplasty procedures. For example, Sekiguchi et al. completed a postoperative study for total knee arthroplasty where the patient outcomes were measured against the rotation of the implant [6]. The study examined 36 different knees that had total knee arthroplasty, and discovered that a more varus implant alignment could more closely match the behaviour of a healthy knee than a neutral alignment for an objective, clinical score while a more valgus alignment would perform worse than the neutral implant alignment. While still looking at total knee arthroplasty, Kim et al. found that in order to avoid mechanical failure of the implant, surgeons should align the implant within a range that varies from within 1.5° of the target to 3.5° of the target [7]. This acceptable range for alignment in total knee arthroplasty is much smaller than the surgeon variability that was observed in Chapter 2, where the smallest standard deviation of error achieved by a senior surgeon was 9.21° in inclination. With total shoulder arthroplasty implants having a larger observed range of error for implant orientation, it could indicate that there will be a significant impact in terms of implant performance due to alignment changes.

Since performing *in-vivo* testing on a range of various cut planes for the same glenoids would be extremely difficult, performing *in-silica* testing using finite element analysis is a reasonable alternative for predictive analysis. These finite element studies are extremely beneficial because of their ability to modify multiple implant, bone or loading parameters with relative ease. Moreover, finite element studies are able to generate results in terms of contact stress and micromotion between the implant and the glenoid which can be used to predict implant performance across the various cut planes.

The purpose of this study is to examine the impact of common TSA implant orientation error on outcome variables that are commonly used as predictors for implant performance. The hypothesis is that the variables used for predicting implant performance will vary greatly alongside the variation in implant orientation. The outcome variables assessed included bone stress, implant micromotion and contact dtress at the articulation. These were assessed for various cut planes consitstent with the observed surgeon orientation errors from Chapter 2.

3.2 Materials & Methods

3.2.1 Model Development and Finite Element Analysis

Computed tomography (CT) data for six unique glenoids were converted into three dimensional models using MIMICS software (Materialise, Leuven, Belgium). The six glenoids were chosen from the same glenoid models that were tested in Chapter 2 (age: 71 ± 10 years). Each glenoid was segmented into a cortical and trabecular bone region using both automatic thresholding and manual segmentation.

Following segmentation, each 3D glenoid model was imported into Abaqus CAE (Dassault Systèmes, Johnston, RI, USA) where the glenoid coordinate system was generated and the resection plane cuts were made. The glenoid coordinate system was generated following a method outlined by Frankle et al. using the center of the glenoid, the inferior tip of the scapula and the medial aspect of the scapula (**[Figure 3-1E](#page-53-0)rror! Reference source not found.**), [8]. There were nine unique resection planes that were applied to each model and they were chosen based on the surgeon variability investigated in Chapter 2 (**[Figure 3-2](#page-57-0)**). The neutral cut plane matched the preoperatively planned case from Chapter 2 and the cuts to represent the variability in surgeon error were generated by rotating the neutral cut plane about either the anterior-posterior axis to simulate error in the inferior or superior direction or rotating about the inferior-superior axis to simulate error in the anterior or posterior direction. For this study, rotations of a single standard deviation and the max recorded value for each direction were selected to examine the predicted results of an average and worst case performance by a senior surgeon (**[Figure 3-3](#page-58-0)**). As such, the 9 dependent variables were neutral, maximum error in the anterior direction (Max-Ant), standard deviation of error in the anterior direction (StdDev-Ant), maximum posterior (Max-Post), standard deviation posterior (StdDev-Post), maximum inferior (Max-Inf), standard deviation inferior (StdDev-Inf), maximum superior (Max-Sup), and standard deviation superior (StdDev-Sup).

In order to generate the medial-lateral axis, a line connecting the center of the glenoid face (A) and the medial aspect of the scapula (B) was generated. The inferior point of the scapula (C) was then projected onto the medial-lateral axis to create the inferior-superior axis. Lastly, the mediallateral and inferior-superior axes were crossed to create the anterior-posterior axis.

Figure 3-3: Glenoid Coordinate System and Resection Plane Variations

The glenoid coordinate system was generated for each model and then resection planes for each case were determined by rotating the cut plane about the opposite axis (rotating about the Inferior-Superior axis to achieve rotation for Anterior or Posterior and vice versa). The table lists the rotational values that were used for each resection plane.

Superior (Sup) 9.71° 15.86°

To simulate the implant joint mechanics, a simplified glenoid baseplate model was generated. The implant was generated with a circular baseplate diameter of 25mm and thickness of 8mm with a centered circular stem of diameter 11mm and a stem length of 9mm. After each glenoid was reamed to match a rotational case, a hole to match the stem of the glenoid baseplate model was cut into the glenoid centered at the insertion location from the preoperative plan. The implant was then centrally aligned with the hole and translated so the backside of the implant would be in contact with the reamed glenoid surface. A friction interaction between the glenoid contact surface and the implant contact surface was defined with a penalty friction coefficient of 0.88 [9]. A boundary condition was established on the medial edge of the scapula that fixed all translation to simulate typical experimental setup.

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Material properties were applied to the cortical regions, modulus of elasticity $E = 20$ GPa and Poisson's ratio of $v = 0.3$, trabecular regions, $E = 500$ MPa and $v = 0.3$, and the implant, $E = 230$ GPa an $v = 0.3$ [10]. For meshing the models, the baseplate implant was seeded with 1.5mm seeds and used C3D8R elements (**[Figure 3-4](#page-60-0)**). The C3D8R elements are eight node brick style elements with reduced integration and were chosen because the point where stress is calculated is in the middle of the element and therefore reduce the risk of an innaccurate stress result. The most lateral region of the glenoid was seeded with 1mm seeds and the more medial regions were seeded with 3.5mm seeds, both using C3D4 elements. The C3D4 elements are linear, four node tetrahedral elements that are able to accurately model the complex anatomic geometry and are well suited for applications where many elements are required for successful modelling. When using finite element methods, the size of the elements used to model the geometry is of significance because it involves a tradeoff between increased computational time and stable results. A study by J. Reeves indicated that using a mesh smaller than 2mm for these implant-bone modelling approaches provide diminishing returns for convergence of results [5].

As the shoulder goes through various ranges of motion, the joint reaction forces experienced by the implant, and thus the glenoid, will also vary. To model this behaviour in the FEA study, loading conditions for humeral abduction angles of 15°, 45°, and 75° were simulated following a loading profile representative of some components the joint load on the glenoid (**[Figure 3-5](#page-61-0)**).

Figure 3-4: Glenoid baseplate implant

The above is the model that was generated to approximate a glenoid baseplate. The implant has a diameter of 25mm and a thickness of 8mm. The implant model was seeded with 1.5mm, C3D8R style elements.

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Figure 3-5: Joint loading conditions

The above illustrates how the loading vector for the joint reaction force is measured with respect to the inferior-superior plane (left) and the anterior-posterior plane (right). To represent different humeral abduction angles, loading was modelled as shown i[nTable 3-1.](#page-61-1) NB: I signifies the inferior direction, S signifies the superior direction, M signifies the medial direction, L signifies the lateral direction, A signifies the anterior direction, and P signifies the posterior direction.

Table 3-1: Loading parameters to simulate humeral abduction angles

At different angles of humeral abduction (ABD), both the magnitude of the joint load and the angle of the vector that represents the joint load change. This table details both the magnitude of the joint load and the angle that the joint load acts with respect to an angle from the inferior-superior axis (α) and an angle from the anterior-posterior axis (β).

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3.2.2 Outcome Variables and Statistical Analysis

Outcome variables were all generated from the FEA simulations run in Abaqus and included; maximum stress in bone, maximum interface contact pressure, and liftoff. These variables are typically those considered most relevent with regard to load transfer at the bone-implant interface, which affect implant performance. Maximum stress was tracked using both the von Mises stress and principal stress output parameters on the glenoid. More specifically, von Mises stress is an approximation of the total stress experienced by a single element whereas principle stress is the observed stress that acts in one of the principle directions. Maximum contact pressure from the simulations was calculated using the CPRESS output parameter from Abaqus and examining contact pressure on the contact surface on the glenoid side. Liftoff was reported using the COPEN output in Abaqus to track changes in the distance between implant and glenoid elements. It is important to note that the absolute values of these outcome variables is not the focus, but rather the relative change in the outcome variables will be the focus for this study. For all parameters, a two-way repeated-measures analysis of variance (RM ANOVA) was completed to examine the results.

3.3 Results

3.3.1 Maximum Bone Stress

For the maximum stress in bone, there was no statistical significance from the RM ANOVA tests for the von Mises stress values or the principal stress values when comparing the different cut planes (all p values > 0.05). The greatest increase in Von Mises stress relative to the neutral cut plane was the maximum anterior cut plane across all angles of shoulder abduction (**[Figure 3-6](#page-63-0)**). Simlarly, the greatest increase in principal stress relative to the neutral cut plane occurred in the maximum anterior cut plane (**[Figure 3-7](#page-64-0)**).

Figure 3-6: Mean (+/- 1 SD) Maximum Von Mises stress present in the glenoid for the previously defined cut plane orientations and abduction angles

Observed mean maximum stress values for each cut plane are displayed with error bars to indicate the standard deviation.

Figure 3-7: Mean (+/- 1 SD) Maximum principal stress present in the glenoid for the various cut planes and abduction angles

Observed mean maximum stress values for each cut plane are displayed with error bars to indicate the standard deviation.

3.3.2 Contact Pressure

In this study, the maximum contact pressure experienced by the bone did not produce statistically significant results (all p values > 0.05) across the various cut planes. However, there was a consistent increase in contact pressure observed when comparing the neutral cut plane with the cut planes that varied the implant inclination (**[Figure 3-8](#page-66-0)**).

Figure 3-8: Mean (+/- 1 SD) Maximum contact pressure present in the glenoid for the various cut planes and abduction angles

Observed mean maximum contact pressure values for each cut plane are displayed with error bars to indicate the standard deviation.

3.3.3 Changes in Implant Liftoff

In this study, there were no statistical differences in the resulting implant liftoff values (all p values >0.05) across the various cut planes. Additionally, there was minimal observed change in the implant liftoff despite the changes in the cut plane (**[Figure 3-9](#page-68-0)**).

Figure 3-9: Mean (+/- 1 SD) Maximum implant liftoff present in the glenoid at various cut planes and abduction angles

Observed mean maximum implant liftoff values for each cut plane are displayed with error bars to indicate the standard deviation.

3.4 Discussion

Despite there not being any statistically significant results between the glenoid cut planes for any of the observed outcome variables, there were some visible trends. In terms of increases in maximum bone stress values, the glenoid was most sensitive to adjusting the cut plane in the anterior direction. However, it was also observed that the principal stress experienced by the glenoid was more sensitive to changes in implant inclination. These changes in stress outcomes are potentially a result of a change in the area of cortical bone in contact with the implant and the change in geometry for the shoulder while the loading remains consistent. As per Wolff's Law, the shape and structure of the bone will modify itself in response to mechanical loads, so any changes in bone stress have a risk to compromise bone quality [11]. With the impact that changes in stress can have on the structural properties of bone, maintaining stress that is as close to the original bone state is ideal. These findings herein suggest that surgeon error for implant orientation that falls within one standard deviation is expected to have minimal impact on implant perfomance but that surgeon error that approaches the maximum orientation error values seen in Chapter 2 can be expected to negatively impact bone response and thus, implant performance.

Results for contact pressure between the implant and the glenoid surface did not produce statistically significant results but there was an observed trend that contact pressure consistently increased cut planes that varied in inclination. As the contact pressure increases, it is reasonable to expect the bone stress to also increase on the surface. This increase in pressure indicates that inclination of the implant can have a larger impact on implant liftoff than version as variations in pressure can have a rocking horse effect on the bone to increase liftoff. With these increases in contact pressure occurring from the changes in implant inclination, prioritizing correct implant inclination over implant version would likely be most beneficial for surgical outcomes of TSA.

While there was some change in the stress results for the change in cut planes, micromotion of the implant experienced minimal change as the cut plane changed. This lack of change in liftoff across cut planes is likely a result of the loading being applied from a singular location that was centered on the implant and the contact between the implant and bone remaining largely unchanged. Interestingly, there were some instances of the liftoff decreasing across the different cut planes and this could be a result of the different cut planes decreasing the contact area of the implant with cortical bone. When the implant is in contact with more cancellous bone, it is able to deform more because of the lower density and Young's modulus, which would allow the bone to conform to the shape of the implant more. This would not be an issue when examining singular, static loading conditions but this is not realistic for everyday use of the shoulder where the bone deforming more easily would present an issue.

It is generally accepted to apply homogenous material properties to cortical bone, the modelling employed in this study also used bone properties that were isotropic and homogenous throughout the cancellous bone. Typically for related studies, the modulus of cancellous bone is assigned based on CT density metric (Hounsfield units). However, as this study was not focused on the prediction of the absolute magnitudes of stresses and implant micromotion, it is reasonable to conclude that modelling the cancellous bone with homogenous material properties would not affect the relative outcomes.

Within this study, there were some other limitations. While using the same glenoids from Chapter 2 allowed for the same glenoids to be tested on that the surgeon variability was based off of, these were glenoids that all had some form of glenoid erosion and are not necessarily representative of an average shoulder. This study also only used one style of glenoid baseplate to test the impact of changes in the glenoid cut plane instead of using a more patient or population based model. Another factor to consider is that all of the neutral cases were manually selected by an experienced surgeon. While it is likely that these implants were planned in such a way to best optimize surgical outcomes, there is a chance that the surgeon might not have picked the most optimal alignment. However, even if the planned case did not match the most optimal alignment, the changes in outcome variables are still indicators of how much implant performance can vary just from changes in the implant cut plane.

For this study, only a time zero response was modelled. Thus, while some of the resulting outcome variables were smaller than expected, this could change if an iterative model was used to model the implant performance over time. In particular, Sharma et al. have shown that using an iterative bone remodelling technique can more accurately predict implant performance over time [11]. However, for the larger time zero responses that were observed in this study, those numbers would only be expected to increase with an iterative modelling process, therefore are likely to be even less favourable in terms of implant performance.

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Another major limitation of this study was that the defined outcome variables did not produce statistically significant results. The lack of statistically significant results is likely a result of the study being too underpowered and requiring a larger sample size. However, while no statistical significance was present for this study, there were some clear observed trends showing that bone stress and contact pressure will increase as the glenoid cut plane deviates from the ideal, planned case. In order to improve the statistical power of this study in the future, it is strongly recommended to use a larger sample size while testing.

Ultimately, the findings of this study are still relevent for future testing and TSA procedures as it indicates that what would normally be considered acceptable surgeon error can have a noticeable impact on factors that are used as common predictors of implant performance. As such, it is recommended that any future studies that are examining TSA implant performance take extra care to properly isolate the effects of implant orientation from the study. Clinically, developing a method to further mitigate the variability in cut plane orientation achieved for patients undergoing TSA would be expected to improve longterm implant outcomes for the patient.

3.5 Conclusion

Variations in the cut plane alignment of the glenoid for total shoulder arthroplasty can have an impact on implant performance. While the largest changes in implant performance predictors occurred in the maximum deviation cut plane scenarios, the changes from the standard deviation cut plane scenarios could also be indicative of future failures in implant performance. From the observed changes, aiming for a cut plane orientation that is as close to the planned inclination and opting to be slightly more posterior than anterior is likely to produce the best results for implant performance. The use of navigation tools to assist the surgeon with making the proper cut to match the planned case is highly encouraged to limit the risk of deviating from the planned case. It would also be beneficial to have a means of planning the TSA case that doesn't have a similar risk of introducing variability of the planned cut plane.

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Chapter 4

4. Overall Discussions and Conclusion

This chapter reviews and concludes all thoughts from this thesis as a whole. The hypotheses outlined in Chapter 1 are addressed as well as some of the overall limitations of the studies completed. There is also some overall discussion linking concepts from the two studies, and the relevance that can be taken from the results. Future directions for this research are also recommended.

4.1 Summary

While the advancements for total shoulder arthroplasty (TSA) implants continue to improve implant design, it is critical to understand how the surgeon implementation can affect the implant performance outcomes. If there is a specific orientation range that the implant must be inserted to realize the benefits of any improvements in design, those improvements might be less effective by regularly accepted surgeon error when making the glenoid cut plane. Since there has not been any development in terms of defining common surgeon cut plane error or the impact that the error has on implant performance, this work addressed the influence of this surgical variable on load transfer from the implant to bone. To achieve this, a finite element (FE) modelling approach was employed to test multiple different parameters on the same boney structure that would not normally be easily achievable in either an *in-vivo* or *in-vitro* setting. Thus, this research was undertaken to establish a more in-depth understanding of the impact of surgeon error on implant performance with a focus on loosening and bone loading.

In the first investigation of this thesis (Chapter 2), the objective was to define expected surgeon error by simulating a surgical setting and having the surgeons follow a simulated surgical procedure. To achieve this, eight glenoids with different levels of glenoid erosion were selected to represent the varied glenoid anatomy a patient might have while undergoing a TSA procedure. The computed tomography (CT) scans of the glenoids were developed into three dimensional models that were then preoperatively planned for a TSA implant by an experienced shoulder surgeon. Once the glenoid models were appropriately planned, they were additively printed to test their variability in cut plane alignment. To test the surgeon performance, two orthopedic fellows and two experienced shoulder surgeons were tasked with inserting a surgical guide pin that matched the trajectory of the preoperatively planned glenoid into the corresponding glenoid model. The

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glenoid model was covered with a soft tissue replica shoulder to more accurately simulate the surgical setting. Following the insertion of the guide pins, the location and orientation was recorded using an optical tracker setup and digitizer stylus. Analysis of the results showed that there was minimal difference between the experience level of surgeons and that it was more common for there to be error collectively in the guide pin version (anterior-posterior orientation) than the guide-pin inclination (inferior-superior orientation). Within this study, guide pin location error was defined as the distance from the planned point to the achieved insertion point measured with respect to the anterior-posterior axis and the inferior-superior axis. Guide pin location error was consistently in the range of 1.7-2.5mm off from the planned case. The standard deviation of error for orientation was observed to be 13.2° for fellows and 11.6° for senior surgeons in version. In terms of inclination, the standard deviation of error for orientation was 7.2° for fellows and 9.7° for senior surgeons. These deviations in surgeon performance could be a result of the limited feedback provided by the preoperative plan for achieving the desired alignment, the difficulty that comes from registering the correct landmarks when comparing the physical model with the planned digital case. These results provide useful data that can be considered when designing implants as well as patient specific surgical tools to improve performance and repeatability.

For the second study of this thesis (Chapter 3), the goal was to use the observed surgeon cut plane alignment error from Chapter 2 to investigate the impact of expected implant orientation error on implant performance. To begin, six of the eight models from the simulated TSA implant alignment study were selected to be developed into FE models. The CT scans of the chosen glenoids were segmented into cortical and cancellous bones using image-based bone density. Once segmented, the glenoid models were exported into Abaqus CAE (Dassault Systèmes, Johnston, RI, USA) to begin modelling the cut planes, loading parameters and material properties. Following protocols used in similar FE studies that examined glenoid implant performance, each of the six glenoid models were cut to follow nine unique cut planes. The nine planes included a neutral cut that matched the planned case, four standard deviation cases matching the observed standard deviation error in anterior, posterior, inferior and superior alignment, and four maximum error cases matching the maximum observed error in the same four anatomic directions. A generic TSA glenoid implant was also modelled for use in the simulation and maintained the same mesh and properties throughout the entire study. Loading simulations approximating joint loads corresponding to a reconstructed shoulder at 15°, 45° and 75° of abduction were completed. While there were some visible changes in outcome variables observed, there was no observed statistical significance across the various glenoid cut planes and outcome variables, likely due to statistical power There were large increases – up to three times - observed in bone stress when the glenoid cut plane was aligned more anteriorly and consistent increases in bone-implant contact pressure when the cut plane's inclination was modified (contact pressure increases of over 1.2 times the contact force observed in the neutral case across all abduction load conditions). These results would indicate that the glenoid response to joint loads is more sensitive to anterior misalignment and that inclination error can still have an observable impact on the contact loads experienced by the glenoid. As previous studies have shown, a change in loading experienced by the bone is likely to result in substandard implant performance, perhaps eventually requiring implant revision surgery.

4.2 Strengths and Limitations

A unique strength of this study is that the same glenoid models were used at every stage of testing. Surgeons were tested on the same glenoid models, with the same preoperative plan and in the same simulated surgical setting to create a testing protocol that could effectively isolate surgeon performance. While cadaveric tests could be deemed to be marginally more realistic to completing TSA surgery, it would not be possible to use glenoids with identical geometry between testers or to reuse the same cadaveric specimens. One drawback of using the additively printed models was that there was the occasional minor resolution error that would result in slight differences in glenoid geometry and could result in lack of clarity for the surgeon. However, it was deemed that this is still representative of challenges that surgeons would regularly have to face while performing surgery since there can be resolution errors from the CT scans that are then imported for the preoperative plan.

There was an interesting tradeoff in using erosion case glenoids. The erosion case glenoids helped to add strength to the study by making each glenoid more unique and a better approximation of surgeon performance when commonly confronted with this erosion. However, the erosion cases then made it more difficult for maintaining contact conditions between the implant and the glenoid when modelling the loading conditions to compare implant performance. This can still be considered representative of regular surgical outcomes as surgeons would encounter the same alignment challenges when performing a TSA procedure on a patient with an erosion case.

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Using a finite element approach provides many benefits in terms of the ease of modifying different parameters while maintaining some consistent parameters across all tests. For this test, the cut planes were able to easily be adjusted to simulate the observed surgeon error while also maintaining the same material properties for the bone and joint loading conditions on the implant. These cut planes were also able to be precisely modelled to be consistent for each cut as opposed to trying to replicate an identical cut in a patient or cadaveric shoulder. The limitation for using an FE model for testing implant behaviour comes from modelling the complex implant and anatomic geometry with tetrahedral and hexahedral elements. To circumvent this limitation, using increasingly smaller elements near the critical areas of the glenoid can minimize the issues by allowing the simulation to converge to a consistent result. Another limitation is that this modelling approach has not been validated with companion experimental tests. However, given that the absolute magnitude of the stresses and the degree on micromotion was not of major interest, it is rational to conclude that validation is not a significant weakness.

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For this study, only a time zero response was modelled. While this does not fully represent how the implant and bone will perform long term, any changes from the initial state can reasonably be expected to only increase in severity over time as the shoulder undergoes cyclic loading. Lastly, testing only six glenoids for the FE modelling made it very difficult to achieve any statistically significant results.

4.3 Future Work

The results of this research have shown that there is a large range of implant alignment that surgeons can be expected to achieve with the current approaches employed for TSA procedures. It would be valuable to determine the impact that basic and more advanced navigation tools can have on mitigating this error. There are a variety of tools available to surgeons, including patient specific guides, augmented reality for visualizing the cut plane more easily and tracking that can provide live feedback for the surgeon to more easily establish correct implant orientation and position. These tools have begun to see use while completing TSA procedures and knowing the impact on surgeon performance would be extremely valuable for understanding what implant outcomes can realistically be achieved as implant design improves.

Specific to FE modelling, there is opportunity for more in depth research to examine some additional factors. Using patient specific or population based glenoid implant models that improve fixation through matching the glenoid geometry and then applying the same testing parameters would be valuable for identifying if the changes in cut plane alignment have the same level of impact on more advanced TSA implants. While updating the FE model with density based cancellous bone properties would provide results that are more representative of the explicit values that would be observed clinically, it likely won't result in significant differences to the magnitude changes between glenoid cut planes in outcome variables. Most importantly, being able to apply an adaptive modelling technique to model the bone behaviour beyond the time zero response would be a more comprehensive predictor of long-term implant performance.

Another parameter of implant performance that would be beneficial to include in future studies is post-operative range of motion. A common issue with TSA is the patient being unable to achieve a shoulder range of motion comparable to an individual with a healthy shoulder. While the initial shoulder range of motion is commonly improved following a TSA procedure, identifying how large of an impact the glenoid cut plane alignment can encourage further research in how best to balance the structural implant performance and range of motion for the shoulder.

4.4 Significance

As continuous improvements are being made to TSA implants and procedures, having a complete understanding of all factors that can influence implant performance is critical. This study has shown that there is a significant range of error that even experienced surgeons will achieve with conventional resources. Compounding upon this error is the fact that the deviations in glenoid cut plane alignment result in noticeable changes in the implant time zero response. Both of these factors identified in this thesis would indicate that improving glenoid cut plane alignment would yield beneficial results for implant outcomes and could potentially reduce the risk of implant failure or revision surgery. If improvements to surgeon performance are not easily achievable, the results of this thesis would indicate that avoiding anterior alignment and attempting to maintain the planned inclination will likely yield optimal implant performance. Also, these findings demonstrate that the assessment and outcomes of computational and experimental studies of these implant-bone constructs are likely affected by the alignment.

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