CENTRAL FIXATION ELEMENT TYPE AND SIZE AFFECT GLENOID BASEPLATE MICROMOTION IN REVERSE SHOULDER ARTHROPLASTY

By

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Abstract

Reverse shoulder arthroplasty (RSA) is typically performed in patients with injured or deficient rotator cuff muscles. Loosening remains to be one of the principal modes of implant failure and the main complication leading to revision. The objective of this study was to mechanically evaluate factors affecting baseplate fixation to inform clinicians of possible implant configurations that may decrease micromotion and reduce the risk of loosening. Delta XTEND™ baseplates (DePuy Synthes) were implanted into Sawbones™ polyurethane foam blocks (N = 40) and varied in terms of their method of central fixation (screw vs. peg), central length (13.5 vs. 23.5 mm), anterior-posterior peripheral screw type (nonlocking vs. locking), and bone density (10 vs. 25 pcf). Samples were cyclically loaded under compression and shear with a 500 N force at 60° to simulate peak loads during shoulder abduction. Implant-bone motion was measured using four linear variable differential transformers. A theoretical plane was used to interpolate micromotion at the four peripheral screw positions for each sample. Micromotion measurements yielded a mean absolute percentage error (MAPE) of (9.5 ± 2.6)%; average displacements at the implant-bone interface were analyzed with a Kruskal-Wallis H test and nonparametric univariate analysis (α = 0.05). Central peg fixation generated greater micromotion at all four screw positions when compared to central screw fixation (p < 0.001). Furthermore, 13.5 mm central elements generated greater micromotion at all four measurement positions than 23.5 mm samples (p = 0.001). A significant interaction existed between the method of central fixation and central element length at all four screw positions (p < 0.001), as well as between peripheral screw type and bone density at all four screw positions (p = 0.015). Use of a central compression screw and a greater central element length that engages with the cortex of the scapula may provide improved baseplate fixation and reduce interface micromotion. Use of locking screws in the anterior and posterior positions may also offset loss of fixation due to lower bone quality. Future work that considers other baseplate factors may reveal additional surgical considerations and factor interactions.
Statement of Co-Authorship

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<td>3D</td>
<td>Three-Dimensional</td>
</tr>
<tr>
<td>AAOS</td>
<td>American Academy of Orthopaedic Surgeons</td>
</tr>
<tr>
<td>ABS</td>
<td>Acronitril Butadiene Styrene</td>
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<td>ADL</td>
<td>Activity of Daily Living</td>
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<td>AOANJRR</td>
<td>Australian Orthopaedic Association National Joint Replacement Registry</td>
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<tr>
<td>A-P</td>
<td>Anterior-Posterior</td>
</tr>
<tr>
<td>BIO</td>
<td>Bony-Increased Offset</td>
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<tr>
<td>CJRR</td>
<td>Canadian Joint Replacement Registry</td>
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<tr>
<td>CPR</td>
<td>Cumulative Percent Revision</td>
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<tr>
<td>CT</td>
<td>Computed Tomography</td>
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<td>CTA</td>
<td>Cuff Tear Arthropathy</td>
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<tr>
<td>DIC</td>
<td>Digital Image Correlation</td>
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<td>DVC</td>
<td>Digital Volume Correlation</td>
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<tr>
<td>DVRT</td>
<td>Differential Variable Reluctance Transducer</td>
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<tr>
<td>FEA</td>
<td>Finite Element Analysis</td>
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<tr>
<td>HA</td>
<td>Hydroxyapatite</td>
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<tr>
<td>LK</td>
<td>Locking</td>
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<tr>
<td>LVDT</td>
<td>Linear Variable Differential Transformer</td>
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<td>MAPE</td>
<td>Mean Absolute Percentage Error</td>
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<tr>
<td>M-L</td>
<td>Medial-Lateral</td>
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<tr>
<td>NL</td>
<td>Nonlocking</td>
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<tr>
<td>NZOA</td>
<td>New Zealand Orthopaedic Association</td>
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<td>OA</td>
<td>Osteoarthritis</td>
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<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
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</tr>
<tr>
<td>PCF</td>
<td>Pounds per Cubic Foot</td>
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<tr>
<td>PHFS</td>
<td>Proximal Humeral Fracture Sequelae</td>
</tr>
<tr>
<td>PMMA</td>
<td>Polymethylmethacrylate</td>
</tr>
<tr>
<td>PU</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>RSA</td>
<td>Reverse Shoulder Arthroplasty</td>
</tr>
<tr>
<td>rTSA</td>
<td>Reverse Total Shoulder Arthroplasty</td>
</tr>
<tr>
<td>S-I</td>
<td>Superior-Inferior</td>
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<tr>
<td>TSA</td>
<td>Total Shoulder Arthroplasty</td>
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Chapter 1

INTRODUCTION

Reverse shoulder arthroplasty (RSA) or reverse total shoulder arthroplasty (rTSA) is a procedure commonly performed to treat patients with injured or deficient rotator cuff muscles, glenohumeral arthritis (often secondary to rotator cuff insufficiency), proximal humeral fracture sequelae (PHFS), and failed prior shoulder reconstructions.\(^1\)-\(^5\) Loosening of the glenoid baseplate remains to be one of the principal modes of implant failure and is the main complication leading to revision.\(^6\),\(^7\) Consequently, the enhancement of baseplate fixation to the glenoid continues to be a focus of discussion as new generations of RSA implants are developed. RSA baseplates offer enhanced fixation with the inclusion of a layer of hydroxyapatite (HA), which allows for the interface bone to mineralize directly onto the HA-coated surface of the implant.\(^8\) The glenoid post-operative micromotion, which is related to the degree of the implant’s primary fixation, should ideally be at least 50 µm and should not exceed 150 µm,\(^9\)-\(^13\) in order to promote osseous on-growth, or secondary fixation. Therefore, the magnitude of glenoid micromotion is a key indicator of glenoid secondary fixation potential. Implant micromotion is defined as the displacement of the implant relative to the resected bone interface. In general, implant designs have evolved with the goal of maximizing the surface area on the underside of the implant, to increase the surface area available for bone on-growth and achieve stable primary fixation.\(^14\) In addition to the surface area of the HA coating, several factors can affect the biomechanical behavior of a glenoid prosthesis.

Factors that can affect the magnitude of baseplate micromotion include peripheral screw arrangement and type, peripheral screw length, baseplate tilt, lateral offset of the glenoid center of
rotation, the type and length of the central fixation element, and the quality of the patient’s bone.\textsuperscript{15} It has been suggested that surgeons emphasize secure placement of the fixation screws in the best quality of bone available.\textsuperscript{1} The literature regarding these factors is limited. Prior studies have researched factors affecting implant micromotions with a variety of methods, such as \textit{in vitro} experiments with bone surrogates or cadaveric specimens, and \textit{in silico} with finite element analysis (FEA).\textsuperscript{13, 15-21} However, few studies have investigated the biomechanics of a central compression screw. Hast and colleagues\textsuperscript{15} evaluated the Titan Reverse Total Shoulder System (Integra Life Sciences, Plainsboro, NJ) with or without a central screw, to implant failure, defined as baseplate dislodgement or joint disarticulation, and observed improved resistance to dislodgement with the use of a central screw. Furthermore, only one study has investigated the effect of central screw cortical engagement. Ahir et al.\textsuperscript{22} conducted a three-dimensional (3D) FEA on the Bayley-Walker Fixed Fulcrum Total Shoulder replacement (Stanmore Implants, Elstree, UK) for two load cases at 60 degrees and 90 degrees abduction, and found that most of the forces were transmitted medially from the glenoid component to the cortical bone engaged with the central screw. Regarding peripheral screw type, Abdic et al.\textsuperscript{16} compared the effects of locking screws at superior and inferior screw positions, versus at the anterior and posterior positions, on micromotion for the AEQUALIST\textsuperscript{TM} Reversed II shoulder system (Wright Medical Group, Memphis, TN, USA) and found no significant differences in effect. These studies demonstrate how individual fixation elements affect implant micromotion, however, surgeons often use combinations of fixation elements. A previous study by Lung et al. examined the effect of a bone density, peripheral screw length, number of peripheral screws, screw angle, and central peg length, in combination, on baseplate micromotion and found that greater bone density, a longer central peg, and longer peripheral screws improved initial glenoid fixation.
There are no published studies on the effects of central element type, cortical engagement, and peripheral screw type, in combination, on glenoid baseplate micromotion. Therefore, the current study sought to determine the effects of central element fixation (i.e., press-fit peg or compression screw), central element length required for cortical engagement (i.e., 13.5 versus 23.5 mm), anterior-posterior peripheral screw-type (i.e., locking or nonlocking), and cancellous bone density (i.e., 10 and 25 pounds per cubic foot [pcf]). The objective of this study was to mechanically test the effects of these factors on glenoid micromotion of the Delta XTEND™ Reverse Shoulder System (DePuy Synthes, Warsaw, IN, USA) under physiological loading. The results of this study will serve to support clinicians when choosing different implant configurations to meet the diverse needs of patients. It was hypothesized that central compression screw, cortical engagement via a longer central element, locking screws in the anterior and posterior positions, and a greater cancellous bone density would result in decreased baseplate micromotion, and that a significant interaction would exist between central element type and level of cortical engagement (i.e., central element length). This work is presented in the format of an integrated article thesis. Some aspects of the Introduction are reiterated in Chapters 2 and 3 and there will be overlap in the methodology between the two chapters.

Chapter 2 describes the evaluation of the accuracy of the methods used in the present work to interpolate micromotion at the glenoid baseplate using LVDT measurements. The results are compared to the accuracy reported by a pilot study conducted at the Human Mobility Research Centre (HMRC; Queen’s University, Kingston, ON).

Chapter 3 outlines the results from an experiment investigating the effect of the central fixation element, central cortical engagement, anterior-posterior peripheral screw type, and cancellous bone density on the fixation of the Delta XTEND™ glenoid component.
Chapter 4 cumulatively discusses the results of the previous chapters by integrating the content of their independent discussions, highlighting the overall impact of the present work, and providing recommendations for future work.

1.1 Anatomy of the Shoulder

The shoulder has the greatest mobility of any joint in the human body. Its movements represent a complex dynamic relationship between bony articulations, ligament constraints, and muscle forces. Both static and dynamic stabilizers allow for this extensive range of motion when positioning the hand and elbow in space, however, this range of motion is not without its risks. The large articulating humeral head and relatively small glenoid surface, which differs from the well-fitting ball-and-socket joint of the hip, necessitates stabilization via associated muscles and ligaments. Trauma or overuse of the stabilizers can put the shoulder at an increased risk of injury. Likewise, injury to any of the osseous members can adversely affect upper extremity mobility. The shoulder’s functional anatomy can be examined from the perspective of each of its key component structures, namely its bony anatomy, articulations, and dynamic stabilizers. Anatomical terminology in this thesis (i.e., anterior-posterior [A-P], medial-lateral [M-L], superior-inferior [S-I], etc.) will be designated with respect to the standard anatomical position of the body.

1.1.1 Bony Anatomy

The shoulder consists of three bones: the clavicle, the humerus, and the scapula (Figure 1-1). The clavicle, also referred to as the “collarbone”, serves as the sole osseous bridge between the shoulder girdle and the trunk and extends laterally from the sternum to the acromion.
Figure 1-1. Anterior view of the shoulder joint; highlighted in red is the glenohumeral joint alongside the primary bony structures of the shoulder. (Retrieved from Langohr, 2015)
The clavicle has a double curve along its long access and exists subcutaneously in its full extent. The flat, lateral third of the clavicle serves as an attachment point for muscles and ligaments, whereas the tubular, medial third accepts axial loading. The middle third is the thinnest portion and is mechanically weak, hence the predominance of fractures in this area.

The humerus is the largest and longest bone of the upper limb. Its proximal portion consists of the humeral head, a partially spherical surface that articulates with the glenoid of the scapula at the glenohumeral joint, and the greater and lesser tuberosities, which act as muscular attachment sites (Figure 1-2). Three of the four rotator cuff muscles, the supraspinatus, infraspinatus, and teres minor, attach to the greater tubercle, while the fourth, the subscapularis, attaches to the humerus at the lesser tuberosity. Between the greater tuberosity and lesser tuberosity is the bicipital groove, through which the tendon of the long head of the biceps passes from its origin on the scapula. The deltid muscle, which is the primary muscle responsible for upper limb abduction, inserts on the deltid tuberosity on the diaphyseal region of the humerus (i.e., the shaft), distal to the greater and lesser tuberosities. The distal end of the humerus is rotated with respect to its proximal end such that the humeral head remains centered within the articular surface of the glenoid when the arm is resting at one’s side. The angle of motion through the lowest angle and the largest achievable humeral elevation angle (0° – 180°) is referred to as the adduction-abduction range of motion and is limited by impingement of the greater tuberosity and the scapular acromion.

The scapula is a large, thin, triangular bone that rests on the posterior aspect of the torso, serving as a site for attachment of various active and passive structures that act between upper limb and the scapula, as well as between the scapula and torso (Figure 1-3). The scapula acts as a means of transmission of the force from the upper limb to the torso and vice versa. It also simultaneously rotates with the humerus to allow for the shoulder’s full range of motion. The glenoid fossa, or
cavity, represents the surface of articulation for the proximal humerus. Its surface area is one third to one fourth that of the humeral head and, thus provides only a slight contribution to glenohumeral stability, or resistance to dislocation.\textsuperscript{23} Two important metrics for the glenoid fossa that affect the joint’s stability are its version and inclination (Figure 1-4). The glenoid surface is retroverted (i.e., posteriorly) 4° to 12°, on average, with respect to the scapular plane and may be inferiorly or superiorly inclined.\textsuperscript{27} Inclination is clinically determined using the $\beta$-angle, which is formed by the intersection of a line on the floor of the supraspinatus fossa with the glenoid fossa line (Figure 1-4).\textsuperscript{27} The scapular plane itself lies 30° to 45° anterior with respect to the coronal plane of the body.\textsuperscript{27} The acromion is a bony process of the scapula that extends from the scapular spine and articulates with the lateral aspect of the clavicle during scapulothoracic rotation. It serves as an attachment site for the deltoid and trapezius muscles and increases the moment arm of the deltoid to augment the mechanics of humeral elevation during arm abduction (i.e., when the arm is raised).\textsuperscript{28}
Figure 1-2. Anterior view of the right humerus and its osseous anatomy.
(Retrieved from Langohr, 2015)
Figure 1-3. Anterior view of the osseous anatomy of the right scapula and clavicle, showing the glenoid. (Retrieved from Langohr, 2015²⁹)
Figure 1-4. An illustration showing a superior view of glenoid version (left) and an anterior view of glenoid inclination (right) for the right scapula, measured with reference to the supraspinatus fossa line. (Retrieved from Bartron, 2015)
Four joints are responsible for the full range of motion of the shoulder: the sternoclavicular joint, the acromioclavicular joint, the scapulothoracic joint, and the glenohumeral joint. The primary focus of this work is on the glenohumeral joint, which allows for relative motion to occur between the humerus and the scapula.

1.1.2 The Glenohumeral Joint

The glenohumeral joint is a synovial joint that provides primarily three rotational degrees of freedom about the center of rotation located at the center of the humeral head. The glenoid fossa is covered with a layer of hyaline cartilage that has an increased thickness at the peripheral margin, which increases glenohumeral joint conformity and resists translation. The labrum, a ring of fibrocartilagenous tissue located at the periphery of the glenoid, augments joint stability by increasing the depth of concavity, as well as the surface area of contact, which reduces the average contact stress experienced by the joint. At any given time, only 25% to 30% of the humeral head is in contact with the glenoid. Despite this lack of articulating surface coverage, the normal shoulder constrains the humeral head to within 1 to 2 millimeters of the center of the glenoid cavity through most of the arc of motion. The relative motion of the glenohumeral joint predominantly consists of rotation of the humerus about its center of rotation. The humeral head has some translational ability due to the slightly greater radius of curvature of the glenoid fossa and the ability of the labrum to deform under shear loading.

The sternoclavicular, acromioclavicular, and scapulothoracic joints allow for relative motion to occur between the scapula and torso. These joints stabilize the scapula during motion and permit scapular rotation, which is important in maintaining glenohumeral stability during humeral elevation. This is accomplished by counteracting and limiting the shear loading that occurs transverse to the glenoid surface.
Stabilization of the glenohumeral joint involves both passive and dynamic stabilizers. Surrounding ligaments and the glenohumeral joint capsule act to stabilize the shoulder when tensioned during glenohumeral rotation and can limit range of motion at extreme joint angles. The glenohumeral joint capsule connects the articular margin of the humeral head to the periphery of the glenoid labrum (Figure 1-5). It is sufficiently loose to allow the joint’s large range of motion but becomes tensioned to passively restrict hypermobility as the joint approaches its end limits. The glenohumeral ligaments reinforce the joint capsule in the superior, anterior, and inferior aspects, and become tensioned during certain motion configurations. In addition to passive structures, active soft tissues (muscles) work to stabilize the shoulder and position the arm.

1.1.3 Dynamic Stabilizers

The dynamic stabilizer muscles of the shoulder can be characterized according to their origin and insertion sites: scapulohumeral, humerothoracic, or scapulothoracic. Given the scope of this work, scapulothoracic musculature, which is responsible for the rotation of the scapula with respect to the torso, will not be explicitly discussed. The pectoralis major and latissimus dorsi are classified as humerothoracic muscles and originate on the torso and insert on the humerus. Their main purpose is to adduct the humerus. The anterior positioning of the pectoralis major allows it to flex and internally rotate the humerus, while the posteriorly situated latissimus dorsi generates extension and internal rotation.
Figure 1-5. Lateral view of the glenoid labrum and soft tissue structures of the scapula.
(Retrieved from Langohr, 2015$^{29}$)
The scapulohumeral muscles include the rotator cuff muscles, the coracobrachialis, and the deltoid (Figure 1-6). The deltoid is the primary muscle responsible for humeral abduction and has been shown to produce roughly one-half of the moment required for glenohumeral abduction. It is divided into three, independent heads with varying lines of action: anterior, middle, and posterior. The anterior and posterior deltoids can produce humeral rotation in the flexion-extension and internal-external rotation planes, in addition to abduction rotation.

The rotator cuff consists of the supraspinatus, infraspinatus, teres minor, and subscapularis. As a group, they are smaller in cross-sectional area and size when compared with larger, more superficial muscles such as the deltoid and latissimus dorsi. These muscles surround the glenohumeral joint in all but the inferior aspect and provides stability during motion via adduction-abduction and internal-external rotational moments. Given that they lie closer to the center of rotation upon which they act, their lever arm is shorter, thus generating lesser forces. The rotator cuff muscles act together due to their integrated musculotendinous junctions and joint capsules. It was shown that all four muscles equally contribute to anterior stability of the shoulder with the arm in neutral and in external rotation. Rotator cuff activation results in concavity-compression and depression during abduction, as well humeral head rotation with asymmetrical contraction.

Trauma, overuse, or bony deformities can adversely affect the structure and function of the rotator cuff. The term arthropathy, when applied to the rotator cuff, refers to wear of the joint articular cartilage (i.e., arthritis) as a result of rotator cuff deficiency. The extent of the damage, as well as the age and lifestyle of a patient, largely determines their course of treatment.
Figure 1-6. The scapulohumeral muscles of the right shoulder viewed from the anterior (left) and posterior (right); rotator cuff muscles are underlined. (Retrieved from Langohr, 2015)
1.2 Reverse Shoulder Arthroplasty (RSA)

Cuff tear arthropathy (CTA), a term first coined by Neer et al in 1983, describes patients with significant rotator cuff tears in addition to various changes in the structure of the glenohumeral joint. Shoulder hemiarthroplasty, which involves replacing one of the two articular surfaces of the joint with a prosthesis, was suggested as the initial surgical treatment for CTA, however subsequently published results indicated that patient outcomes were inconsistent and were associated with poor function. This led to the development of total joint replacements and, eventually, reverse shoulder replacement designs. Reverse total joint replacements restricted humeral translation with respect to the glenoid, which effectively replaced the relatively unconstrained geometry of the native shoulder with a configuration that constrains the joint’s center of rotation to the center of the glenoid.

RSA is an accepted treatment for CTA, glenohumeral arthritis, proximal humeral fractures, and failed prior shoulder reconstructions. Its use has grown, representing roughly 50% of all total shoulder arthroplasties (TSAs) performed in 2012 out of 100 hospitals reviewed. Treatment of CTA via RSA involves changing the normal anatomy of the glenohumeral joint by affixing the convex ball of the prosthesis to the glenoid via a baseplate and implanting a humeral stem in the proximal humerus to support a concave polyethylene cup, thus reversing the ball-and-socket association of the glenoid and humerus (Figure 1-7).
Figure 1-7. Reverse shoulder arthroplasty implant components, showing the reversed the ball and-socket association of the glenoid and humerus. (Retrieved from Langohr, 2015)
1.2.1 History of Reverse Shoulder Arthroplasty

Initial RSA designs had high rates of clinical failure, mostly caused by loosening of the glenoid component, and were relatively constrained.\textsuperscript{59, 69} These early difficulties led to the innovation of a semi-constrained prosthesis by Grammont and Baulot\textsuperscript{70} in 1985, the Grammont RSA. The preliminary design evolved into the Delta III prosthesis (DePuy International Ltd, Warsaw, IN), released in 1991, and its early findings demonstrated an increase in function and reduction of pain.\textsuperscript{71} Its design was intended to medialize the humerus’ center of rotation, as well as to lengthen the humerus, in order to tension the deltoid muscle and impart a compressive force from the humeral socket to the glenosphere for added stability.\textsuperscript{59} Medializing the glenohumeral center of rotation allowed for enhanced recruitment of deltoid muscle fibers and a more efficient deltoid lever arm.\textsuperscript{72} It was also suggested that a center of rotation located closer to the bone-glenosphere junction would decrease the likelihood of baseplate loosening.\textsuperscript{73}

1.2.2 Reverse Shoulder Biomechanics

Concavity-compression describes the biomechanics of a normal shoulder.\textsuperscript{52} Matsen et al.\textsuperscript{74} described this concept as a ball compressed within a concave surface; the greater the depth of the concavity, the greater the force required to displace the ball while subject to a given compressive force (Figure 1-8). In a healthy shoulder, this compressive force is applied by the rotator cuff muscles. This force is diminished in the rotator cuff-deficient shoulder, leading to instability on account of the imbalance in muscle forces.\textsuperscript{47, 73, 75, 76} The resulting instability and consequent wear of the glenohumeral cartilage can cause pain and reduced mobility.
Figure 1-8. Concavity-compression demonstrated using billiard balls. Deeper concavities require a greater displacing force for a given compressive load. (Retrieved from Walker et al., 2011\textsuperscript{59})
A second biomechanical concept proposed by Matsen and Lippitt is the notion of a glenoid center line, which represents a line perpendicular to the articular surface of the glenoid and directed, on average, approximately 10° posterior (retroverted) to the plane of the scapula. It can be thought of as a pillar upon which the humeral head rests. The concerted movement of the glenohumeral and scapulothoracic joints maintain the center line beneath the humeral head throughout the shoulder’s range of motion. Ideally, the glenoid component is implanted along the glenoid center line. In cases of severe or eccentric glenoid wear, a consequence of rotator cuff deficiency, this may not be possible and stable fixation can only be achieved by placing the component along an alternate glenoid center line (Figure 1-9). Depending on the type and length of a baseplate’s central element, implantation along the glenoid center line could potentially allow it to engage with the cortex of the scapula where the glenoid center line emerges from the scapular neck.
Figure 1-9. Computer-generated model of the anterior view (top left), inferior view (top right) of the glenoid center line. The anterior (bottom left) and inferior (bottom right) views of the alternate glenoid center line are shown below. (Retrieved from Walker et al., 2011^59)
1.2.3 Clinical Implications of Reverse Shoulder Arthroplasty

Fixation in total joint arthroplasty has evolved considerably from early implants and, over time, the concept of osseointegration was introduced. Osseointegration occurs between the patient’s bone and the HA layer present on the underside of an RSA baseplate. Various implant surface characteristics can be used to allow bone ingrowth or on-growth, which provides a more enduring attachment and a decreased long-term likelihood of mechanical failure. For the bone to grow, the implant requires an initial stable attachment with micromotion limited to a range of 50 µm to 150 µm and a surface with the appropriate properties to allow for osseous healing.9-13 These properties are affected by both the type of coating (HA versus porous metal), surface roughness, and porosity.78

Osteoarthritis (OA) of the glenohumeral joint is characterized by inflammation, articular cartilage degradation, and bone remodeling. It is likely that both alterations of the supporting soft tissue structures lead to the progression of OA and the associated inflammation caused by OA leads to soft tissue changes.79 In either case, malalignment due to rotator cuff imbalances can cause pathological glenoid erosion patterns that occur superiorly, inferiorly, anteriorly, posteriorly, or globally, with respect to the glenoid.76 These abnormal wear patterns are likely the result of the altered biomechanical and biochemical environment of the cuff-deficient shoulder and often appear in eccentric patterns.47, 52, 80 Glenoid erosion can be classified using various grading systems, as summarized in a review by Jean.81 In cases of glenoid erosion, surgeons may opt to use either a bone graft or an augmented baseplate to accommodate the defect (Figure 1-10).
Figure 1-10. The top figures show the Zimmer Biomet Comprehensive shoulder system small (top left), medium (top middle), and large (top right), half-wedge augmented baseplates. Below is the Tournier BIO-RSA with a bone wedge between the baseplate and the glenoid surface (bottom left), the Tournier BIO-RSA with an angled bone wedge (bottom middle), and an angled BIO-RSA mounted on a Tournier baseplate post. (Retrieved from Mourad et al., 2020)
In the rotator cuff-deficient shoulder, impingement may also occur between the greater tuberosity and the acromion, potentially leading to acromial erosion, or “acetabularization”. The loss of rotator cuff stabilization allows for the humeral head to migrate superiorly until making contact with the underside of the acromion. In these cases, a fixed fulcrum, such as the one provided by a reverse shoulder prosthesis, can neutralize the instability, and renew the relative position of the humerus. In RSA, there is a possibility of mechanical impingement that can occur between the humeral cup and the scapular neck inferior to the glenoid, referred to as scapular notching. Scapular notching is an important caveat for RSA and often leads to implant wearing and generation of polyethylene debris. Notching is a frequently reported complication of Grammont RSA, occurring in 44% to 93% of patients. Lateralization of the glenosphere using an augmented baseplate could potentially mitigate the likelihood of scapular notching.

1.2.4 Clinical Results

The volume of primary shoulder arthroplasty surgeries has increased significantly in recent years, as reported by national joint arthroplasty registries, however, registry data relating to patient outcomes and implant survival for reverse shoulder procedures remains limited. The Canadian Joint Replacement Registry (CJRR) only collects information regarding hip and knee replacement surgeries, highlighting the need for a broader scope of documentation of Canadian orthopaedic procedures. The most common reasons for revision of RSA are instability/dislocation (47.7%), infection (17.1%), fracture (16.2%), and aseptic loosening (11.7%). The AOANJRR cumulative incidence of RSA revision diagnoses is shown in Figure 1-11, with roughly 1.4% of cases revised due to loosening after 12 years. Of the 4,002 shoulder arthroplasties submitted to the American Academy of Orthopaedic Surgeons (AAOS) Shoulder & Elbow Registry, dating 2015–2020, a majority of 60.3% were for RSA. A review of the New
Zealand Orthopaedic Association (NZOA) Joint Registry outlined that patients with proximal humerus fractures who underwent RSA achieved better 5-year functional outcomes when compared with patients who underwent hemiarthroplasty. Critchley et al. showed, in a review of the 2018 Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Annual Report, that RSA had a significantly lower revision rate compared to hemiarthroplasty when treating proximal humerus fractures (Figure 1-12).

Despite the increasing number of RSA procedures, long-term results are rarely reported and those that are, have conflicting findings. A systematic review by Ernstbrunner and colleagues found significant improvements in outcome scores up to 20 years after RSA surgery for patients with irreparable rotator cuff tears. In contrast, Bacle et al. reported deterioration of long-term RSA outcomes, compared with medium-term results, and suggested patient aging coupled with bone erosion and/or deltoid impairment over time as a probable factor. Glenoid loosening was observed in 40% of cases after 2 years. A study that compared the short- to medium-term outcomes of RSA and anatomical TSA showed similar outcomes, complication rates, needs for revision, and range of motion between RSA and TSA at 2 years of follow-up. Wall et al. reported substantial clinical and functional improvements for patients who underwent RSA for a variety of etiologies and observed better outcomes for patients with primary rotator cuff tear arthropathy, primary osteoarthritis with a rotator cuff tear, and irreparable rotator cuff tears than those who had post-traumatic arthritis or revision arthroplasty. Glenoid baseplate loosening was reported to occur in 6% of cases that had complications prior to the two-year follow-up period. The conflicting nature of these findings and the limited data regarding implant-specific factors reinforce the importance of the present work.
Figure 1-11. Cumulative incidence revision diagnosis of primary RSA. 
(Retrieved from the AOANJRR, 2020)

Figure 1-12. CPR of primary shoulder replacement by shoulder class. The CPR rate of RSA is lower than that of stemmed hemiarthroplasty. (Retrieved from Boyle et al., 2013)
1.2.5 Glenoid Baseplate Fixation

An important factor for glenoid component fixation is the baseplate’s central stabilizing element. A variety of options exist in the form of a modular central screw, a monoblock baseplate screw, or a central peg/post (Figure 1-13). Baseplates with a central peg are typically monoblocks and are coated with HA, porous metal, or both, to encourage bony on-growth.

Modular central screw baseplates have a compression screw that is inserted through a central hole in the baseplate and tightened to provide baseplate-bone compression. Central screw baseplates offer enhanced post-operative (primary) fixation due to the initial compression, but the screw lacks the long-term ingrowth potential of a HA-coated central peg. An in vitro biomechanical study by Harman and colleagues found that implants with either a central peg or a central screw had micromotion that fell within the desired range of 50 – 150 µm.

Baseplates and their central elements are available in a range of sizes and lengths. It has been shown that increasing central peg length may effectively reduce micromotion in bone surrogates, although, it is important to note that the capacity for a longer central element length may be limited by the patient’s bone stock. Currently, it is not known whether different central fixation designs improve arthroplasty longevity by delaying revision.

After securing the baseplate to the glenoid via the central element, additional fixation is achieved by peripheral fixation screws, which can be compression screws, locking screws, or a combination of both. The revision rate of RSA components decreased significantly after the introduction of locking screws. The number of screws, screw-type, length, and angle can all affect peripheral screw fixation. Circular baseplates can typically accommodate two to four peripheral screws, while ovoid baseplates can accommodate from two to six.
Figure 1-13. Baseplates with different central fixation elements: the Tornier Aequalis Reform Reversed central screw baseplate (top left; Wright Medical Group N.V., Memphis, TN), the Tornier Aequalis Reversed II baseplate with long post (top right; Wright Medical Group N.V., Memphis, TN), the DJO RSP 26-mm monoblock baseplate screw (bottom left; DJO Surgical, Austin, TX), and the Mathys Affinis Inverse Metaglene with two pegs (bottom right; Mathys Ltd. Bettlach, Switzerland). (Retrieved from Mourad, 2020)
A bone surrogate study by Roche et al. showed that a configuration of four peripheral screws imparted superior fixation strength compared to the use of two screws, and had the strength equivalent to that of six screws.\textsuperscript{19} Furthermore, they found that the use of longer peripheral screws resulted in enhanced fixation.\textsuperscript{19} Formaini et al. found no observable difference when comparing the use of hybrid configurations of locking and nonlocking screws with configurations that used all locking screws in a bone surrogate model.\textsuperscript{96} A study by Lung et al. examined the effect of the insertion angle, length, and number of peripheral screws on glenoid baseplate micromotion in a bone surrogate model, and found that longer peripheral screws contributed to improved baseplate primary fixation; whereas, angle and the number of peripheral screws had no significant effect.\textsuperscript{18} It has been suggested that surgeons emphasize secure placement of the peripheral screws in the best quality of bone available.\textsuperscript{1}

Prior work has also focused on cancellous bone density distributions of three columns of bone extending medially from the base of the glenoid along the scapular spine, the lateral border, and the base of coracoid process, to guide the positioning of peripheral screws.\textsuperscript{3, 5, 97} Daalder et al. found that slightly higher densities existed in the scapular spine and lateral border compared to the base of the coracoid process.\textsuperscript{98} These regions may thus provide better bone purchase for baseplate peripheral screws.
1.3 Mechanical Testing of Micromotion

The American Society for Testing and Materials (ASTM) International outlines standards for the test methods used for dynamic evaluation of glenoid loosening for experiments intending to investigate RSA baseplate loosening, dissociation of modular components, and/or dislocation. It stipulates that the implant must be fixed to the bone surrogate using standard surgical technique. Initial fixation should be measured before and after cyclical loading and the biaxial test apparatus should be configured such that an axial load is applied approximately through the center of rotation of the glenoid component (Figure 1-14).

The tests should be performed on either electromechanical or servohydraulic load frames, with adequate load capacity, in either air at room temperature or in water at 37°C. A loading frequency of 0.5 Hz is recommended, although faster or slower rates may be used and should not exceed 1.0 Hz. The ASTM standards require that at least three samples are tested. When measuring the displacement of the glenoid component, a measurement precision of at least 5 µm is required.
Figure 1-14. Application of a compressive load to an RSA implant through the center of rotation of the glenoid component. (Adapted from Hast et al., 2019)
Micromotion has been experimentally measured in a variety of ways. Some studies have conducted FEA on models constructed from computed tomography (CT) scans of cadaveric scapulae. Biomechanical cadaveric studies have used polymethylmethacrylate (PMMA) cement to secure thawed, fresh frozen cadavers during mechanical loading while measuring micromotion using either a motion capture system or linear variable differential transformers (LVDTs). Abdic et al. used a rigid plate secured to the baseplate to translate its displacement to three LVDTs placed radially around the implant at 120°, 200°, and 240°, relative to the superior-inferior axis. A coordinate system established from these three points was used to compute the micromotion at the edge of the baseplate. Hast and colleagues evaluated micromotion using a six-camera motion capture system to record the relative change in displacement between marker clusters located on the scapula/bone stock and the glenosphere. In this study, the micromotion observed in cadaver models was compared to that of synthetic bone composed of polyurethane (PU) foam. The accuracy of 3D motion capture systems for mechanical testing was documented by Schmidt et al., who found that the distance between the camera systems and the rigid body, as well as the tilt angle of the markers, affected measurement accuracy (< 30 µm). In a similar study, Göpfert et al. found that the accuracy of their motion capture system (36 µm) was dependent on the number of cameras tracking the reflective markers.

ASTM International provides specifications for rigid PU foam blocks for use in the testing of orthopaedic devices. It states that “The uniformity and consistent properties of rigid polyurethane foam make it an ideal material for comparative testing of bone screws and other medical devices and instruments”. The present work used Sawbones™ rigid polyurethane foam blocks (Pacific Research Laboratories, Vashon Island, WA, USA) of 10 pcf, 25 pcf, and 30 pcf to simulate osteoporotic cancellous bone, nominally healthy cancellous bone, and cortical bone,
respectively. The specific densities used were recommended by the manufacturer and were consistent with ASTM guidelines and prior work.\textsuperscript{1, 15, 18, 94, 96, 103-108} The rationale for the use of bone surrogates instead cadaveric specimens is that they reduce variability in experimental measures,\textsuperscript{109} they are less costly and easier to procure, and they are non-biological.\textsuperscript{15}

Formaini et al. investigated the effect of locking screw configuration on RSA baseplate micromotion in a Sawbones\textsuperscript{TM} rigid polyurethane model.\textsuperscript{96} Micromotion was measured using a 3 \(\mu\m\)-precision differential variable reluctance transducer (DVRT) mounted to the sample in the inferior-superior direction, relative to the baseplate, such that the sensor was in contact with the periphery of the baseplate. Roche et al. used two 1 \(\mu\m\) resolution digital indicator probes to measure the displacement of a baseplate in a Sawbones\textsuperscript{TM} model.\textsuperscript{19} A study by Lung et al. evaluated the micromotion of the Delta XTEND\textsuperscript{TM} baseplate by using three 3 \(\mu\m\)-precision LVDTs that measured displacement values during loading from a metal ring affixed to and surrounding the glenosphere.\textsuperscript{18} The accuracy of such methods in the context of measuring glenoid micromotion has not yet been reported.

### 1.4 Motivation

Prior studies have investigated the effects of a variety of baseplate factors on micromotion using rigid polyurethane foam,\textsuperscript{1, 15, 18, 94, 96, 103-105, 107, 108} cadavers,\textsuperscript{15, 16, 106} and finite element models.\textsuperscript{17, 21, 22} Formaini and colleagues tested the effects of locking peripheral screws on baseplate stability of the RSP\textsuperscript{®} system using one, two, three, or four locking screws and found no significant differences in micromotion.\textsuperscript{96} Similarly, the cadaveric study by Abdic et al. examined locking screw placement at the superior-inferior or anterior-posterior baseplate positions and found
no significant effect on micromotion.\textsuperscript{16} The literature regarding the effects of a central screw and cortical engagement with the scapula on baseplate stability is limited. Hast et al. observed that a central screw improved resistance to dislodgement in a cadaver model, but not with a bone surrogate.\textsuperscript{15} A FEA study of a monoblock central screw prosthesis, conducted by Ahir et al., showed that most of the forces of the model under load were experienced by the cortical bone of the scapula at the site of central screw purchase.\textsuperscript{22}

To date, no study exists that investigates the effects of central element type, cortical engagement, and peripheral screw type, in combination. Therefore, the purpose of this study was to determine the effects of central element fixation (i.e., press-fit peg or compression screw), cortical engagement of longer central elements with 30 pcf cortical density polyurethane (i.e., 13.5 and 23.5 mm), anterior-posterior peripheral screw-type (i.e., locking or nonlocking), and cancellous bone density (i.e., 10 and 25 pounds per cubic foot [pcf]) on glenoid baseplate micromotion.

1.5 Objectives and Hypothesis

Gaining a better understanding of the factors that affect RSA baseplate fixation is critical to the design of future implants and to the practice of clinicians. Improving the fixation of primary RSA could improve patient outcomes and decrease the likelihood of revision. The first objective was to characterize the accuracy of the apparatus with which micromotion was measured. The second objective was to mechanically test the effects of central fixation element type, central cortical engagement, peripheral screw configuration, and cancellous bone quality on glenoid micromotion of the Delta XTEND\textsuperscript{TM} reverse shoulder prosthesis under simulated physiological
loading. The results of this study will serve to support clinicians when selecting combinations of factors that could potentially improve the outcomes of RSA, as well as to determine possible configurations that may be better suited for various, case-specific morphologies. It was hypothesized that a central compression screw, cortical engagement via a longer central element, locking screws in the anterior and posterior positions, and a greater cancellous bone density would result in decreased baseplate micromotion, and that an interaction would exist between central element type and cortical engagement.
Chapter 2

ACCURACY OF AN APPARATUS FOR MEASURING GLENOID BASEPLATE MICROMOTION IN REVERSE SHOULDER ARTHROPLASTY

2.1 Introduction

Reverse shoulder arthroplasty (RSA) is typically performed to treat patients with rotator cuff arthropathy, osteoarthritis (OA), and complex proximal humerus fractures.\textsuperscript{1-5} RSA systems are characterized by reversing the native ball-and-socket aspects of the glenohumeral joint. Implant designs consist of a polyethylene humeral cup affixed to a stem that is placed in the proximal humerus and a glenosphere secured to a baseplate implanted on the glenoid fossa of the scapula. Baseplates may be centrally secured by means of a press fit peg or a central compression screw. Although it has a high rate of complications, RSA has been shown to be effective in improving patient functional outcomes, pain, and quality of life.\textsuperscript{110-112}

One of the most common complications in RSA is glenoid baseplate loosening, which requires revision.\textsuperscript{113-115} Given the increase in the volume of primary RSA, understanding the factors that affect baseplate loosening is of critical importance to prevent or delay revision of the glenoid component.\textsuperscript{85} RSA implants allow for enhanced long-term fixation with the inclusion of a hydroxyapatite (HA) coating and, in order for the interface bone to effectively mineralize onto the HA-coated implant, micromotion of the baseplate with respect to the implant should be limited to a range of 50 µm to 150 µm.\textsuperscript{9-13} Implant-related factors that may affect fixation of the baseplate to the glenoid, and thus, micromotion, include the patient’s bone quality, peripheral screw properties, and the central fixation element. The literature regarding these factors is limited as are
reports of long-term outcomes. There is therefore a significant need for mechanically testing the micromotion of RSA implants with reliable measurement systems.

Implant micromotion is defined as implant displacement relative to the site of bone resection while under cyclic loading and has been measured and modelled in a variety of ways. Some studies have used computer-generated models to simulate mechanical loading of baseplates by means of finite element analysis (FEA). Others have tested baseplate fixation using cadavers or polyurethane (PU) foam bone surrogates. The rationale for the use of PU foam instead of cadaveric material is threefold: (1) to reduce variability in experimental measures; (2) to reduce costs and simplify procurement; and, (3) to avoid using biological material. Bone-implant micromotion has been measured using various devices, such as displacement transducers (e.g., linear variable differential transformers [LVDTs], differential variable reluctance transducers [DVRTs] and three-dimensional (3D) motion capture systems. Digital Image Correlation (DIC) or Digital Volume Correlation (DVC) with micro-computed tomography (CT), may also be used in micromotion analyses. Several studies have reported the results of the mechanical testing of micromotion, but few have reported on the accuracy of the apparatus. A study by Göpfert et al., using a 3D video-based system, found that the accuracy of the system (36 µm) was dependent on the number of cameras tracking the reflective markers. Another study found that the distance between the camera systems and the rigid body, as well as the tilt angle of the rigid body, affected the accuracy (< 30 µm) of such measurements.

An experiment was designed to evaluate factors that affect micromotion of the Delta XTEND™ Reverse Shoulder System (DePuy Synthes, Warsaw, IN, USA), specifically, the effects of varying central element fixation, cortical engagement, peripheral screw configuration,
and bone density. The purpose of this study was, therefore, to determine the accuracy of the LVDT system used to measure baseplate micromotion relative to the bone surrogate in this experiment. Accuracies were expected to closely resemble the results of a preliminary pilot experiment (N = 6), which used this apparatus and reported an error of (6.0±1.2)%.

2.2 Materials and Methods

This study measured the micromotion of the Delta XTEND™ glenoid baseplate relative to a bone surrogate under a combined compressive and shear load. For this study, micromotion was defined as the displacement range of the glenoid baseplate relative to the bone surrogate in the medial-lateral (Z) direction (Figure 2-1). The factors investigated were central element fixation (i.e., press-fit peg or compression screw), cortical engagement of longer central elements with 30 pounds per cubic foot (pcf) cortical density PU foam (i.e., 13.5 and 23.5 mm), anterior-posterior (A-P) peripheral screw-type (i.e., locking or nonlocking), and cancellous bone density (i.e., 10 pcf and 25 pcf).

The glenoid bone was physically modelled with a bone surrogate that was custom-made from laminating Sawbones™ rigid PU foam blocks (Pacific Research Laboratories, Vashon Island, WA, USA) of 10 pcf or 25 pcf, and 30 pcf densities. These densities simulated osteoporotic cancellous bone, nominally healthy cancellous bone, and cortical bone, respectively. Both cancellous densities had a thickness of 16 mm, which simulated cancellous bone stock of the scapula, and were laminated over a 134 mm thick 30 pcf PU foam block, which represented the density of cortical bone. All Sawbones™ PU foam blocks were cut to dimensions of 40 mm x 40 mm x 150 mm (Appendix A). The thickness of the cancellous layer (16 mm thick)
was chosen to prohibit deep cortical engagement of samples with a short central fixation element (13.5 mm long). Central screw baseplates were modified by removing the peg of an original baseplate and milling a countersunk hole. This was done to accommodate a 6.5 mm diameter central cancellous screw (Product #218.030, DePuy Synthes).

Figure 2-1. The experimental configuration used for each run with the labels for the modified glenosphere and LVDT highlighted in bold. Samples were secured at 60° to the loading platform. Implants were cyclically loaded with 500 N maximum and 20 N minimum sinusoidal load at 1 Hz for 1000 cycles. The X-, Y-, and Z-axes represent the superior-inferior (S-I), anterior-posterior (A-P), and medial-lateral (M-L) directions, respectively.
2.2.1 Experimental Design

This experiment was designed as a half-fractional factorial \( (2^{k-1}) \) to omit factor combinations that were specifically relevant to higher order interactions. The design involved four factors \( (k = 4) \) at two levels each. The experiment therefore had eight unique factor conditions, each of which was repeated five times for a total of 40 runs \( (N = 40) \). The eight conditions were the following: (1) 13.5 mm central peg with nonlocking A-P screws in 10 pcf PU foam; (2) 13.5 mm central screw with nonlocking A-P screws in 25 pcf PU foam; (3) 23.5 mm central peg with nonlocking A-P screws in 25 pcf PU foam; (4) 23.5 mm central screw with nonlocking A-P screws in 10 pcf PU foam; (5) 13.5 mm central peg with locking A-P screws in 25 pcf PU foam; (6) 13.5 mm central screw with locking A-P screws in 10 pcf PU foam; (7) 23.5 mm central peg with locking A-P screws in 10 pcf PU foam; and, (8) 23.5 mm central screw with locking A-P screws in 25 pcf PU foam (Table 2-1; Figure 2-2).

Each sample was cyclically loaded in an inferior-to-superior and lateral-to-medial direction with a load range of 20 N to 500 N at 1 Hz to simulate the peak loads experienced by the shoulder when performing activities of daily living\(^{29}\) (e.g., brushing one’s hair) during the first three post-operative months, which are most important for initial osseointegration.\(^{7}\) The load was force-controlled and applied using a materials testing system (Bionix Servohydraulic Test System; MTS Systems Corporation, Eden Prairie, MN, USA); axial force and displacement across time were collected using a load cell (5 kN capacity) and the loading frame crosshead, respectively, at a sampling rate of 20 Hz. Each sample was initially loaded with 20 N before taring the system and was then cyclically loaded up to 500 N for 1000 sinusoidal cycles. Baseplate displacement data was recorded on a laptop by four LVDTs at a sampling rate of 20 Hz. The standard operating procedure can be found in Appendix A.
Table 2-1. The half-fractional factorial experiment showing the eight unique factor conditions.

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<tr>
<td>A: Central Fixation</td>
<td>Peg</td>
<td>Screw</td>
</tr>
<tr>
<td>B: Central Length</td>
<td>13.5 mm</td>
<td>23.5 mm</td>
</tr>
<tr>
<td>C: A-P Screw Type</td>
<td>Nonlocking</td>
<td>Locking</td>
</tr>
<tr>
<td>D: Cancellous density</td>
<td>10 pcf</td>
<td>25 pcf</td>
</tr>
</tbody>
</table>

2.2.2 Micromotion Apparatus

The apparatus consisted of an angled 5-degree of freedom vice, a custom-made LVDT support fixture, the baseplate implanted within the PU foam block, a modified glenosphere with a measuring disc, and a humeral loading cup (Figure 2-1). The glenosphere was modified to include three spokes that were welded to a circular stainless-steel disc from which displacement measurements were recorded. Baseplates were implanted at the center of the top face of each PU foam block. The measurement disc served to expand the area of the implant plane to allow four LVDT probes (Orbit 3, Solartron™ Metrology, West Sussex, United Kingdom) to record displacement of the implant relative to the PU foam block. The 5-degree vice positioned the sample at 60° to the loading platform such that compressive loading occurred at 30° to the implant axis (Z-axis, M-L). This apparatus resembled a configuration used in a previous micromotion study.18
Figure 2-2. Section views (transverse plane with respect to anatomical position) of each of the eight unique factor combinations: central element length, nonlocking versus locking, and central peg versus screw. The long central elements engaged with the denser PU foam of the bone surrogate.
The LVDTs had a resolution of 3 µm and a measuring range of 2000 µm. Each LVDT was fastened within a custom-made support fixture (3D-printed with acronitryl butadiene styrene [ABS]; Appendix B) that was fixed to each PU foam block using Steinmann pins. The fixture included a 40 mm x 40 mm central square locating-hole for the PU foam block to ensure that the radial distance of each LVDT from the center was repeatable from sample-to-sample. Displacement was measured in the medial-lateral direction, represented by the Z-axis (Figure 2-1). Each LVDT was located at a radius of 52.5 mm from the center of the baseplate at 0°, 135°, 225°, and 270°, with respect to the position of the inferior peripheral screw (Figure 2-3). Displacement data were collected during the last 10 cycles of the loading phase, as well as at the beginning and end of the cycle without any loading. Any difference between these values was subtracted from the micromotion measurements obtained during loading to account for any migration of the implant.
Figure 2-3. The positions of each LVDT in the supporting fixture (circled numbers). $L_1$ and $L_2$ (blue lines) were vectors connecting LVDT #1 and #2, and #2 and #3, respectively (green arrows). The position of LVDT #4, indicated by the red arrow, served as the reference position to be compared to the predicted displacement at the anterior screw position. The inset at the top right shows four screw positions: inferior (I), medial (M), superior (S), and anterior (A).
2.2.3 Measurement Accuracy

The X-Y position for each LVDT was determined using their radius and angular position in the supporting fixture (Figure 2-4). Measured displacements in the Z-direction were used to determine the Z-coordinate of the measurement disc where it contacted the LVDT probe with respect to the supporting fixture. The micromotion in the Z-direction was determined by subtracting the minimum displacement (i.e., the reference) from the maximum displacement \((z_{LVDTi} - z_{LVDTi\ reference})\) for each LVDT obtained during the loading phase. The X-Y positions of LVDTs #1, #2 and #3 were used to determine two vectors, \(L_1\) and \(L_2\). The cross product of these two vectors defined the plane of the supporting fixture (and the parallel measurement disc) with planar coefficients \(a\), \(b\), \(c\), and \(d\). Once the equation of the plane was established, the position of LVDT #4 was substituted into the equation of the plane to determine its predicted displacement in the Z-direction. Finally, the measured and predicted displacement values were compared to quantify the accuracy of the micromotion measurements. The data from the LVDTs was used to interpolate the micromotion at each respective screw position: inferior, anterior, superior, posterior. The difference between the predicted and measured micromotion value for LVDT #4 for each sample at the screw position of LVDT #4 (anterior) was averaged and used to compute the MAPE of the system, respective of condition. The mean absolute percentage error (MAPE) for each condition was found using equation (1):

\[
\text{Mean absolute percentage error (MAPE)} = \frac{1}{n} \sum \left| \frac{(z_i)_{\text{measured}} - (z_i)_{\text{predicted}}}{(z_i)_{\text{measured}}} \right| \tag{1}
\]

where \(n\) was the number of conditional repeats, \((z_i)_{\text{measured}}\) is the measured displacement in the Z-direction at LVDT #4, and \((z_i)_{\text{predicted}}\) is the predicted displacement in the Z-direction at the anterior screw position.
Figure 2-4. The four-step algorithm used to compute the predicted displacement of a given LVDT in the Z-direction. The micromotion, $z_i$, was found by subtracting the maximum displacement of a given LVDT, $z_{LVDTi}$, from its minimum displacement, $z_{LVDTi reference}$. 

$$x_i = r \cos \theta_i$$
$$y_i = r \sin \theta_i$$
$$z_i = z_{LVDTi} - z_{LVDTi \text{ reference}}$$

Step 1: 

$$(x_i, y_i, z_i)_m, \quad i = 1 ... 3$$

Step 2: 

$$\overrightarrow{L_1} = (x_2, y_2, z_2) - (x_1, y_1, z_1)$$
$$\overrightarrow{L_2} = (x_3, y_3, z_3) - (x_2, y_2, z_2)$$
$$[a, b, c] = \overrightarrow{L_2} \times \overrightarrow{L_1}$$
$$d = [a, b, c] \begin{pmatrix} x_1 \\ y_1 \\ z_1 \end{pmatrix}$$

Step 3: 

$$(z_4)_m = \frac{d - ax_4 - by_4}{c}$$

Step 4: 

$$(z_4)_p - (z_4)_m$$

$$(z_4)_p$$
2.3 Results

The mean absolute percentage error (MAPE) for each condition ranged from 6.8% to 12.9% for an overall MAPE of (9.5±0.9)% (Table 2-2). An example of the micromotion data recorded by LVDTs #1 to #4 for a sample with a combination of a 23.5 mm central peg, locking A-P screws, and 10 pcf cancellous bone can be seen in Figure 2-5. This shows the cyclic displacement of the implant relative to the bone surrogate during cyclic loading. The peak micromotion, 39 µm, was recorded by LVDT #2, and the peaks for LVDTs #1 to #3 were 32 to 34 µm. The peaks vary slightly due to the tilting of the baseplate and the relative positions of the LVDTs. Tilting of the baseplate was confirmed by the equation of the plane for each sample and nonzero a and b coefficients indicated that the plane displacement was not orthogonal to the Z-direction.

Table 2-2. Micromotion averaged from each screw position and the associated MAPE for each condition with average MAPE and standard error.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Inferior (µm)</th>
<th>Anterior (µm)</th>
<th>Superior (µm)</th>
<th>Posterior (µm)</th>
<th>Average (µm)</th>
<th>MAPE (%)</th>
<th>Error (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Peg/13.5 mm/NL/10 pcf</td>
<td>317</td>
<td>310</td>
<td>274</td>
<td>280</td>
<td>295</td>
<td>6.8</td>
<td>20.1</td>
</tr>
<tr>
<td>(2) Screw/13.5 mm/NL/25pcf</td>
<td>38.8</td>
<td>39.5</td>
<td>39.5</td>
<td>38.8</td>
<td>39.2</td>
<td>12.9</td>
<td>5.0</td>
</tr>
<tr>
<td>(3) Peg/23.5 mm/NL/25pcf</td>
<td>43.8</td>
<td>46.0</td>
<td>49.3</td>
<td>47.1</td>
<td>46.6</td>
<td>8.3</td>
<td>3.9</td>
</tr>
<tr>
<td>(4) Screw/23.5 mm/NL/10 pcf</td>
<td>16.0</td>
<td>20.0</td>
<td>30.4</td>
<td>26.4</td>
<td>23.2</td>
<td>11.7</td>
<td>2.7</td>
</tr>
<tr>
<td>(5) Peg/13.5 mm/LK/25pcf</td>
<td>146</td>
<td>137</td>
<td>131</td>
<td>91.4</td>
<td>138</td>
<td>6.9</td>
<td>9.5</td>
</tr>
<tr>
<td>(6) Screw/13.5 mm/LK/10 pcf</td>
<td>42.5</td>
<td>44.8</td>
<td>52.0</td>
<td>49.7</td>
<td>47.3</td>
<td>8.8</td>
<td>4.2</td>
</tr>
<tr>
<td>(7) Peg/23.5 mm/LK/10 pcf</td>
<td>44.0</td>
<td>43.7</td>
<td>40.0</td>
<td>40.2</td>
<td>42.0</td>
<td>7.9</td>
<td>3.3</td>
</tr>
<tr>
<td>(8) Screw/23.5 mm/LK/25pcf</td>
<td>23.2</td>
<td>23.4</td>
<td>22.7</td>
<td>22.5</td>
<td>23.0</td>
<td>12.9</td>
<td>3.0</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>9.5</strong></td>
<td></td>
<td><strong>6.5</strong></td>
</tr>
<tr>
<td><strong>St. Error</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>0.9</strong></td>
<td></td>
<td><strong>2.1</strong></td>
</tr>
</tbody>
</table>
Sample #3
Condition (7) - 23.5 mm Central Peg, Locking A-P, 10 pcf

Figure 2-5. Displacement data showing five cycles for sample #3 (23.5 mm central peg, locking A-P screws, 10 pcf cancellous bone).

A peak displacement of 39 µm was recorded by LVDT #2.
2.4 Discussion

The long-term success of RSA relies partly on the primary fixation of the glenoid baseplate to the interface bone. Reliable and accurate micromotion test methods are therefore required to draw clinically relevant conclusions regarding optimal baseplate factors, such as the implant design and positioning, peripheral screw configuration, or patient bone quality. This is also of importance to computer-assisted modelling studies that use such experimental data as a standard for validation.\(^{117}\) Therefore, this study evaluated the accuracy of a measurement system designed to test factors that affect glenoid baseplate micromotion \textit{in vitro}, specifically, the effects of central element type, central cortical engagement, peripheral locking screw configuration, and bone density. Loading in this experiment was limited to 1000 cycles, given that a cycle count that exceeds 1000 does not provide additional information related to primary fixation.\(^{94}\) Micromotion was measured using a displacement transducer system consisting of four LVDTs.

Previous studies have used a variety of measurement systems for measuring glenoid baseplate micromotion, however, the accuracies of said systems have gone relatively undocumented. The analysis of this study yielded a MAPE range of 6.8\% to 12.9\%, an error range of 2.7 \(\mu\)m to 20.1 \(\mu\)m, and an overall MAPE of (9.5\(\pm\)0.9)\%. The error range was lower than those reported by studies using optical systems,\(^{100,101}\) indicating enhanced precision. These results are similar to the findings of a related pilot experiment conducted at our center, in which a MAPE of (6.0\(\pm\)1.2)\% was measured. The present study included more combinations of factors and a larger sample size than the pilot experiment, however, both experiments yielded similar and promising results regarding the accuracy of such measurement systems.
The average micromotion observed for each condition varied with respect to the osseointegration threshold of 50 to 150 µm. The micromotion measurement error range (2.7 µm to 20.1 µm) was significantly lower than the measured micromotion. The average micromotion for condition 6 (138 µm, error 4.2 µm), which was tested in 25 pcf PU bone, remained within the osseointegration range, and conditions 3 and 5, which involved 25 pcf and 10 pcf PU bone, respectively, had average micromotion values that came close to the lower limit of 50 µm (46.6 µm and 47.3 µm; error range: 3.9 – 9.5 µm, respectively). Conditions 2, 4, 7, and 8 fell well below the lower threshold (39.2 µm, 23.2 µm, 42.0 µm, and 23.0 µm, respectively; error range: 2.7 – 5.0 µm). Condition 1 was the only condition to exceed the upper limit of the threshold (295 µm; error: 20.1 µm), indicating a lower stability compared to the other conditions. These results suggest that the micromotion measurements were accurate enough to differentiate between factor combinations. For example, a long central peg and nonlocking A-P screws (condition 4; error: 2.4 µm), or a short central peg with locking A-P screws (condition 4; error: 9.5 µm), may be suitable for implantation within nominally healthy bone. Furthermore, a short central screw with locking A-P screws (condition 6; error: 4.2 µm) may provide adequate fixation in osteoporotic bone.

Prior groups have acknowledged the limitation of displacement transducers given that such methods, in many cases, quantified micromotion in a single axis.\textsuperscript{118-121} This was the case for the present study, which measured baseplate micromotion in the medial-lateral (Z) direction. This study was limited in that only one measurement system was used (LVDTs), measuring micromotion in one axis, and that it modelled baseplate micromotion in a synthetic PU foam bone surrogate. An evaluation of identical factors using cadaveric specimens and/or FEA could potentially corroborate the micromotion results of the present work and confirm the accuracy of
the apparatus. Additionally, use of digital image correlation (DIC),\textsuperscript{117} or digital volume correlation (DVC) with micro-computed tomography (CT),\textsuperscript{122} may be a potential avenue for overcoming the limitations of displacement transducers in micromotion analyses.

The findings presented here support the use of displacement transducers, specifically LVDTs, as an accurate system for determining RSA baseplate micromotion in a rigid PU foam bone surrogate. Future work investigating factors that affect the accuracy of baseplate micromotion measurements in cadaveric models, as well as finite element models, could expand and validate the present results.
Chapter 3

CENTRAL FIXATION ELEMENT TYPE AND LENGTH AFFECT GLENOID BASEPLATE MICROMOTION IN REVERSE SHOULDER ARTHROPLASTY

3.1 Introduction

Reverse shoulder arthroplasty (RSA) is commonly used to treat a variety of pathologies, including rotator cuff tear arthropathy, glenohumeral arthritis with rotator cuff deficiency, proximal humerus fractures, failed shoulder arthroplasty, and other shoulder impairments that are not reparable with anatomical shoulder arthroplasty. RSA implant designs consist of a humeral cup secured to the proximal humerus and a glenosphere secured to the glenoid of the scapula via a glenoid baseplate. Despite the success of RSA, there is a high complication rate (24%) associated with the procedure. Loosening of the glenoid component remains one of the principal modes of failure and is the main complication leading to revision surgery.

The enhancement of baseplate fixation continues to be a focus of discussion as new generations of RSA implants are developed. RSA baseplates offer enhanced secondary fixation with the inclusion of a hydroxyapatite (HA) coating on the glenoid surface of the implant, which allows for interfacing bone to mineralize directly onto the surface of the implant. Long-term fixation via this osseous on-growth is promoted by limiting interface micromotion to a range of 50 µm to 150 µm. Interface micromotion is the total displacement of the implant relative to the resected bone surface. Therefore, the magnitude of post-operative glenoid micromotion is a key indicator of long-term glenoid fixation potential. Prior studies have used a variety of methods to evaluate glenoid micromotion, in vitro, with rigid polyurethane (PU) foam or cadaveric specimens; and, in silico, with finite element analysis (FEA).
Rigid PU foam is a standard bone surrogate for biomechanical evaluations of orthopaedic implants and its specifications for such use are outlined in the ASTM standards for testing orthopaedic devices and instruments.\textsuperscript{102} In comparison to testing with cadaveric material, the benefits of PU foam as a bone surrogate are: reduction of variability in experimental measures,\textsuperscript{109}; cost and easy of procurement; and, safety, as PU foam is not biologically hazardous.\textsuperscript{15} Generally, three testing methods have been used to evaluate primary fixation of RSA implants: (1) simulation of the mechanics of the “rocking-horse effect” experienced by glenoid baseplate components; (2) application of an external load to the baseplate at a fixed abduction along the long axis of the humerus; and, (3) moving the implant through a dynamic range of joint angles while applying a constant compressive load.\textsuperscript{15} The loading conditions of the first test method may not be fully representative of the joint mechanics experienced by patients with a deficient rotator cuff during activities of daily living (ADLs). The second allows for the application of joint loads that more closely resemble those experienced during ADLs via a uniaxial load frame, but only for a specific joint angle. The third test method resembles the ASTM standard for dynamic testing of RSA implants;\textsuperscript{99} however, the required testing equipment is not as common as uniaxial load frames and thus such experiments may not be readily performed in many biomechanics labs.\textsuperscript{15} Previous biomechanical studies have applied these methods and others to characterize and improve glenoid baseplate primary fixation. Multiple factors of glenoid baseplate design and positioning have been shown to affect baseplate micromotion and implant fixation.\textsuperscript{5, 15, 72, 94, 105, 107, 129, 130}

The literature concerning the effect of a central screw on primary fixation is limited.\textsuperscript{15, 22, 94} Some studies have investigated scapular anatomy to identify regions that may maximize screw purchase have investigated fixation strength,\textsuperscript{2, 5, 15, 98, 103} while others have investigated the individual effects of various screw-types and configurations on baseplate micromotion, including
peripheral screw positioning, \textsuperscript{1, 4, 19, 106, 129, 131} central screws,\textsuperscript{15, 22, 95} and locking versus nonlocking screws.\textsuperscript{1, 3, 5, 16, 96} Few studies have examined micromotion in osteopenic and osteoporotic bone, which is a common comorbidity associated with the RSA patient population.\textsuperscript{15, 18} These prior studies have shown glenoid micromotion to occur within or well beyond the osseointegration range, with factors such as a central screw, long central elements, long peripheral screws, a greater number of screws, and greater bone density showing a significant effect in reducing micromotion.\textsuperscript{15, 18, 19} A central screw that engages with the cortex of the scapula was shown to transmit most of the glenoid forces to the cortical bone, with the remaining forces carried by the cancellous bone.\textsuperscript{22}

Clinically, surgeons use various combinations of baseplate factors, however the literature concerning the biomechanical testing of multiple factors is sparse. Therefore, the purpose of this biomechanical study was to evaluate the effects of varying combinations of factors that affect RSA baseplate micromotion, specifically, the effects of central fixation element type, central cortical engagement, peripheral screw configuration, and cancellous bone density, under simulated physiological loading in a rigid PU bone surrogate. It was hypothesized that a central compression screw, cortical bone engagement via a longer central element, locking screws in the anterior and posterior positions, and greater cancellous bone density would increase the resistance of the baseplate to micromotion, and that an interaction would exist between central element type and the degree of cortical engagement.
3.2 Materials and Methods

3.2.1 Experimental Design

This study examined the effects of central fixation element type, central cortical engagement, peripheral screw configuration, and cancellous bone density on the micromotion of the Delta XTEND™ Reverse Shoulder System (DePuy Synthes, Warsaw, IN, USA). The resected glenoid bone was modelled with custom-made Sawbones™ rigid PU foam blocks (Pacific Research Laboratories, Vashon Island, WA, USA) of two, different cancellous densities (10 pounds per cubic foot [pcf] and 25 pcf), laminated over a higher density block (30 pcf), which was used to represent the cortical bone density of the scapula. Delta XTEND™ baseplates were implanted within the PU blocks. Four linear variable differential transducers (LVDTs; Orbit 3, Solartron, Metrology, West Sussex, United Kingdom), mounted to the PU block, measured the micromotion of the glenoid baseplate from a surrounding measurement disc that was welded to the glenosphere. Sinusoidal loading was applied to the glenoid components at a fixed humeral abduction angle of 60°, in line with the long axis of the humeral component.

The experiment was designed as a half-fractional factorial design (number of conditions = 2^{k-1}) and tested four factors (k = 4) at two levels each: central element fixation (central peg versus central screw), level of cortical bone engagement based on central element length (13.5 mm versus 23.5 mm), anterior-posterior (A-P) peripheral screw type (nonlocking versus locking), and bone surrogate density (10 pcf versus 25 pcf). This experimental design created eight unique conditions that omitted higher order interactions (Figure 3-1).

The central screw baseplates were modified from original Delta XTEND™ central peg baseplates by removing the peg and milling a countersunk hole that could accommodate a 6.5 mm diameter central cancellous screw (Figure 3-2; Product #218.030, DePuy Synthes,
Warsaw, IN, USA). Central screw lengths were selected to match the two lengths of central pegs used in this study. The thickness, 16 mm of each Sawbones™ cancellous bone surrogate layer, was chosen to prohibit deep cortical bone surrogate engagement of samples with a 13.5 mm central element, while allowing 23.5 mm central elements to engage with the 30 pcf cortical block. This bone surrogate design allowed for at least three threads of the central screw to engage with the cortical block (Figure 3-3). Locking screws were used in the superior and inferior screw positions for all samples and were inserted at a divergence angle of 17°, in accordance with the manufacturer recommendations (Appendix C). Nonlocking (Product #130770024, DePuy Synthes) or locking screws (Product #130790024, DePuy Synthes) were used in the A-P screw positions and both peripheral screw types had identical lengths (24 mm). Each of the eight conditions were repeated five times for a total of 40 trials (N = 40). Testing order was randomized.
Figure 3-1. Section views (transverse plane with respect to anatomical position) of baseplate factor combinations: central element length, nonlocking versus locking, and central peg versus screw. Inferior, central, and superior fixation elements are shown. Anterior and medial elements are out of plane and not shown. Each baseplate combination was implanted in either 10 pcf or 25 pcf cancellous PU foam. Long central elements engaged with the denser (30 pcf) PU foam of the bone surrogate.
Figure 3-2. The modified Delta XTEND™ central screw (front) and original central peg baseplates (back).
Figure 3-3. Custom-made Sawbones™ rigid PU foam blocks with a 16 mm thick cancellous layer laminated over a 30 pcf cortical density block.
3.2.2 Biomechanical Testing

A materials testing system (Bionix Servohydraulic Test System; MTS Systems Corporation, Eden Prairie, MN, USA) applied a compressive load range of 500 N in the inferior-to-superior (I-S) and lateral-medial (L-M) direction, at a frequency of 1 Hz, for 1000 cycles to simulate peak loads experienced by the shoulder while performing activities of daily living (e.g., brushing one’s hair; Figure 3-4). This cyclic load was chosen to simulate shoulder loading within the first three post-operative months, which are the most important for osseointegration of the baseplate.7 According to Harman et al., 1000 cycles of loading is sufficient for preclinical evaluation of the primary fixation of glenoid components.94 The PU foam block was mounted at 60° to the loading platform, which corresponded to 60° of glenohumeral abduction and simulated the largest joint reaction forces experienced at the glenoid surface.7,132 The load cell (Force Transducer; MTS Systems Corporation, Eden Prairie, MN, USA) had a measuring a capacity of 5 kN and a precision of 5 N. The 500 N sinusoidal load range was applied after taring at 20 N. The authors’ previous study (Chapter 2) found a MAPE of (9.5±0.9)% for this testing apparatus.
Figure 3-4. The experimental configuration used for each. Implants were cyclically loaded with a 500 N load range and a 20 N minimum sinusoidal load at 1 Hz for 1000 cycles.
Four LVDTs were fastened within a 3D-printed supporting fixture that was secured to the PU foam bone surrogate via Steinmann pins and measured displacements of the implant from the measuring disc in the M-L direction. The LVDTs had a resolution of 3 µm and a measuring range of 2000 µm. The glenosphere measuring disc served to expand the area of the implant plane to allow each of the four LVDT probes to record the displacement of the implant relative to the PU block. Micromotion of the PU-foam-implant interface was determined by defining the implant plane based on the measurements obtained from the glenosphere disc and interpolating its displacement to the four respective screw positions. All LVDTs were zeroed prior to loading and the micromotion values obtained from the last 10 loading cycles were used for analyses. Recorded displacements were corrected to account for any migration of the implant by comparing pre- and post- load calibration measurements.

3.2.3 Statistical Analysis

Micromotion was quantified as the displacement range at the implant-PU interface, averaged over the last ten cycles of loading. A non-parametric Kruskal-Wallis $H$ test with a univariate analysis was used to determine the main and interaction effects of the factors on micromotion. A Bonferroni correction was used to reduce the likelihood of a Type I error when making multiple comparisons. Significance was defined with alpha of 0.05, $p < 0.05$.

3.3 Results

Central peg fixation generated greater micromotion at all four screw positions compared to samples that were implanted with a central screw ($p < 0.001$; Table 3-1). The greatest mean micromotion overall (295 ± 67 µm) was recorded from condition 1, which included samples with
a 13.5 mm central peg with nonlocking A-P screws in 10 pcf PU foam. Condition 5 had the second greatest mean micromotion of 138 ± 34 µm and included samples with a 13.5 mm central peg. The average micromotion at each screw position, respective of condition, can be seen in Table 3-2; Figure 3-5 shows the associated boxplot.

A significant effect was observed for cortical bone engagement, with shorter central pegs generating greater micromotion compared to samples with a longer peg or screw ($p = 0.001$). These results are reflected in Figure 3-6. Significant interactions were observed between the central element and its length/level of cortical bone engagement at all four screw positions ($p < 0.001$). In addition, an interaction effect was observed between A-P peripheral screw type and bone surrogate density at all four screw positions (inferior: $p = 0.006$; anterior: $p = 0.007$; superior: $p = 0.008$; posterior: $p = 0.006$).

Table 3-1. Micromotion for all factors with results from the Kruskal-Wallis H test.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Inferior Mean (µm)</th>
<th>Inferior SE</th>
<th>Inferior p</th>
<th>Anterior Mean (µm)</th>
<th>Anterior SE</th>
<th>Anterior p</th>
<th>Superior Mean (µm)</th>
<th>Superior SE</th>
<th>Superior p</th>
<th>Posterior Mean (µm)</th>
<th>Posterior SE</th>
<th>Posterior p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central fixation</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peg</td>
<td>138 ± 26.7</td>
<td>134 ± 26.2</td>
<td>123 ± 23.5</td>
<td>126 ± 23.8</td>
<td>30.1 ± 5.6</td>
<td>31.9 ± 4.7</td>
<td>36.2 ± 3.8</td>
<td>34.3 ± 4.0</td>
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</tr>
<tr>
<td>Central length</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>13.5mm</td>
<td>136 ± 27.4</td>
<td>133 ± 26.7</td>
<td>124 ± 23.4</td>
<td>126 ± 23.9</td>
<td>31.8 ± 3.9</td>
<td>35.6 ± 3.6</td>
<td>35.6 ± 3.6</td>
<td>34.1 ± 3.4</td>
<td>3.4 ± 0.9</td>
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</tr>
<tr>
<td>23.5mm</td>
<td>104 ± 29.1</td>
<td>104 ± 28.5</td>
<td>98.2 ± 25.4</td>
<td>98.1 ± 25.4</td>
<td>64.0 ± 12.8</td>
<td>62.3 ± 11.2</td>
<td>61.3 ± 10.3</td>
<td>62.5 ± 11.3</td>
<td>11.3 ± 0.9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>A/P Peripheral screw type</td>
<td>0.218</td>
<td>0.181</td>
<td>0.180</td>
<td>0.209</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonlocking</td>
<td>104 ± 29.1</td>
<td>104 ± 28.5</td>
<td>98.2 ± 25.4</td>
<td>98.1 ± 25.4</td>
<td>64.0 ± 12.8</td>
<td>62.3 ± 11.2</td>
<td>61.3 ± 10.3</td>
<td>62.5 ± 11.3</td>
<td>11.3 ± 0.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locking</td>
<td>105 ± 29.0</td>
<td>105 ± 28.4</td>
<td>99.0 ± 24.7</td>
<td>99.1 ± 25.2</td>
<td>63.0 ± 12.8</td>
<td>61.5 ± 11.4</td>
<td>60.5 ± 10.7</td>
<td>61.5 ± 11.6</td>
<td>11.6 ± 0.9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3-1. Micromotion for all factors with results from the Kruskal-Wallis H test.
Figure 3-5. Box-Whisker plot of the average micromotion measured for each condition. Outliers were defined as values that exceeded the 95% confidence intervals (CI). The 50 – 150 µm osseointegration range is highlighted with green. The greatest micromotion was found for the 13.5 mm central peg in both 10 pcf and 25 pcf PU foam, indicated with red arrows.

Table 3-2. Mean micromotion from each screw position for each of the eight conditions.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Inferior (µm)</th>
<th>Anterior (µm)</th>
<th>Superior (µm)</th>
<th>Posterior (µm)</th>
<th>Average (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Peg/13.5 mm/NL/10 pcf</td>
<td>317</td>
<td>310</td>
<td>274</td>
<td>280</td>
<td>295</td>
</tr>
<tr>
<td>(2) Screw/13.5mm/NL/25pcf</td>
<td>38.8</td>
<td>39.5</td>
<td>39.5</td>
<td>38.8</td>
<td>39.2</td>
</tr>
<tr>
<td>(3) Peg/23.5mm/NL/25pcf</td>
<td>43.8</td>
<td>46.0</td>
<td>49.3</td>
<td>47.1</td>
<td>46.6</td>
</tr>
<tr>
<td>(4) Screw/23.5mm/NL/10pcf</td>
<td>16.0</td>
<td>20.0</td>
<td>30.4</td>
<td>26.4</td>
<td>23.2</td>
</tr>
<tr>
<td>(5) Peg/13.5mm/LK/25pcf</td>
<td>146</td>
<td>137</td>
<td>131</td>
<td>91.4</td>
<td>138</td>
</tr>
<tr>
<td>(6) Screw/13.5mm/LK/10pcf</td>
<td>42.5</td>
<td>44.8</td>
<td>52.0</td>
<td>49.7</td>
<td>47.3</td>
</tr>
<tr>
<td>(7) Peg/23.5mm/LK/10pcf</td>
<td>44.0</td>
<td>43.7</td>
<td>40.0</td>
<td>40.2</td>
<td>42.0</td>
</tr>
<tr>
<td>(8) Screw/23.5mm/LK/25pcf</td>
<td>23.2</td>
<td>23.4</td>
<td>22.7</td>
<td>22.5</td>
<td>23.0</td>
</tr>
</tbody>
</table>

NL: non-locking A-P screws; LK: locking A-P screws
Figure 3-6. Grouped boxplot comparing each of the eight baseplate factors. A statistically significant difference was found for the central element type and level of cortical bone engagement, indicated by an asterisk ($p \leq 0.001$).
3.4 Discussion

This *in vitro* study examined the effects of central element fixation, cortical engagement based on central element length, A-P peripheral screw type, and bone surrogate density on RSA baseplate micromotion. Prior work has suggested a micromotion threshold of 50 – 150 µm as the optimal osseointegration standard for long-term baseplate fixation.4, 15, 18, 103, 105, 107, 108, 128 The results of the current study partially confirmed what was hypothesized, that a central compression screw and cortical bone engagement via a longer central element would result in decreased micromotion of the baseplate relative to the PU foam, and that an interaction would exist between central element type and the length required to achieve purchase with the cortex. However, the micromotion generated when using locking screws in the A-P screw positions or higher density PU foam was not statistically different from the micromotion generated with nonlocking screws or lower density PU foam, respectively. An interaction existed between central element type and level of cortical engagement, as well as between A-P peripheral screw type and bone surrogate density, which suggests that a central screw that cortically engages with the scapula and A-P locking screws in lower density bone may reduce post-operative micromotion.

The micromotion measured for each condition varied with respect to the osseointegration thresholds and three test conditions (3, 5, 6) had experienced micromotion near or within the 50 – 150 µm range. It is important to note that this is a suggested range for *in vivo* osseointegration. The micromotion for condition 6 (138 ± 34 µm), which was tested in 25 pcf PU foam, were within the threshold range, and conditions 3 and 5, which were tested with 25 pcf and 10 pcf PU foam, respectively, had average micromotion near the lower limit of 50 µm (46.6 µm and 47.3 µm, respectively). Conditions 2, 4, 7, and 8 fell below the lower limit (39.2 µm, 23.2 µm, 42.0 µm, and 23.0 µm, respectively). Condition 1 was the only condition to exceed the upper threshold.
(295 ± 67 µm), indicating a lower primary fixation compared to other conditions. \textit{In vivo} micromotion in this range renders bone ingrowth impossible and permits only the ingrowth of fibrous tissue. In summary, these results suggest that either a long central peg, that engages with the cortex of the scapula, with nonlocking A-P screws, or a short central peg that lacks cortical engagement, but uses locking A-P screws, may be suitable for implantation within nominally healthy cancellous bone densities. Furthermore, a short central screw baseplate with locking A-P screws may provide adequate fixation in both low and healthy cancellous bone densities, however, further \textit{in vivo} testing is required to substantiate these claims.

There is a paucity of literature comparing the effects of a central screw with a central peg on baseplate micromotion. In theory, central screw baseplates offer enhanced post-operative fixation due to the initial M-L compression applied by the screw, although the screw itself lacks the long-term on-growth potential of a HA-coated peg.\textsuperscript{14} The results presented here indicated that greater primary fixation is achieved with a central compression screw, which conflicts with the findings of Harman et al., who demonstrated no significant difference between the two central element types.\textsuperscript{94} Although, it is important to note that their experiment compared two different RSA baseplate designs, while the present study compared one baseplate design with a central element modification. A study by Hast and colleagues tested a single baseplate design, with or without a central screw in both PU foam and cadaveric specimens, and found a greater resistance to dislodgement with the use of a central screw in the cadaveric specimens, but not the PU foam.\textsuperscript{15} Their methodology differed from the present work in that the central screw provided additional depth to the implant construct, likely providing greater resistance to the applied moment.\textsuperscript{15} Furthermore, the present study included a layer of higher density PU foam for longer central elements with which to engage in order to simulate cortical engagement. Nonetheless, the results
from the cadaveric cohort support the notion that the initial M-L compression applied by the central screw reduces baseplate micromotion. Another study conducted by Ahir et al. assessed the fixation of a central screw implant with FEA. Their results showed that most of the forces were transmitted from glenoid component to the cortical bone of the scapula, with the remaining load being carried by the cancellous bone. In the present study, the average micromotion experienced by samples with a central screw and a long central element fell roughly 15 – 20 µm below the lower osteointegration threshold of 50 µm. Implant displacement in this range may negatively affect osseointegration by limiting the effect loading has on stimulating bone deposition.

In contrast to past findings, no statistically significant difference was observed, when varying bone surrogate density. A prior study by Lung et al. observed a significant effect of bone surrogate density when comparing implant micromotion healthy (24 pcf) versus osteoporotic (10 pcf) bone surrogates made with PU foam. Their results showed greater micromotion in lower density bone surrogates compared to greater density PU foam. Lung et al. also compared the effect of central peg length on baseplate fixation and found that a longer central peg significantly reduced micromotion. The results of the present experiment echoed these findings; however, it is important to note that the bone surrogate used by Lung et al. did not include a cortical density PU foam layer and therefore did not assess the effect of cortical engagement.

To date, the authors are not aware of existing studies that have assessed the effects of central element fixation, cortical engagement based on central element length, anterior-posterior (A-P) peripheral screw type, and cancellous bone density, in combination, on glenoid baseplate micromotion. These factors have been investigated individually, however, until now, their interactions were uncharacterized. Locking screws were used in both the inferior and superior screw positions for all samples in this experiment, as per the recommendations outlined in the
manufacturer’s operative guidelines. Given that physiological loading of the glenoid during abduction primarily occurs in the I-S direction, placement of the inferior screw is most critical since it is in the position that receives the greatest tensile load.\textsuperscript{1, 7} The results from this experiment demonstrated that locking screws in the A-P positions had no observable effect on baseplate micromotion, consistent with the findings of previous studies. A study that evaluated peripheral locking screw configurations using 1 – 4 peripheral locking screws found no significant difference in baseplate micromotion.\textsuperscript{96} Likewise, a cadaveric study by Abdic and colleagues found no statistically significant difference between S-I and A-P locking screw configurations.\textsuperscript{16} Therefore, it is likely that the use of a full locking screw configuration is not required to achieve optimal baseplate fixation, although, the current study did not evaluate other peripheral screw variables, such as angle and length.

This study has several limitations. This study evaluated primary fixation for a single implant design with a limited combination of factors. Although primary fixation is associated with secondary fixation, this \textit{in vitro} study could not evaluate osseointegration and long-term fixation. The factors investigated did not include other variables that contribute to glenoid baseplate primary fixation, such as peripheral screw angle and length, graded glenoid defects or lateralization of the glenoid center of rotation. The strength of this study was its ability to test multiple baseplate factors and their interactions in a standardized model; however, it is important to note that the half-fractional factorial design of this experiment confounds 2-factor and 3-factor interactions. This was an accepted risk of the design, given that 3-factor interactions were unlikely to be clinically significant. Testing occurred in PU foam bone surrogates to minimize variation between samples and accommodate a greater number of factors, although further testing is required to validate the present results. Considering that this was an \textit{in vitro} biomechanical study, future work involving
the factors discussed may benefit from testing in anatomically correct Sawbones™ models, which may more accurately simulate in vivo cortical engagement, or cadaveric specimens, which bear the closest resemblance to in vivo conditions. In addition, the present data can be used to validate an FEA model that assesses these factors independently and collectively, to further strengthen these conclusions. Understanding the effects of the central screw versus the central peg would be of particular significance to corroborating the present results.

In nominally healthy bone densities, clinicians may consider the use of either a long central peg baseplate with nonlocking A-P screws, or a short central peg with locking A-P screws. When treating osteoporotic shoulders, a shorter central screw baseplate with locking A-P screws may provide baseplate primary fixation that allows for osseointegration. A central screw, as well as central elements that engage with the cortex of the scapula may reduce implant micromotion and improve primary fixation of RSA glenoid components.

3.5 Conclusions

In reverse shoulder arthroplasty, a central compression screw and cortical engagement via a long central element may reduce glenoid baseplate micromotion. These findings highlight the importance of a central compression screw and central element cortical bone engagement in improving RSA glenoid primary fixation. Furthermore, the results suggest that in nominally healthy cancellous bone densities either a long central peg, that engages with the cortex of the scapula, with nonlocking A-P screws, or a short central peg that lacks cortical engagement, but uses locking A-P screws, may provide adequate primary fixation. In addition, a short central screw baseplate with locking A-P screws may also maintain micromotion within 50 – 150 µm in both
osteoporotic and healthy cancellous bone densities. Further studies are required to validate these results, in vivo. The cumulative results serve to inform surgical decision-making regarding baseplate fixation elements to minimize the risk of glenoid loosening and thus, the need for revision surgery.
Chapter 4

DISCUSSION

4.1 Summary and Conclusions

The main contributions of this thesis were the determination of the accuracy of the apparatus used to measure glenoid baseplate micromotion, and the quantifying of the effects of central element fixation, cortical engagement, A-P peripheral screw type, and cancellous bone density on micromotion. This thesis reviewed the relevant literature pertaining to the various factors that affect glenoid baseplate micromotion in RSA. Specifically, the various models for testing baseplate micromotion, properties of the glenoid baseplates, and prior research regarding RSA micromotion testing with a specific focus on central element fixation, central cortical bone engagement, peripheral screw type, and scapular bone quality.

RSA is often used to treat patients with CTA, glenohumeral arthritis, proximal humerus fractures, and failed prior shoulder arthroplasties. Glenoid baseplate loosening is the main complication that requires revision surgery and optimizing the factors that contribute to loosening is an important topic of discussion with the design of new RSA implants. A variety of factors have been investigated, however, the literature regarding the effects of central screw fixation, central cortical engagement, peripheral screw configuration, and bone density are limited. Therefore, this thesis aimed to develop itself as a resource to inform the “surgineering\textsuperscript{133}” community about possible RSA design benefits and caveats, as well as to provide information regarding glenoid baseplate stability using a combination of factors that have not yet been investigated.
The first objective of this thesis was to characterize the accuracy of the mathematical model used to interpolate baseplate micromotion. This was done using the vector algorithm described in Chapter 2 to predict the displacement of one of the four LVDT probes. The measured and predicted displacements were compared and used to calculate the MAPE for each sample, yielding a conditional range of 6.8% to 12.9% and an overall MAPE of (9.5±0.9)%. The MAPE of the system fell below 10% (error range: 2.7 – 20.1 µm), which represented an acceptable margin of error and reasonably good predictive accuracy. How this accuracy compares to prior studies of a similar nature is relatively unknown, since the accuracies of systems that use displacement transducers have not yet been reported, however, it has been suggested that use of digital image and digital volume correlation provides a more accurate measurement system for baseplate micromotion, compared to the use of displacement transducers.\textsuperscript{117, 122} The error range was lower than those reported by previous studies that used optical tracking systems,\textsuperscript{100, 101} indicating better precision. Fulfilling this objective served to support the results of the experiment outlined in Chapter 3.

The second objective was to determine the effects of central element fixation, cortical bone engagement, A-P peripheral screw type, and cancellous bone density on glenoid baseplate micromotion. Once the accuracy of the apparatus was determined, the micromotion measurements obtained during mechanical loading of the various baseplate configurations was analyzed. It was found that condition 1 (13.5 mm central peg without cortical bone engagement, nonlocking A-P screws, 10 pcf cancellous bone) exceeded the upper threshold of the 50 µm – 150 µm osseointegration range. This was expected, as this combination of factors was thought to have the lowest fixation potential compared to the other conditions. Condition 5, which also included a short central peg, had the second greatest micromotion of all conditions, highlighting the importance of cortical bone engagement when using a central peg with a length that exceeds the
cancellous bone stock of a patient. When considering baseplates that omitted cortical bone engagement, those that included a short central screw provided much greater fixation compared to that of a short central peg. Regarding the individual baseplate factors, use of a central screw and central cortical bone engagement effectively reduced glenoid baseplate micromotion. This was likely due to the enhanced initial fixation provided by the compression of the central screw and the ability of longer central elements engaged with higher density bone to provide greater resistance to externally applied moments. Locking screws in the A-P positions did not have a significant effect, likely since the inferior and superior locking screws provided most of the peripheral resistance of the baseplate to moments generated during simulated humeral abduction. Varying cancellous bone density also showed no significant effect, however, this was likely confounded due to the cortical bone engagement experienced by half of the samples. These results partially confirmed the stated hypothesis that a central compression screw and cortical bone engagement via a longer central element would result in decreased micromotion. Furthermore, an interaction existed between central element type and cortical engagement, as hypothesized, as well as between A-P peripheral screw type and cancellous bone density.

In summary, the main contributions of this thesis were the determination of accuracy of the micromotion apparatus (overall MAPE of (9.5±0.9)%; error range: 2.7 – 20.1 µm) and the findings of the biomechanical testing of baseplate micromotion. These findings demonstrated that the use of a central compression screw, and cortical bone engagement via a longer central element, reduced baseplate micromotion. In addition, interactions were noted between central element type and cortical engagement, as well as between A-P peripheral screw type and cancellous bone density. This indicated that a factor combination that uses a long central screw that engages with
the scapular cortex and locking A-P screws in nominally healthy cancellous bone may result in the greatest reduction of the micromotion experienced by glenoid baseplates during primary fixation.

4.2 Limitations

The study presented here had various limitations. Regarding measurement accuracy, systematic error may have arisen from an imperfect calibration of the LVDT probes, which was done by measuring the height of a calibration coupon with each LVDT, and/or from subtle variations between samples with regards to surgical technique. In the context of *in vitro* biomechanical experiments, these sources of error are mostly unavoidable. Despite these faults, the MAPE of the present system validated this model as an acceptable methodology for reporting accurate micromotion measurements. An FEA model that has been validated with the present results can be used to better understand the system and would eliminate the physical sources of error. In addition, the use of digital image and digital volume correlation to evaluate baseplate micromotion may further develop the understanding of the impact of apparatus accuracy on micromotion results.

The present study was limited as it evaluated a limited number of glenoid baseplate factors on one specific RSA design. Given that that are an extensive variety of baseplates available for surgical use, it is fair to infer that their respective fixation properties differ. One central screw or central peg baseplate may behave in subtly different ways than another when tested biomechanically. Furthermore, the central screw baseplate used in this study was custom-modified and does not bear any relation to any of the existing central screw baseplates available on the market.
The strength of this study was its ability to test multiple baseplate factors and their interactions. Testing occurred in PU foam bone surrogates to minimize the variation between samples and accommodate a greater number of factors. The half-fractional factorial design of this experiment confounded second-order and third-order interactions, but this was acceptable given that third-order interactions are unlikely to be clinically relevant. This study biomechanically evaluated glenoid baseplate fixation, \textit{in vitro}, with the use of Sawbones™ PU foam, therefore, the anatomical variations that are typically seen in the clinical population were not accounted for. Cortical bone engagement was modelled with higher density PU foam such that at least three central screw threads, and the equivalent central peg length, could fully engage with the cortex on all sides of the element. Due to the scapular anatomies of some patients, full central element purchase on all sides may not be possible, and how this would affect glenoid baseplate micromotion remains unclear. PU foam may only partially reflect baseplate behavior in clinical cases due to varying scapular anatomies, however, the use of PU foam serves as an initial standard to which more advanced, yet varied, representations of \textit{in vivo} bone can be compared. This study examined the effect of peripheral screw type at two positions, A-P, and did not evaluate other possible locking screw configurations or factor in additional peripheral screw properties, such as variable insertion angles and lengths of the screws.

4.3 Future Direction

The work outlined in this thesis is unique in that it examined the combined effects of central element fixation, cortical bone engagement, A-P peripheral screw type, and cancellous bone density on glenoid baseplate micromotion. To further this work, replication studies can be performed and should address the limitations discussed. Replication of this experiment using
measurement techniques such as DIC or DVC with micro-CT, and a modified micromotion apparatus, may allow for further development of an understanding of the accuracy limitations of the present methodology. In addition, the use of anatomically-correct Sawbones™ specimens may elucidate the effects of partial central cortical bone purchase on micromotion. A logical follow-up may also include the biomechanical evaluation of the factors that had a significant effect on micromotion in this study (i.e., central screw fixation, cortical bone engagement) in cadaver specimens, to provide more clinically applicable results. As previously mentioned, the present results can be used to validate a replicated FEA model and would serve as a useful comparison that would eliminate any of the potential physical sources of error encountered during this experiment. Finally, an evaluation of additional factor combinations that include augmented baseplate designs, graded glenoid defects, and/or lateralization of the center of rotation, would further contribute to the understanding of factors that affect glenoid baseplate fixation, and their interactions.

4.4 Clinical Significance

The use of RSA is expected to climb with the increase in population of patients aged 65 and older. With this increase, clinicians can expect to encounter a wider variety of osseous morphologies and consequently, surgical complexities. Developing an understanding of the factors that can address these issues before they arise could potentially reduce procedural times, thus reducing healthcare costs, extend the lifespan of the implant, and provide patients with greater relief and satisfaction.

The findings discussed herein highlight the potential of the use of a central compression screw and a longer, cortically engaging central element in improving RSA baseplate fixation. The
initial M-L compression imparted by a central screw may provide greater initial fixation, post-operatively, allowing for micromotion to remain within the acceptable osseointegration range. Cortical bone engagement with the scapula via the baseplate’s central element could potentially offset anticipated instability in patients with osteoporotic or osteopenic cancellous bone, and the use of a full locking screw configuration may not be required to achieve adequate baseplate fixation. Additionally, the use of either a long central peg baseplate that engages with the cortex of the scapula, with nonlocking A-P screws, or a short central peg that lacks cortical engagement, but uses locking A-P screws, may be suitable for implantation in patients with nominally healthy cancellous bone. A short central screw baseplate with locking A-P screws may also provide adequate fixation for patients with either nominally healthy bone, osteopenic, or osteoporotic bone. Given that the literature regarding baseplate central fixation is relatively limited, it is our hope that this work will positively contribute to the existing body of research on the factors contributing to RSA implant fixation and accelerate the improvement of RSA baseplate design.
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References


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Appendix A

Sawbones™ Shop Drawing

PU block with cuts
Appendix B

MICROMOTION STANDARD OPERATING PROCEDURE

The following steps are the instructions for operating the MTS machine and preparing the experimental configuration in the context of micromotion testing.

MTS System

1. Ensure that the hydraulic pump in the Environmental Services room (located across the hall from the Biomechanics Lab) is ON and in the “Ready” state.
   a. Make sure that the E-Stop button on the MTS is released.

2. Return to the Biomechanics Lab and turn on the MTS designated computer to the right of the MTS machine.
   a. Login to the Administrator account; password → admin.

3. Open Station Manager by clicking the desktop icon
   a. Open the station ConfigTemplate.cfg
   b. Ensure that MicromotionTesting1 is selected.
   c. Click Open.
   d. Click Applications, select Basic TestWare.
4. Check that the Test Name is **Warm Up.tst**. If not, click the Open Test button in the Basic TestWare window. In the Open Test window select Warm Up.tst and click Open. The Basic TestWare window in Station Manager will now show the name Warm Up.tst.

![Basic TestWare](image)

5. In the Station Controls window you will see a red indicator beside **Interlock 1**.
   a. Click the Reset button.
   b. If you cannot reset Interlock 1, refer to the troubleshooting case below. If you are able, proceed to Step 6.

🔗 Notes/Error messages:
Error Message Troubleshooting:

Example: *Torsional Torque Limit.*

Click Display > click Station Setup > expand Channels > expand Torsional > highlight Torque.

If the Invalid Detect indicator is red, open the dropdown menu and deselect Invalid Signal by clicking Indicate. You should now be able to reset Interlock 1.
6. In the Station Controls window, check the **Exclusive Control** box.  
      i. Click the **Low Power** button.  
      ii. Wait for the Low Power button to stop blinking.  
      iii. Click the **High Power** button. It will stay green and you will hear the MTS powering up.

7. In the Basic TestWare window, select **Axial** from the Channel dropdown menu to initialize the actuator for tension/compression.

8. Under **Test Counters** click to reset the **Current** count to zero.

9. Prepare the MTS actuator prior to running the Warm Up program.  
   a. Confirm that the **5 kN Load cell** is secured to the actuator and is plugged in to the MTS.  
   b. Attach the **upper loading fixture** that contains the **concave polyethylene block** to the load cell.  
   c. Apply a small amount of **lubricant** to the concave surface of the polyethylene.  
   d. If necessary, adjust the distance of the crosshead from the imagined sample.  
      i. Loosen the four bolts at the periphery of the crosshead.  
      ii. Tilt the nob near the E-stop button on the MTS until you’ve achieved the desired height.
e. To adjust the distance of the upper load cell via the MTS actuator, click the Manual Command button in the Station Controls window. This will open the Manual Command window.

i. Click the box to Enable Manual Command. Ensure that the channel is set to Axial and that the Control Mode is Displacement.

ii. Use the sliding scale towards the positive 105.00 value to raise the upper load cell.

iii. Uncheck the Manual Command box and return your attention to the Station Controls window.

10. Click the Program Run button to run the Warm Up program. The MTS will now warm up by oscillating for 1000 cycles. This takes approximately 17 minutes.

   a. While the MTS is warming up you can start preparing the sample for testing.

   Ensure that you keep your hands, and any other appendages clear of the hydraulic actuator while it is in motion!

Sample Preparation

11. Begin preparation of the sample by surgically implanting the baseplate according to the Delta XTend (DePuy Synthes) operative guidelines for the unmodified central peg baseplate.

   a. Ensure that there is full contact between the Hydroxyapatite-coated surface of the inferior baseplate and the Sawbones block. Be sure not to ream too deeply into the sample such that the implant is counter sunk.

   b. Record three measurements for both the diameter and the depth of the reamed area using digital Vernier calipers. Note the averages.

Guidelines for the central screw baseplate:

   i. After reaming, use the pin driver drill attachment to remove the guide pin.

   ii. Using the marked drill bit accompanying the central screw baseplate, drill into the hole that was left by the guide pin until the appropriate depth is achieved (marked by a piece of tape).

   iii. Position the baseplate in the ream area and begin inserting the central screw.

12. Slide the square of the LVDT fixture over the block and rest it on the vice. Ensure that the distance between the top of the LVDT fixture is roughly 18–20mm from the top face of the Sawbones block.

13. Using a drill, insert the four Steinmann pins through each of the designated holes to secure the LVDT fixture to the Sawbones block.

14. Place the welded glensphere over the baseplate and apply a small amount of lubricant to the contact patch.
**Loading Platform**

15. Place the small aluminum **loading platform** with the **5-axis vice** onto the MTS loading area.
   a. Secure platform into the channels using the Allen keys indicated below.
   b. Secure the experimental specimen using the 5-axis vice. Ensure that the bottom face of the sample is aligned with the bottom edge of the vice.
   c. Adjust the tilt of the vice (if necessary) to ensure that the sample is positioned at 60 degrees to the plane of the loading platform and ensure that the sample’s plane is aligned with the plane of the crosshead.
      i. To confirm the angle, use the **AngleCube**. If necessary, you can further adjust the height of the upper loading fixture to accommodate the sample (refer to Step 9c/d.)

**LVDTs**

16. The yellow protective case contains the **LVDT modules**. Unload them very carefully and be sure not to drop the probes or the modules. You may use your own laptop or the designated Dell laptop. If using the Dell laptop, keep it connected to a power socket via the adapter.
   a. If using your personal laptop, download the Orbit3 Excel® Add-in. Instructions can be found [here](#).

17. Slide the LVDT probes into the LVDT fixture at the position perpendicular to each face of the Sawbones block, in-line with the peripheral screw positions. The socket fasteners may need to be loosened using a 2.5mm Allen key.

18. Return to the Station Manager program on the MTS desktop and click the Auto Offset button under Station Controls.
   a. Click [Auto Offset](#) in the Station Signals window. This will zero the displacement and force values of the upper load cell.
   b. Close the Station Signals window.
   c. Disable Station Manager control by deselecting the Exclusive Control box.

**Multipurpose Elite**

19. Open Multipurpose Elite by clicking the desktop icon [mpelogo](#).
   a. In the left-hand Explorer panel, click on Procedure and check the loading conditions to ensure they are set correctly for the cyclic loading pattern needed for the test. When clicked, the force values, times, and applied loading frequencies in the cyclic loading program box can be adjusted as necessary in the Properties panel on the right.

20. Select the name of the test, 0001-Lawrence-Glenoid Micromotion, in the Explorer panel.
   a. Click [New Test Run](#) on right hand side.
   b. Add new item by clicking [NEW ITEM](#) on top right side of Specimen Selection window.
   c. Name the specimen (ex: Configuration 1) and click OK.
   d. In the Setup Variables window record the Date in the Comments Value and click OK.
   e. A new screen will appear with graphs above and meters below.
      i. Right click anywhere in the Meters tab to Add or Remove meters or to change a Unit.
      ii. Ensure that Axial Displacement, Time, and Axial Force 2 are displayed.
   f. Double check the applied force to ensure that it is consistent with what was specified in the Procedure.
21. Ensure that the four hex bolts on the MTS crosshead are tightened prior to running the test.

22. Create two additional sheets and name each of them, “Initial Calibration”, “Test”, and “Final Calibration”, respectively.

23. Open Microsoft Excel and connect the LVDTs’ USB cable to a functioning USB port.
   a. In Excel, go to the Add-Ins tab to access the Solartron Metrology Orbit panel.
   b. Click Connect to link the probes to the spreadsheet.

24. Click Settings and the Configuration window will appear with the Spreadsheet tab open.
25. For the initial setup, select SameRow. This will display the readings in the same cells where you can view the real-time measurements.
   a. Stop After Enter or Spacebar.
   b. Sample On Timer.
   c. Check the Display Module ID Headings box to label the columns by LVDT module.

26. Select the Orbit Networks tab.
   a. Click Find All Modules.
   b. Select each module and ensure that the resolutions are set at 14 bits.
   c. Change the averaging to 1 count for each module to reduce jitter.
   d. Click Update or it won’t save.
   e. Click OK in the Configuration window.

27. Click Zero Modules in the Excel Add-Ins tab and zero all LVDT modules.

28. Click Take Readings or press Enter/Spacebar to begin recording. Position the LVDTs such that they are making contact with the glenosphere disc and measurements begin to appear on the spreadsheet.
   a. Each LVDT should ideally be positioned such that the measurement probe is approximately halfway down the LVDT’s total stroke length/resolution.
      i. The total stroke length is 2.00mm, so continue taking readings and adjusting the probes until each of them is as close to 1.00mm as possible.
29. Once all of the LVDTs have been set in the proper configuration and each probe is about halfway down the stroke length at 1.00 mm, the Settings in the Excel file should be modified for data acquisition. Open Settings.
   a. **Confirm that the appropriate worksheet is selected.**
   b. Double check that the Sample On setting is set to Timer.
   c. Enable the readings to be placed in the NextRow.
   d. Stop recording after 500 readings.
   e. Set the Delay to 0.05 sec.
   f. Ensure that Display Module ID Headings is enabled.
   g. Click OK to save these settings.

30. Click **Take Readings** to start recording. The LVDTs will then record the 500 data points that were specified in the Settings. Ensure that the Worksheet Name is set to “Calibration” for this round of readings.

30. Return to the Multipurpose Elite program and run the test by clicking **.**
   a. Ensure that the applied force stays consistent with what was specified in the Procedure.

31. About halfway through the loading cycle (around 9 minutes), set the Worksheet to “Testing” and take another set of data by clicking **Take Readings**.

32. Once the MTS program has finished its second run, set the Worksheet to “Final” and take the final set of readings in the Excel program.
   a. Save the file as “**Test ## – Length (Short/Long) – Central (Peg/Screw) – Peripheral (NL/LK) – Sawbones density (10/25).**
      E.g., 01-Long-Peg-NL-25
   b. Once testing is complete, save the file 0001-Lawrence-Glenoid Micromotion; close Multipurpose Elite.

33. In the Excel file on the laptop, ensure all data has been saved in the appropriate files with the appropriate names.
   a. Click the Disconnect button to disconnect the LVDTs.
   b. Copy all relevant testing data to a personal USB key.

34. Return equipment and parts to their homes. On the desktop computer, in the Station Manager program, enable Exclusive Control and power down HPU-J25 and HSM-J28 from High Power to Low Power, then to Off. Close the program and shut down the computer.
Appendix C

LVDT FIXTURE DRAWING
Appendix D

DEPUY SYNTHES DELTA XTEND™ OPERATIVE MANUAL
(pages 18-27, 35-41)

Positioning the Metaglene Central Peg

Position the plate as low as possible so that its border follows the inferior edge of the glenoid. Note that inferior osteophytes may result in malpositioning. X-rays should therefore be checked to avoid this problem.

Providing that the morphology of the glenoid hasn’t been altered by the disease, the guide plate is perpendicular to the plane of the glenoid face. Make sure that the proximal handle of the instrument is not tilted superiorly. The guide pin should be inserted either perpendicularly to the glenoid face or with the distal tip of the guide pin in a slightly superior direction. This ensures that the glenosphere will either be perpendicular to the plane of the glenoid face or have a slight inferior tilt which may reduce the risk of scapular notching.

Place the 2.5mm metaglene central guide pin in the plate is central hole and drill it through the far cortex using a power tool (Figure 25).

Remove the metaglene positioner, leaving the guide pin in place (Figure 26).

Note: The 2.5mm Breakaway Guide Pin (2230-00-019) may be used as a substitute for the Metaglene Central Guide Pin (2307-87-004).

The grooves on the 2.5mm Breakaway Guide Pin are exclusively used for the breakaway feature and are not intended to indicate the depth to which the pin should be inserted.

The pin is designed to break at the grooves. Be aware that it may break unintentionally if subjected to too much bending force.

After use of the guide pin is complete, confirm that all sections (totaling the full length of the original, unbroken pin) have been removed.
Reaming the Glenoid Bone

Slide the 27mm glenoid resurfacing reamer onto the central guide pin and ream either manually or using a power tool. This reamer prepares a smooth curved surface with the same diameter as the metaglene (Figure 27). Use the metaglene reamer carefully to avoid any inadvertent fracturing of the glenoid, especially if the glenoid is sclerotic. Make sure the axillary nerve is protected. Initiate and proceed with the reaming, turning at low speed prior to engaging the glenoid. It is useful to collect the osseous products of reaming and irrigate often to maximize visualization and thereby ensure optimal reaming. Be careful not to over ream and to preserve the subchondral bone.

Ream the superior glenoid bone by hand, using the manual 42mm glenoid reamer (Figure 28). This step is necessary to avoid any potential conflict between the glenosphere and the superior area of the glenoid bone (Figure 29).

Manual reaming should be carried out until the central part of the manual reamer is in full contact with the curved central glenoid surface.
Reaming the Glenoid Bone

Use the manual glenoid reamer to ream the glenoid anteriorly, posteriorly and inferiorly if necessary. A smooth surface without any remaining cartilage should be obtained.

Check the adequacy of the reaming by applying the glenoid reaming level checker on the glenoid surface. No space (except if due to bone erosion) should be seen between the instrument and the glenoid surface (Figure 30).

Remove the resurfacing reamer, leaving the metaglene central guide pin in place (Figure 31).

Referring to the chart below, connect the appropriate size cannulated stop drill to the power source and drill the central hole over the guide pin until full contact between the drill and bone is obtained (Figure 32).

Remove the stop drill and the central guide pin.

Note: After use of the guide pin is complete, confirm that all sections (totaling the full length of the original, unbroken pin) have been removed.

<table>
<thead>
<tr>
<th>Size</th>
<th>Metaglene</th>
<th>Cannulated Drill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (13.5mm)</td>
<td>1307-60-000</td>
<td>2307-89-000</td>
</tr>
<tr>
<td>+10mm</td>
<td>1407-60-020</td>
<td>2407-89-010</td>
</tr>
<tr>
<td>+15mm</td>
<td>1407-60-025</td>
<td>2407-89-015</td>
</tr>
</tbody>
</table>
Metaglene Implantation

Assemble the internal rod of the metaglene holder in the metaglene holder main body. Insert the metaglene holder hex tip in the desired final metaglene implant central hole and tighten the assembly. (Figure 33).

Place the metaglene on the glenoid bone and ensure that the metaglene is fully seated. Apply bone graft if necessary to help fill surface irregularities between the metaglene and the glenoid bone. Rotate the metaglene so that the inferior screw can be aimed toward the scapular neck. The vertical metaglene marking should be aligned with the scapular neck inferiorly and with the base of the coracoid process superiorly (long axis of the glenoid bone) (Figure 34). The metaglene peg is 0.6mm larger in diameter than the drill to enable a press fit. Gently impact with a mallet in the proper orientation for inferior screw placement and then remove the metaglene holder.

Figure 33

Figure 34
Inferior and Superior Metaglene Screw Placement

Locking metaglene screws allow an angulation of ± 10 degrees around the optimal 17 degrees screw positioning recommended by Professor Grammont (Figure 35).

Place the 2.5mm drill guide in the metaglene inferior hole. The drill guide can be angled to ± 10 degrees but should always be seated fully in the metaglene hole. Palpate the scapular neck and aim into good bone. Using the 2.5mm drill bit, start drilling through the subchondral bone to approximately 10 to 12mm deep (Figure 36). Then stop drilling and push gently on the drill bit to make sure that the drill is contained in the bone. Redirect and redrill if uncontained. When a satisfactory drilling direction has been obtained, drill and push until the cortex is perforated.
The goal is to have a sufficiently long screw inferiorly, usually 36mm or more. The length of the screw is indicated on the drill bit by laser markings (Figure 37). The screw depth gauge can also be used to assess optimal screw length.

Insert the 1.2mm guide pin through the drill guide and then remove the drill guide (Figure 38).

Slide the locking screw of the appropriate length onto the guide pin. Check that the internal tightening screw is unlocked (it should rotate freely) (Figure 39).
Inferior and Superior Metaglene Screw Placement

Slide the locking screwdriver body on the guide pin and insert the tip into the four slots on the screw (Figure 40). Do not use the internal screwdriver rod at this stage.

**Note:** Slide down the screwdriver sleeve completely to protect the screw head.

Tighten the screw to compress the plate (Figure 41a).

Remove the screw guide pin with the pin extractor before final tightening to avoid stripping, making sure that the internal locking screw stays in place.

Repeat the same steps for the superior locking screw.

**Note:** Use care to ensure that the driver remains in axial alignment with the screw so that the driver tip remains fully engaged (Figure 41b).

**Note:** The tip of the screwdriver can lose contact with the fins and does not torque evenly on all sides if the protecting sleeve is not used (Figure 41c).

**Note:** The protecting sleeve is not designed to lock onto the screw. It must be held in place with a finger during insertion.
Inferior and Superior Metaglene Screw Placement

Drill the hole for the superior locking screw anticipating exit through the far cortex using the same methods as Figure 36 (inferior screw placement) (Figure 42). The superior screw should be directed at the base of the coracoid process and should have an anterior orientation to avoid the suprascapular nerve.

To obtain optimal compression of the metaglene plate on bone, alternate tightening of the superior and inferior locking screws (Figure 43).

**Note:** Use care to ensure that the driver remains in axial alignment with the screw so that the driver tip remains fully engaged.
Anterior and Posterior Metaglene Screw Placement

The surgeon may use locking or non-locking screws in the anterior or posterior holes. Both types of screws will allow an angulation of up to ±10 degrees, but not in a direction convergent to the central peg axis to avoid conflict with the central peg (Figure 44).

Use the 2.5mm drill bit with the drill guide to set the most appropriate angle for ensuring that each screw is located in reliable bone stock (Figure 45).

The preferred position is usually chosen by palpating the anterior and posterior aspects of the scapula as well as examining the X-rays and CT scans. Drill in the direction of the central glenoid vault in an attempt to maximize the anterior and posterior compression screw lengths, in a direction parallel to or divergent from the central peg.
Anterior and Posterior Metaglene Screw Placement

Screw length is determined from the laser marks on the drill bits or by using the depth gauge.

Slide the corresponding screws onto the guide pin and tighten using the 3.5mm cannulated hex screwdriver for non-locking screws or the locking screwdriver for locking screws (Figure 46).

Follow the same procedure for the posterior screw, then alternately tighten both screws until they are fully tightened.

Proceed with locking all variable angle screws used. Place the locking screwdriver main body in the head of the inferior screw. Make sure that the screwdriver sleeve is in its upper position and not in contact with the screw head.

Slide the locking screwdriver internal rod into the main body. The tip of the internal rod will make contact with the screw head. Tighten it fully, locking the screw in place by expanding its head (Figure 47).

**Note:** After inserting all four screws, tighten the locking screws with the internal rod for the locking screwdriver. Pull the sleeve up and off the screw head for this step.

Repeat the same steps to secure the superior locking screw and anterior or posterior screws if variable angle screws have been used.

The metaglene is left in place (Figure 48) and the humeral preparation is then carried out.
Glenosphere Trial Placement

The glenosphere implants are available in two diameters, 38 and 42mm, and are either standard or eccentric spheres.

An overlap of 3 to 5mm is recommended to avoid conflict with the scapular neck (Figure 70). Depending on the shape of the scapular neck, this overlap can be achieved by using a standard metaglene just by lowering the metaglene. The 42mm glenosphere is recommended if the size of the joint allows (increases both the overlap and the range of motion). The eccentric glenospheres are recommended for more transverse scapular necks.

Fit the appropriate trial glenosphere (38mm or 42mm, centered or eccentric) to the the metaglene using the metaglene holder (Figure 71). The trial glenosphere utilizes an interference fit to make the connection with the metaglene.

For eccentric glenospheres, the vertical laser mark on the trial glenosphere should be aligned with the base of the coracoid superiorly and the scapular neck inferiorly (Figures 71 and 72).

The arrow indicates the position of the eccentricity and should be positioned inferiorly, aligned with the scapular neck (Figures 72).

Note: If it is difficult to place the glenosphere trial, then check to ensure the superior portion of the glenoid has been reamed adequately and that there is no soft tissue in the way.
Cup Trials and Trial Reduction

Place the humeral trial cup (38 or 42mm depending on the glenosphere size), with +3mm of lateral offset, in the trial epiphysis (Figure 73). The shoulder should then be reduced with longitudinal traction and assessed for a full range of motion (Figure 74).
Joint Tensioning and Stability Assessment

Joint tensioning and stability assessment should be performed with particular care, using the following guidelines:

- Tension within the conjoined tendon should be noticeably increased and detectable by palpation.

- With the arm in a neutral position, apply a longitudinal traction force to the arm while observing the movement of the shoulder with respect to the entire shoulder girdle as well as the trial prosthetic joint. Tension is appropriate if, in response to the longitudinal traction, the entire shoulder moves before detectable separation of the trial prosthetic surfaces.

- External rotation may appropriately demonstrate slight gapping between the glenosphere and articular surface (2 to 3mm maximum).

- Positioning a hand or fist near the axilla to serve as a fulcrum, further adduct the arm and look for undesirable tendencies to sublux or dislocate laterally (a small opening of 2 to 3mm is acceptable). Estimate the maximum forward elevation.

- Assess stability at 90 degrees, abduction with the humerus in neutral, maximum internal and maximum external rotation. Estimate the maximum forward elevation.

If instability can be demonstrated, it is critical to identify the cause and develop a solution to the problem. Make sure that the implants have been positioned correctly with respect to the bone and to each other. Overcome any conflicts between the proximal humeral component and soft tissues or osseous structures that surround the glenosphere (e.g. non-union of the greater tuberosity) by excision of the conflicting elements. Inadequate tensioning may be overcome using:

- A thicker cup (+6mm or +9mm)
- A 42mm glenosphere
- A modular humeral lengthener or retentive cups in more extreme cases

If unable to reduce the joint, the options include additional soft tissue releases and lowering the level of humeral resection. When the trials are satisfactory, the trial glenosphere should be removed using the extraction T-Handle so that final implant fixation can be performed.
Definitive Glenosphere Fixation

Standard Glenosphere

Insert the 1.5mm guide pin through the central hole of the metaglene.

Engage the 3.5mm cannulated hex screwdriver in the final glenosphere. Slide the glenosphere on the 1.5mm guide pin until it is in contact with the metaglene (Figure 75). Proper alignment between the glenosphere and metaglene is absolutely essential to avoid cross threading between the components.

If the glenosphere seems difficult to thread onto the metaglene, do not force engagement but re-align the components. If necessary, remove the inferior retractor or improve the capsular release. It is also important to check that there is no soft tissue between the metaglene and glenosphere.

When accurate thread engagement is obtained and after a few turns, remove the guide pin to avoid stripping in the screwdriver.

Tighten until the scapula begins to rotate slightly in a clockwise direction, meaning that the glenoid bearing is closing on the taper of the metaglene.

Gently tap on the glenosphere with the glenosphere impactor a minimum of three times (Figure 76). Tighten the glenosphere central screw again. Care should be taken to ensure that the glenoid bearing is fully locked onto the metaglene. The gentle hammering procedure and screw tightening can be repeated, if necessary, until the screw is fully tightened.

Note: Glenosphere will sit about 1mm proud on the metaglene with consistent uniformity
Definitive Glenosphere Fixation

Eccentric Glenosphere

Slide the glenosphere orientation guide onto the screwdriver core and position it in the eccentric glenosphere central slot (Figure 77).

The arrow marked on the orientation guide should be aligned with the base of the coracoid process to position the eccentricity correctly. Maintain the orientation guide in the required position and screw the glenosphere into place using the screwdriver until the glenoid bearing closes on the taper of the metaglene (Figure 78).

Obtain further impaction of the junction by gently hammering the glenosphere with the glenosphere impactor a minimum of three times (Figure 79). Then tighten the glenosphere central screw again. Care should be taken to ensure that the glenoid bearing is fully locked onto the metaglene.

Repeat if necessary until screw is fully tightened.

**Note:** Glenosphere will sit about 1mm proud on the metaglene with consistent uniformity
Definitive Glenosphere Fixation

Glenosphere Removal

If it is necessary to remove the glenosphere (revision or intra-operative size modification), the glenosphere/metaglene junction can be disassembled by unscrewing the glenosphere central screw using the 3.5mm hex head screwdriver (Figure 80). This operation should be done smoothly to avoid central screw damage.