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CYCLIC ELONGATION AND PULL OUT OF UNICORTICAL AND BICORTICAL SUTURE ANCHOR DESIGNS

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A THESIS

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BIOMEDICAL ENGINEERING

ABSTRACT

A novel suture anchor design was introduced and biomechanically tested. The novel design involved lengthening a standard metal screw type anchor so as to achieve greater fixation in bone. Along with utilizing a greater amount of trabecular bone, this design also allows a second layer of cortical bone to be involved in order to further enhance fixation. This “bicortcal” design is intended to be used under unique clinical circumstances. Such circumstances may include RC repair in patients with extreme osteoporosis, in cases where standard unicortical anchors have pulled out during surgery or in revision RC repairs where there is little unused bone available.

Unicortical and bicortical suture anchors were implanted into cadaveric humeri and subjected to cyclic and single ramp failure loading in order to measure the fixation of the two anchor designs in the anchor to bone interface. The purpose of this study was to identify if there was a difference in the performance of the two anchor designs. Our hypothesis is that anchors of the bicortical design will show significant reduction in cyclic elongation as well as a significant increase in failure strength than anchors of the unicortical design. This study also compared cyclic elongation and failure strength with respect to anchor diameter, anchor position, gender and age between and within the two anchor designs. This was done in order to analyze trends, eliminate artifacts and isolate differences to unicortical vs. bicortical anchor designs.

Keywords: Rotator Cuff, bicortical, suture anchor

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BACKGROUND

Anatomy of Rotator Cuff

The rotator cuff consists of a group of four tendons in shoulder. These tendons join their associated muscles from regions of the scapula to the humerus. The rotator cuff tendons and muscles facilitate movement of the shoulder in the glenohumeral joint. The four tendons that make up the rotator cuff (RC) correspond to the subscapularis, supraspinatus, infraspinatus, and teres minor muscles. These muscles originate from their respective regions of the scapula and insert into the proximal humerus via the RC tendons. The subscapularis tendon attaches to the lesser tuberosity of the humerus while the remaining tendons attach to the greater tuberosity. Figure 1 shows the four tendons and their attachment sites on the proximal humerus in a color coded configuration: yellow – subscapularis, red – supraspinatus, green – infraspinatus and blue – teres minor.

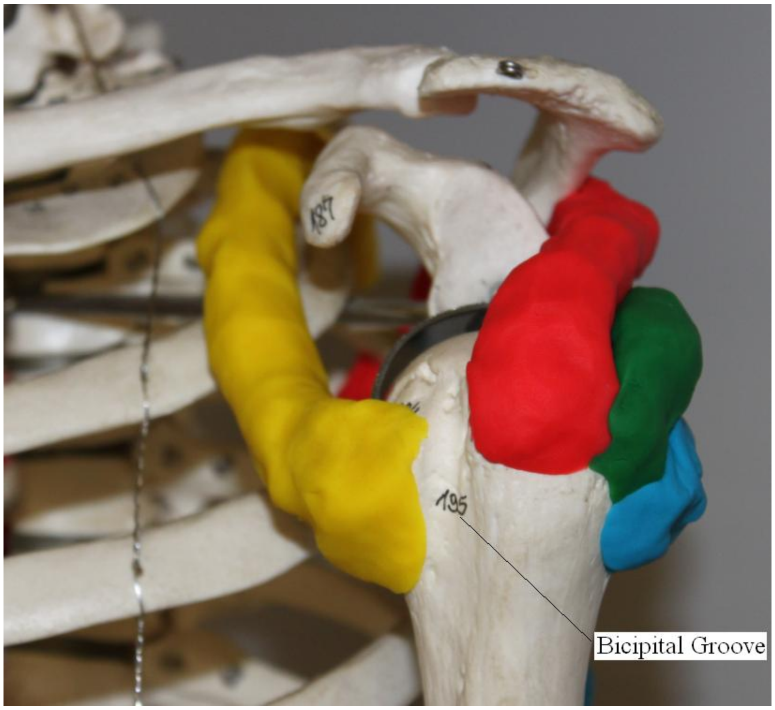

Figure 1: Anatomy of the rotator cuff.

Rotator Cuff Injuries

Rotator cuff tears represent a very common class of injury. A study in England in 2006 found that up to 40% of their test population had experienced a rotator cuff tear.[1] In 2007 a study conducted in the U.S. by the Millennium Research Group found that 460,000 shoulder surgeries requiring suture anchors were performed during that year.[2] In this study over 1,030,000 suture anchors were used. Surgeries to repair RC tears are relatively expensive, thus there is a large market for the equipment used therein. In a cost-effectiveness study in 2007, Vitale et al found that the average cost of a RC repair surgery in the U.S. was $10,605 for hospitals and physicians.[3] RC repairs are not always a onetime procedure. Sometimes they require a revision surgery. If only 1% of surgeries require revision, the annual cost of RC revision surgeries alone in the U.S. would be $48,783,000.[4]

RC injuries may stem from a number of causes, the most general being acute trauma and chronic degeneration with many cases being a combination of the two. Athletes, for example are highly susceptible to RC injury. Those competing in sports involving overhand motion are likely to experience microtrauma in the RC.[5] The overhand motion inflicts tiny lacerations within the RC which can eventually cause a debilitating tear. Athletes competing in contact sports are more susceptible to RC macrotrauma which involves a singular impact to the shoulder inducing a tear.[5] One theory pertaining to degeneration as a cause of RC tears is that small partial-thickness tears of the RC tendons allow the humeral head to toggle in the glenoid cavity. This in turn causes abrasion of the rotator cuff tendons against bony surface of the acromion leading to full-thickness tears.[6,7] Of the four tendons that make up the RC, tears most commonly involve the supraspinatus tendon.[8] Because this tendon inserts at the greater tuberosity, most surgical repair is focused on this region of the humerus.

RC tears are not all created equal. They can range in severity from a miniscule laceration to a full thickness tear. Surgical necessity is based on the comfort level of the patient and the recommendation of their physician. Benson et al classifies RC tears that are less than 3 cm in length to be small to medium whereas tears over 3 cm are labeled as large tears.[9]

Surgical Repair Techniques

Transosseous Suture Technique

The two most widely accepted methods of tendon to bone fixation during RC repair involve the use of either transosseous sutures or suture anchors.[10,11] The transosseous technique was the original gold standard of RC repair and involves drilling holes or “bone tunnels” in the greater or lesser tuberosity and passing sutures through the holes in order to fix the RC tendons to the bone. A study by Burkhart et al[12] used such a surgical procedure in which three bone tunnels were formed in the lateral humerus creating a 2 cm bone bridge. The tunnels were oriented in a parallel fashion and spaced 8 mm apart. A common mode of failure for the bone tunnel technique is the suture sawing through the bone. In this study, 9 of the 16 trials failed at the bone interface as compared to 1 of 16 trials when the study was repeated using suture anchors instead of bone tunnels.[12,13] Trends are moving away from the transosseous technique because it involves large exposure of bone and is not well suited for tight workspaces during surgery.[14]

Suture Anchor Technique

The second method of tendon to bone fixation is the use of surgically implanted suture anchors. During repair, suture anchors are fixed into the greater or lesser tuberosity. This is generally accomplished by drilling a hole in the bone and either screwing the anchor into place or releasing a “hook” of some sort according to the design of the anchor being used. Suture anchors are simply a means for surgeons to bind the torn RC tendon to the proximal humerus. Many biomechanical studies have been conducted to compare the transosseous and anchor techniques. Chhabra et al[15] conducted such a study in which he used a cyclic loading construct and defined gap formation as the mode of failure. This study found that suture anchors required significantly higher cycles to reach a 5 mm gap than did transosseous sutures. Thus, the suture anchor technique was found to maintain its initial fixation significantly longer than the transosseous sutures technique which improves healing. Overall, the anchor technique has become more popular than the bone tunnel technique because of reduced surgical exposure, ease of insertion, and decreased morbidity.[16-18]

Open Surgery vs. Arthroscopy

RC repair surgery can generally be performed arthroscopically, which has advantages compared to open surgery RC repair techniques. This has been supported by numerous recent clinical studies. Lo et al[19] studied the results of 15 arthroscopic RC revision surgeries and concluded that there are several advantages of arthroscopic RC procedures in comparison to open surgical procedures. First, arthroscopy gives better visualization of the rotator cuff and thus allows surgeon to make a more complete evaluation of the glenohumeral joint and subacromial space. This is crucial to the correct diagnosis and classification of a RC injury. Arthroscopic procedures also minimize the disruption of the deltoid muscle. Finally, arthroscopic procedures significantly reduce postoperative stiffness and eliminates the need for rehabilitation exercises that could compromise the repair.[19] Not only does arthroscopic RC repair have many short term advantages, but the long term results have been found to be superior or equal to open surgery results.[20]

Complications After Repair

Though RC repair surgeries are generally successful, revision surgery is sometimes necessary. In two clinical studies, Benson et al and Cummins et al found that 2.4% and 6% of RC repair surgeries required revision surgery respectively.[9,21] The methods used in revision surgery are dependent on the nature of failure from the primary surgery. For example, if a 4 mm (in diameter) screw type anchor that was inserted in the primary surgery has pulled out then revision surgery may include the replacement of the original anchor with one of greater diameter in order to achieve a better hold in the anchor to bone interface. In the more common case of failure, gap formation, a revision surgery may simply involve the addition of one or more anchors to strengthen the repair. A clinical study by Djurasovic et al showed that placing a second anchor parallel to the original significantly increased the strength of revision repairs.[22] This study also found that pain reduction in patients undergoing RC repair surgery is greater in primary surgery rather than revision surgery.[22]

Categories of Failure

Gap Formation vs. Pullout

The goal of RC repair is to reattach a torn RC tendon to its original attachment site on the proximal humerus. The failure of this goal can be caused by a variety of factors; however, all of which ultimately result in a loss of adhesion between tendon and bone. This is detrimental to the success of the repair because healing cannot take place unless there is continuous contact between tendon and bone.[23] Any loss of adhesion in this context is termed as gap formation. The modes responsible for gap formation will be covered in following sections.

Biomechanical suture anchor studies use two main variables to compare various suture anchor designs and measure their clinical utility: gap formation and pull out strength. One way these studies measure gap formation is by loading the specimens to a set force or number of cycles and comparing the extent of gap formation between anchor groups. Another method is to measure how much force or how many cycles it takes each anchor group to reach a specified gap length. For example, Burkhart et al defined complete failure of an RC repair to be 10 mm of gap formation and 50% failure to be 5 mm of gap formation.[12,13] A gap formation of 3 mm is a common definition of clinical failure.[24] The measurement of anchor pull out strength is more simplified in that specimens are loaded until the anchor is ripped out of the bone. As with gap formation, pull out strength can also be measured using single ramp loading or cyclic loading.

Authors of biomechanical suture anchor studies generally utilize methods to replicate either clinical loading of the RC repair or a worst case scenario loading situation. Cyclic loading is the best way to replicate clinical loading of the RC.[25,26] This is to be expected as daily activities involve cycles of loading and unloading the shoulder by pushing, pulling, lifting, or grasping relatively light loads as opposed to single, high force, jerking loads. Because of its high clinical relevance, cyclic loading is generally used in these studies to measure suture anchor performance by mimicking loads incurred during daily activity. Single ramp loading, however, is used to replicate the infliction of large loads at a very high loading rate. This is the worst case scenario within the context of loading categories. Many studies attempt to give a more comprehensive analysis of suture anchor performance by combining cyclic loading as well as single ramp loading.

It is important for the reader to understand that gap formation and pull out are not exclusive events; rather, they are closely related. In fact, gap formation often occurs as a result of pull out in cases where gap formation is created at the anchor to bone interface. Let us consider the case of a metal screw type suture anchor. Under cyclic loading, whether it be clinical or recreated in a laboratory, the anchor can start to “toggle” within the trabecular bone of the proximal humerus. This can be visualized as a windshield wiper-type motion.[24] Due to this toggling phenomenon, fixation between the bone and anchor is compromised, and the anchor will be more likely to pull out. The form of gap formation described here may also be referred to as anchor displacement or cyclic elongation in the literature.

The clinical prevalence of early metallic suture anchor pullout after arthroscopic rotator cuff surgery was examined by Benson et al in 2010.[9] In this study postoperative radiographs were taken 12 weeks after repair and a pull out incidence of 2.4% was recorded. The study contained a test population of 269 patients who underwent arthroscopic rotator cuff surgery involving the use of metal unicortical suture anchors. This study excluded partial pull outs and it did not report medium to long term pullouts which would be anticipated to be even higher.

Variables Contributing to Failure of RC Repair

Tear Severity

The size of an RC tear greatly affects the success rate of repair. Benson et al found that incidence of anchor pullout in repairs of RC tears less than 3 cm was 0.5% whereas RC tears greater than 3 cm pulled out 11% of the time.[9] Tears with a greater degree of retraction frequently require greater tension to restore the tendon to its anatomic insertion and therefore places greater stress on the repair.

Suture Cutting Through Tissue

Many physicians believe that the tendon to suture interface is the weakest link in RC repairs.[12,13,21,27,28] This is true regardless of repair technique. Studies have been conducted to improve methods for fixing suture to tendon and have concluded that more complex suture configurations that allow sutures to pass through the tendon more times greatly improve the strength of the suture to tendon interface.[10] Cumins et al found a 3 fold increase in strength when comparing simple stitches with a modified Kessler stitch configuration.[10] Failure in this study was defined as total loss of fixation between the tendon and the proximal humerus due to suture cutting through the tendon. Goradia et al found that 75% of clinically loaded specimens failed by suture cutting through the cuff tissue.[29] Failure of RC repair using the transosseous sutures technique can also be caused by suture sawing through bone.

Sutures and Eyelets

Sutures are said to be one of the two limiting factors in RC repair along with suture eyelets.[30] Braided UHMWPE (ultra high molecular weight polyethylene) suture is the current gold standard for RC repair.

The suture to eyelet interface is a significant area of concern in RC repair. Meyer et al tested 22 varying metallic suture anchors loaded with No. 2 braided nonabsorbable suture material in an effort to analyze the effects of eyelet geometry in RC repair.[32] In this study all cases showed suture breakage at the anchor eyelet at up to 73% lower loads as compared to when the suture was tested on a smooth hook.[32] Failure in this study was again defined as a complete loss of fixation due to suture breakage.

The use of high strength sutures has placed a great demand on the eyelet. Moving the position of the eyelet is one method that is currently being tested to increase the strength of suture eyelets. More specifically, eyelets are being shifted from the top of the anchor to the core.[30]

Thread diameter and thread count are also considered to be important design components in screw type anchors, though Barber et al showed diameter was not a significant factor.[30]

Anchor Depth

Bynum found that anchor insertion depth greatly affects the mode of suture failure in RC repair.[31] In this study, anchors were placed in three depths: deep, normal and proud. Anchors placed in the deep position were shown to be more likely to saw through the cortical margin of bone. They were also significantly more resistant to suture breakage than anchors inserted at standard or proud depth. This indicates that there is a tradeoff between strength of the repair and mode of failure depending on anchor insertion depth.

Anchor Insertion Angle

Burkhart published an article in 1995 in which he described his “Deadman Theory of Suture Anchors.”[33] This theory was derived from his observations of fence posts and the techniques associated with their erection, specifically the corner post. The top of these posts are fitted with a wire that is tied to a large rock (deadman) that is buried in the ground at the specific distance away from the corner post so as to make the angle between the wire and the ground equal to 45°. The wire is used as a counter balance for the forces of the fence in the x direction. Ranchers found that if the angle between the wire and the ground is greater than 45° the corner post will lean under the force of the fence until the angle reaches 45°. Burkhart’s theory is that the deadman is analogous to a suture anchor and that the force of the wire holding the fence post is analogous to the force of the RC. This theory is very prevalent in the biomechanical literature, and it is standard clinical practice for surgeons to employ its use.

Strauss et al recently conducted a biomechanical study that challenged the benefits of a 45° insertion angle.[24] This study involved cyclically loading of an induced RC repair at the greater tuberosity/supraspinatus tendon interface in cadavers. Anchors were placed at either 45 or 90° and failure was defined as a 3 mm gap. The study found that anchors placed at 90° required significantly more cycles to failure than anchors placed at 45° (380 and 297 respectively).[24] This study also found that anchors placed at

45° exhibited toggling in a butterfly or windshield wiper pattern when a cross section of the insertion area was examined. Anchors placed at 90° did not show this toggling.

Anchor Location

Location of anchor insertion is another important factor in the success of RC repair.[34,35] Anchor placement can vary proximally, distally, anteriorly or posteriorly in the greater or lesser tuberosity depending on the location of the RC tear. Carpenter et al showed that anchor performance improved as anchors were moved distally.[14] This should be expected due to increased cortical bone as opposed to trabecular or spongy bone when moving away from the articular surface of long bones. This may not be the case, however, when restricting the insertion area to trabecular bone only. Tingart et al showed that within the greater tuberosity, more proximally placed anchors showed improved fixation than those placed more distally.[11] Benson et al found that suture anchors are more likely to pull out of the greater tuberosity than the lesser tuberosity.[9] The question of anterior vs. posterior superiority with respect to anchor fixation in the humeral head is another area of conflict in the literature. Tingart et al found that pull out strength of metal anchors was higher in anterior insertion sites.[11] Benson et al found supporting data with 67% of pullouts in a clinical study coming from posterior anchor positions.[9] In a study focused on anchor displacement under cyclic loading Brown et al found contrary results with anchor displacement increasing as anchor positions moved anteriorly.[36] Mahar et al found that anterior vs. posterior anchor locations did not appear to affect failure modes.[37]

Anchor Categories

The first suture anchor patent came in 1985. This anchor was simply a 4.6 mm self tapping screw with a suture bonded to it.[38] This basic design is still in use today, although alternative suture anchor designs have evolved significantly. Some current designs include screw type, hook type, knotless, and sutureless anchors. Sutureless anchors can range from staples to tacks and even simple screws. A biomechanical study by Lee et al compared a PLLA sutureless screw with a metal screw type suture anchor.[39] In this study it was shown that the sutureless screw required significantly less cycles to reach a 10 mm gap than did the metal suture anchor.[39] There is even an anchor design that has been termed an “all suture” anchor.

Along with form, current anchor designs also vary in material. Some common anchor materials include metals like titanium and biodegradable polymers like poly L-lactic acid (PLLA) and polyetheretherketone (PEEK).[40] There are advantages and disadvantages to anchors made from such materials. One disadvantage of implants made from bioabsorbable polymers is the possibility of inflammatory reaction. A clinical study by Bostman et al found that 4.3% of patients had such a reaction after surgical implantation of implants made from polyglycolic acid or polylactic acid.[41] A comparison of some early anchor designs was performed by Carpenter et al in which it was found that metallic designs were superior to polymeric designs under mechanical pull out testing.[14] A more recent study by Tingart et al found that metal screw type anchors required significantly higher forces to induce anchor pull out than did biodegradable hook type anchors.[11] This study utilized cyclic loading prior to pull out tests in order to mimic clinical loading. A study by Schneeberger et al; however, found that pull out strength was similar between absorbable and metal anchors.[35] In his most recent suture anchor update, Barber et al found no difference in pull out strength for various designs of metal vs. PEEK anchors.[30] Due to these and other factors, suture anchor trends are moving toward biodegradable materials.[42,43]

Age

Age of bone and bone density greatly affect the strength of the anchor to bone interface in RC repair.[11,13,44] These factors are directly correlated in the context of RC repair. As people age they experience a progression of proximal humeral osteoporosis.[9] This is supported by a clinical study in which Sher et al found that RC tears are highly prevalent in patients older than 60 years of age, with an incidence of up to 54%.[45] In two biomechanical studies, Barber et al found significant differences in pull out strength at an age threshold of 60 years[44] while Burkhart et al found significant differences in gap formation in bone above and below 45 years of age.[13] These age thresholds were not meant to be exclusive dividing lines, rather the groupings were assigned due to the age range and availability of cadavers within these studies.

BMD

Bone becomes weaker with age and can fall into one of three categories according to the World Health Organization.[46] Normal bone is that which has a bone mineral density T-score of -1 or higher. Osteopenic bone (Osteopenia is a precursor to Osteoporosis) is that which has a T-score between -1 and -2.5. Finally, Osteoporotic bone has a T-score that is less than -2.5.[46] The T-score is found by comparing the bone mineral density (BMD) of the person in question to that of a healthy person of the same sex and ethnicity. The values used to describe the aforementioned categories are standard deviations below the mean BMD.[46]

There have been conflicting results in the literature as to the correlation between BMD, anchor pull out strength, and anchor displacement. Some studies suggest that bone density and pull out strength are not correlated at all;[11,47] however, others show correlation between cortical thickness and pull out strength.[14,18,22,29,48,49] Tingart et al found a correlation between bone density and failure strength in cortical bone but no correlation in trabecular bone in a study with metal anchors.[11] Brown et al showed a correlation between BMD and anchor displacement.[36] This study compared two knotless anchor designs and one metal anchor design and found that as BMD decreased anchor displacement increased in all three anchor designs. Meyer et al concludes that bone distribution in the humeral head is inhomogenous and unpredictable with respect to external inspection, gender and age.[32] He also found that patients with longstanding RC tears have lower BMD in the proximal humerus.[32]

Trabecular Microstructure: Plate vs. Rod

Yakacki et al found very convincing results pertaining to the relationship between anchor fixation and BMD; more specifically they found a relationship between fixation and trabecular microstructure.[4] This study utilized micro computed tomography (µCT) to analyze the architecture of bone. Structural model index (SMI) is a value given to distinguish between plate and rod geometry within trabecular bone. Ideal plate and rod structures have SMI values of 0 and 3, respectively. This study found that pull out strength increased with decreasing SMI, thus finding that plate geometry within trabecular bone provides better fixation than rod geometry.[4] Yakacki et al also found that the humeral head had lower SMI values than the greater or lesser tuberosities along with higher BMD and trabecular thickness.[4]

BICORTICAL ANCHOR STUDY

Introduction

A novel suture anchor design was introduced and biomechanically tested. The novel design involved lengthening a standard metal screw type anchor so as to achieve greater fixation in bone. Along with utilizing a greater amount of trabecular bone, this design also allows a second layer of cortical bone to be involved in order to further enhance fixation. This “bicortcal” design is intended to be used under unique clinical circumstances. Such circumstances may include RC repair in patients with extreme osteoporosis, in cases where standard unicortical anchors have pulled out during surgery or in revision RC repairs where there is little unused bone available.

Unicortical and bicortical suture anchors were implanted into cadaveric humeri and subjected to cyclic and single ramp failure loading in order to measure the fixation of the two anchor designs in the anchor to bone interface. The purpose of this study was to identify if there was a difference in the performance of the two anchor designs. Our hypothesis is that anchors of the bicortical design will show significant reduction in cyclic elongation as well as a significant increase in failure strength than anchors of the unicortical design. This study also compared cyclic elongation and failure strength with respect to anchor diameter, anchor position, gender and age between and within the two anchor designs. This was done in order to analyze trends, eliminate artifacts and isolate differences to unicortical vs. bicortical anchor designs.

This study was designed to mimic clinical repair and loading scenarios as will be discussed in detail in the methods section. In the load to failure portion of the study, the clinically used suture was found to be a limiting factor for failure which did not allow adequate failure data to be recorded. Because of this, the tests were repeated using steal wire to replace the suture. This technique has been used previously in similar biomechanical studies.[11,40] Replacement of the suture with wire shifted the limiting factor of failure to the anchor to bone interface which was the goal of the failure tests. This change was the only variation between the two sets of tests. All other constructs were kept constant including the test specimens, anchors and loading protocol. The anchors were simply shifted 1 cm superior from their original positions which will be discussed in the methods. Because of the aforementioned circumstances, cyclic elongation data was collected from the first set of tests which utilized suture, and failure data was collected from the second set of tests which utilized steel wire.

Methods

Specimens

Nine paired human cadaver shoulders were harvested fresh and stored frozen. Shoulders were thawed at room temperature, dissected and removed of all soft tissue. Humeri were cut so as to extract the most proximal 20 cm of the bone. Age and gender information of one of the donors was unknown. Of the remaining 8, there were 5 males and 3 females that ranged in age from 26 to 65. The average age of donors was 53.25.

Test Groups

Three anchors were inserted into the proximal humerus of each specimen as described in Tingart et al.[11] Anchors in position 1 were inserted just posterior of the bicipital groove with positions 2 and 3 following in a linear, posterior fashion as shown in Figure 2.[11] The anchors were spaced 1.5 cm apart to reduce cracking between insertion sites. For the second set of tests, anchors were inserted 1 cm superior to their original positions. Unicortical and bicortical metal screw type anchors of three diameters were tested. This created six anchor groups: Unicortical anchors of diameters 4, 5, and 6.5 mm and bicortical anchors of the same diameters. Each humerus received either two unicortical anchors and one bicortical anchor or vice versa. Unicortical and bicortical anchors of each diameter were inserted into three matched pairs of humeri alternating in location. This insured that each diameter and location was tested with an equal amount of trials. With each humerus in the nine matched pairs of shoulders receiving three anchors, a total of 54 anchors were tested in each set of tests.

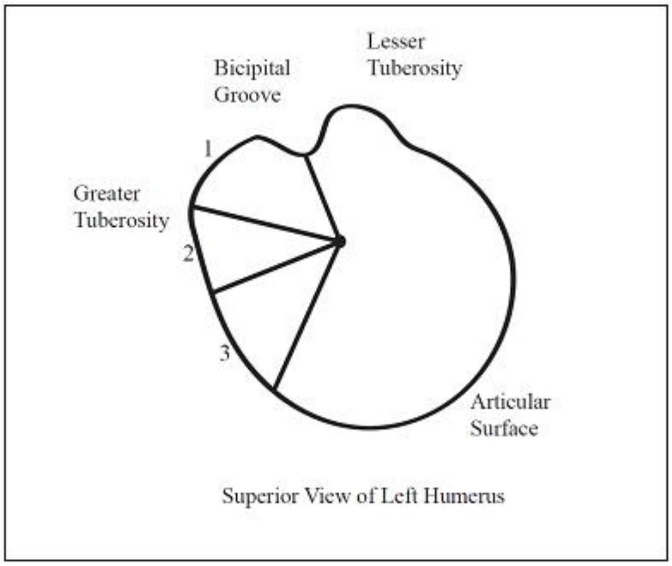

Figure 2: Anchor locations in the greater tuberosity.

Anchor Description

The anchors tested were made by Meta Bio Industrial Ltda (Rio Claro, São Paulo, Brazil) out of Titanium. Unicortical anchors were 1.9 cm long and bicortical anchors were 5.5 cm long. One No. 2 Fiberwire suture (Arthrex) tied in a closed loop with a series of stacked half hitch knots was used for all anchors in the first set of tests. The length of the closed suture loop was kept constant at 5.5 cm in length when held taught. Figure 3 shows 5 mm anchors of each design along with the associated suture configuration. For the second set of tests, a similar loop-like construct was used with stainless steel wire (diameter 0.62 mm; Malin Co, Brook Park, OH). All anchors were inserted into the humeral head at an angle of 45 degrees to the adjacent bone as described by Burkhart's deadman theory of suture anchors.[33] Anchor insertions for each set of tests were performed by one surgeon using appropriate drilling equipment.

Figure 3: Unicortical and bicortical suture anchors.

Biomechanical Testing

After specimen preparation and anchor insertion, the specimens were loaded into a servohydraulic materials testing system (MTS Model 858 Bionix; MTS Corp, Minneapolis, MN) that was fitted with a 15kN load cell. The long axis of each humerus was placed at 135° to the load actuator using a custom made, adjustable angle fixture as seen in Figure 4. This arrangement was previously described by Barber et al to represent anatomical direction of load applied to the RC.[44] Specimens were clamped at 2 points on the bone shaft using U bolts. The sutures and steel wires were looped over a bolt connected to the actuator during respective test sets. The constructs were preloaded to 4 N,[11] and then cyclically loaded from 10 to 60 N at 1 Hz for 500 cycles as described by Barber et al.[44] This was followed by a single ramp load to failure at 33 mm/s.[44,16] Cyclic elongation, failure strength and mode of failure was recorded for all tests.

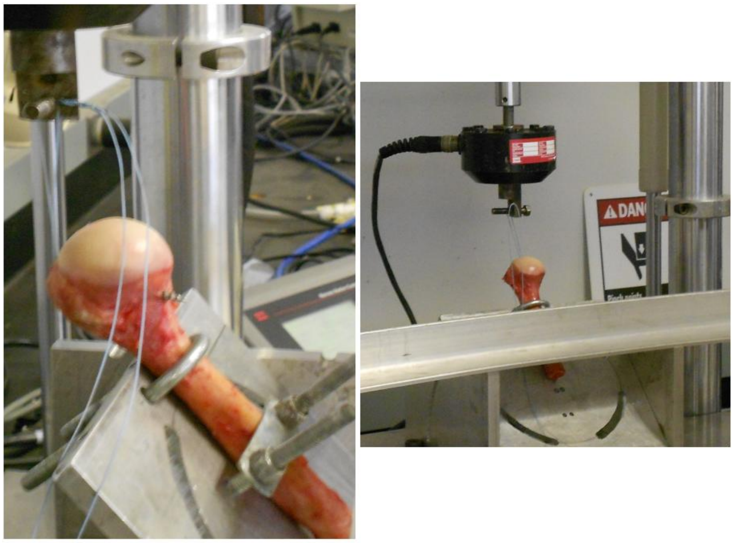

Figure 4: Arrangement of a specimen in the testing apparatus and MTS machine.

Cyclic elongation is a form of gap formation created by the toggling of suture anchors in bone as they are subjected to cyclic loading. This negatively affects RC repair thus minimizing elongation is an important goal in anchor design. Cyclic elongation was found by subtracting the average displacement of the first three cycles from the average displacement of the last three cycles and is shown in Figure 5. This variable represented the elongation of the anchor/suture complex. After the first set of tests, 8 control suture loops were loaded into the MTS machine by looping the bottom end around a bolt at the base of the machine and the top end around the bolt on the actuator as seen in Figure 6. The suture loops were then cyclically loaded in the same way as was described earlier and elongation was recorded. The elongation of the control suture loops was subtracted from the elongation data of the anchor/suture complex. The control tests were performed in order to isolate the elongation data to the anchor by eliminating artifacts created by the stretching of the suture.

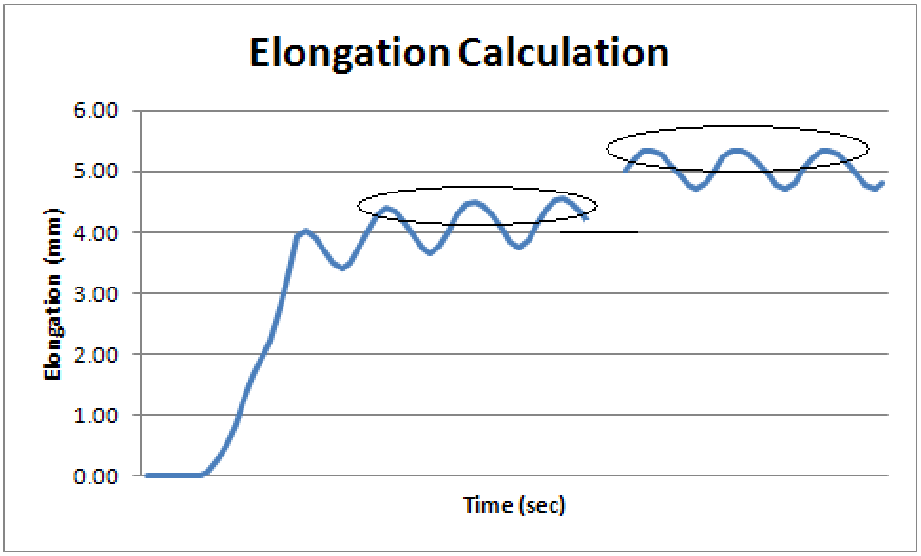

Figure 5: Sample elongation calculation.

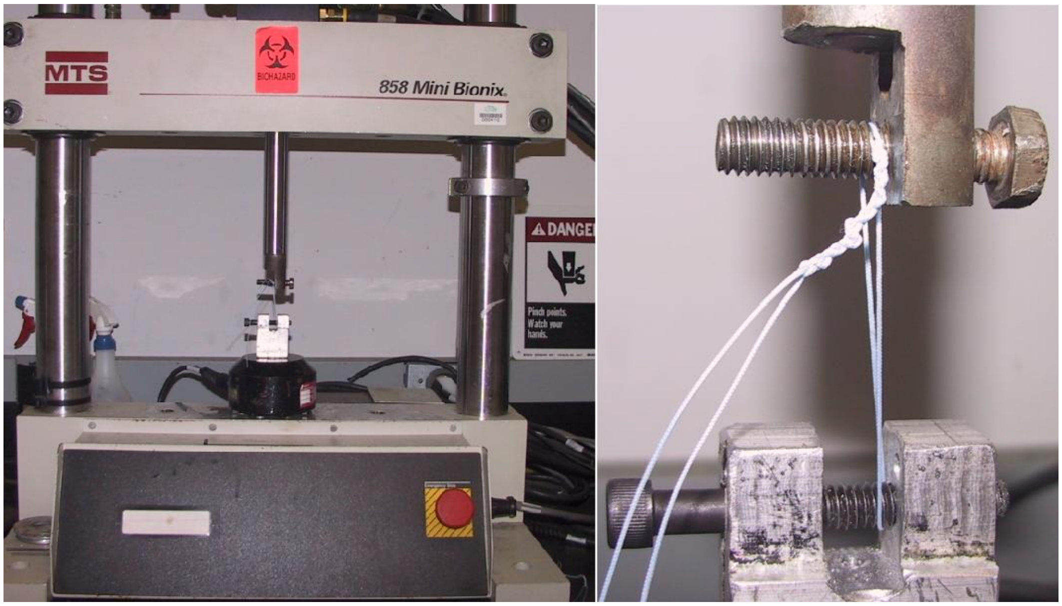

Figure 6: Testing apparatus for control suture testing.

Statistical Analysis

A pooled t-test was used to compare cyclic elongation and failure strength between unicortical and bicortical anchors when grouped regardless of other variables. A linear regression model coupled with an ANCOVA was used to compare the relationship between cyclic elongation and failure strength with age. Comparisons of cyclic elongation and failure strength of anchors with respect to gender, diameter and location were made using ANOVA. Statistical significant was set to $\alpha = 0.05$.

Results for Cyclic Elongation Tests

In the first set of data, 1out of the 54 anchors failed during cyclic loading. The mode of failure was suture breakage. All other tests required load to failure force constructs to reach failure. Eight anchors pulled out and the remaining 45 failed by suture breakage. The 8 anchors that failed by pulling out were unicortical anchors whereas bicortical anchors failed exclusively by suture breakage. Unicortical anchors failed at an average of 185.6 N, and bicortical anchors failed at an average of 204.4 N. Because of the high prevalence of suture breakage, all statistical data was generated using cyclic elongation in the first set of tests. Cyclic elongation results are listed in appendix A.

Comparisons of cyclic elongation were analyzed between unicortical and bicortical anchors within gender. Results are shown in Figure 7. Elongation of bicortical anchors was significantly smaller in males with a p value of 0.005. There was no difference in elongation of the two anchor designs in females (p=0.57). Comparisons were also made between genders within unicortical and bicortical anchor groups. Elongation was not significantly different between genders for unicortical or bicortical anchors with the resulting p values being 0.1 and 0.5 respectively. Comparisons were made using ANOVA.

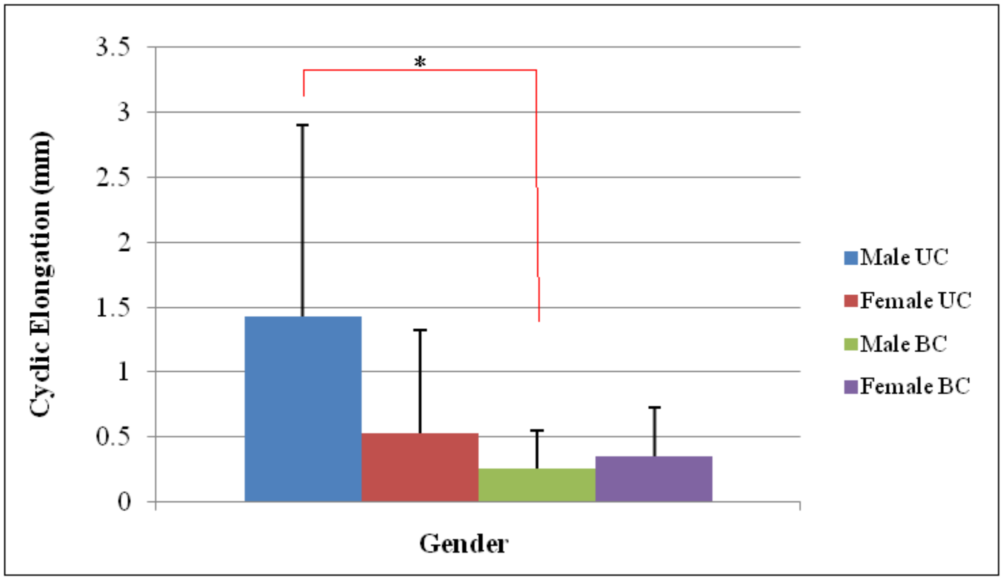

Figure 7: Cyclic elongation data for gender (UC- unicortical, BC – bicortical).

Cyclic elongation of the two anchor designs was analyzed with respect to age and modeled using linear regression. A correlation was found for unicortical anchors but not for bicortical anchors. The correlation in unicortical anchors approached statistical significance with a p value of 0.09. The results for bicortical anchors returned a p value of 0.74. ANCOVA analysis confirmed that cyclic elongation of bicortical anchors was significantly smaller than that of unicortical anchors with a p value of 0.007. Figure 8 demonstrates this data.

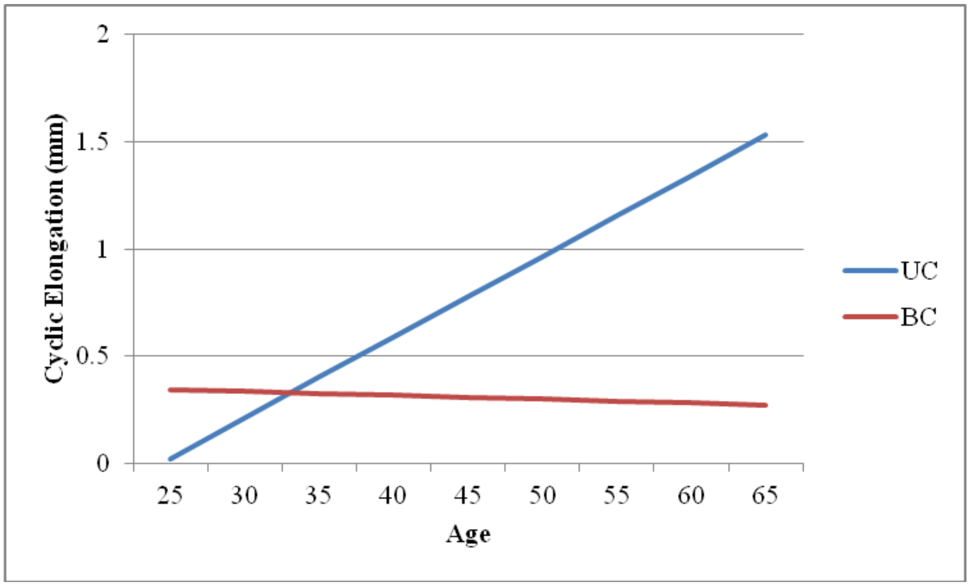

Figure 8: Predictive correlation between cyclic elongation and age.

Comparisons of cyclic elongation were analyzed between unicortical and bicortical anchors within the three diameters that were listed earlier. These comparisons are shown in Figure 9. Elongation was smaller in bicortical anchors than in unicortical anchors for all diameters with statistical significance being reached for the 5 mm group (p=0.02). The 4 and 6.5 mm groups did not reach significance and resulted in p values of 0.16 and 0.23 respectively. Comparisons were also made between the different diameters within unicortical and bicortical anchors. No correlation was found between diameter and cyclic elongation in either unicortical or bicortical anchor groups. Comparisons were made using ANOVA. Statistical results are shown in Table 1.

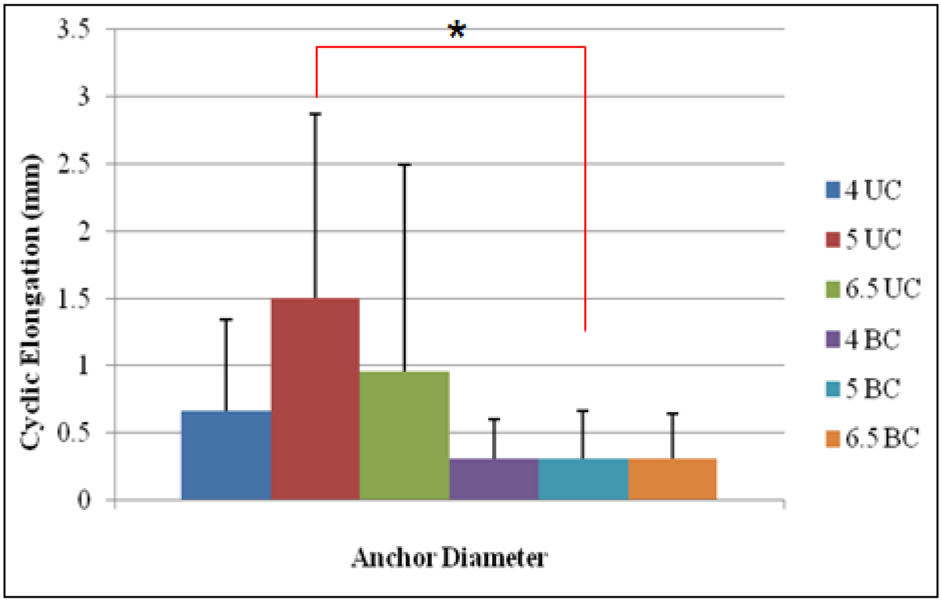

Figure 9: Cyclic elongation for different anchor diameters.

Table 1: Statistical differences of cyclic elongation between anchors grouped by diameter.

	4 mm vs 5 mm	4mm vs 6.5 mm	5mm vs 6.5mm
Unicortical Anchors P value	0.19	0.64	0.38
Bicortical Anchors P value	0.99	0.98	0.99

Because differences of cyclic elongation did not reach statistical significance between anchors of different diameter, data from all unicortical anchors was grouped and compared with grouped bicortical anchor data using a paired t test. Cyclic elongation of bicortical anchors was less than one third of elongation of unicortical anchors. The difference between the groups was significant with a P value of 0.007. This comparison is shown in Figure 10.

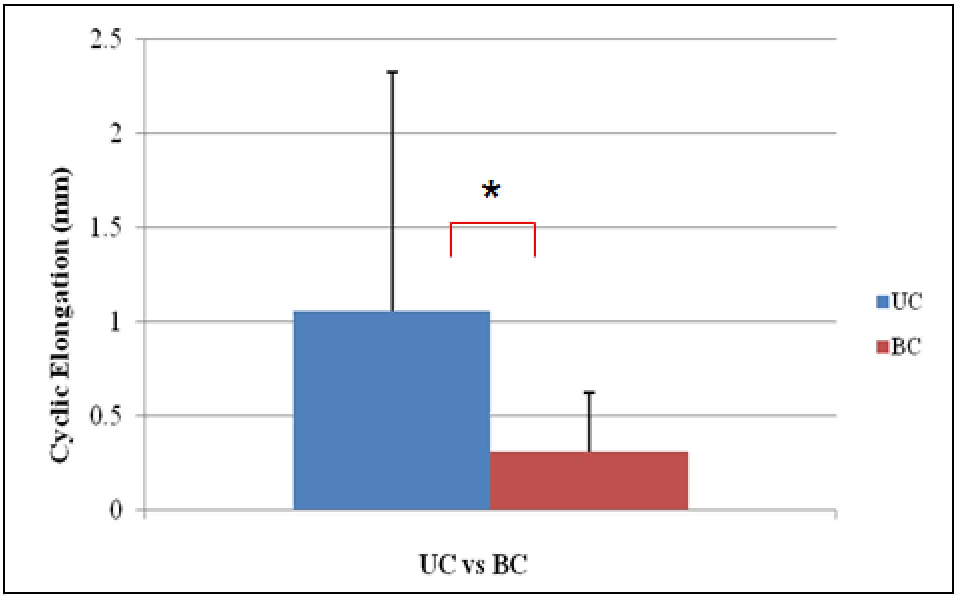

Figure 10: Cyclic elongation of unicortical vs. bicortical anchors.

Comparisons of cyclic elongation were analyzed between unicortical and bicortical anchors within the three locations that were described earlier. These comparisons are shown in Figure 11. Bicortical anchors showed smaller elongation than unicortical anchors on average for all three locations though differences did not reach statistical significance. The differences did, however, approach significance with p values for locations 1, 2 and 3 being 0.14, 0.06. and 0.08 respectively. Comparisons were also made between the different locations within unicortical and bicortical anchors. We found that the anteriorly placed anchors showed smaller elongation values for both unicortical and bicortical anchors than those placed posteriorly. Though statistical significance was not reached between positions for unicortical anchors, cyclic elongation in location 1 was significantly smaller than elongation in location 3 for bicortical anchors. Comparisons were made using ANOVA. P values for these comparisons are shown in Table 2.

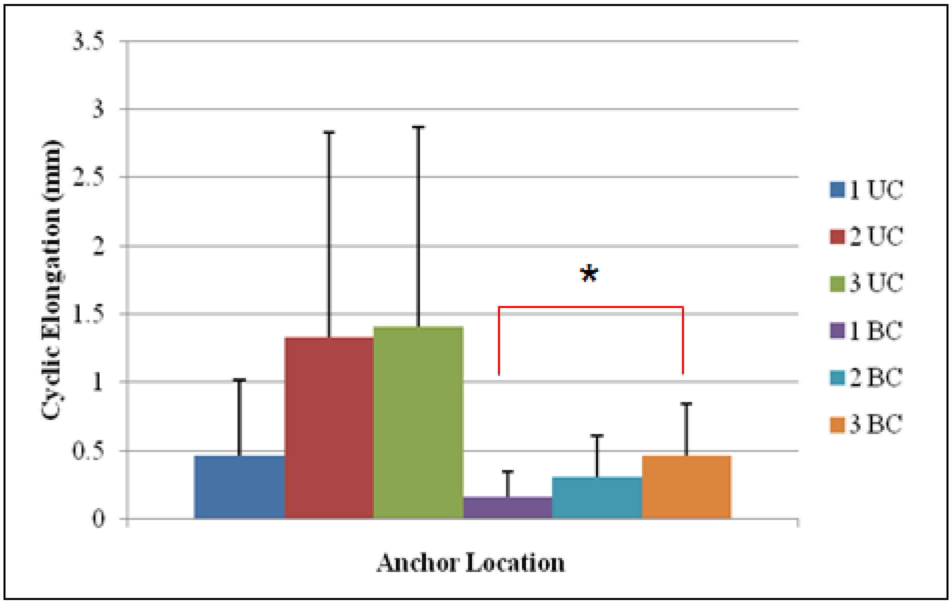

Figure 11: Cyclic elongation data for different anchor locations.

Table 2: Statistical differences of cyclic elongation between anchors grouped by location.

	Location 1 vs 2	Location 1 vs 3	Location 2 vs 3
Unicortical Anchors P value	0.16	0.12	0.89
Bicortical Anchors P value	0.3	0.04	0.28

Results for Failure Tests

In the second set of data, none of the anchors failed during cyclic elongation. Failure modes during ramp loading were anchor pull out, eyelet breakage, wire breakage, humerus placement apparatus failure and catastrophic breakage of the humeral head. Failure strength data is detailed in appendix B.

Comparisons of failure strength were analyzed between unicortical and bicortical anchors within gender. Failure strengths of bicortical anchors were significantly higher than unicortical anchors in both males and females with p values being less than 0.001 for both genders. Comparisons were also made between genders within unicortical and bicortical anchor groups. Failure strength was found to be significantly higher in the female group than the male group within bicortical anchors (p=0.02). The female group also showed higher failure strength than the male group for unicortical anchors with the difference being marginally significant (p=0.06). This is shown in Figure 12. Comparisons were made using ANOVA.

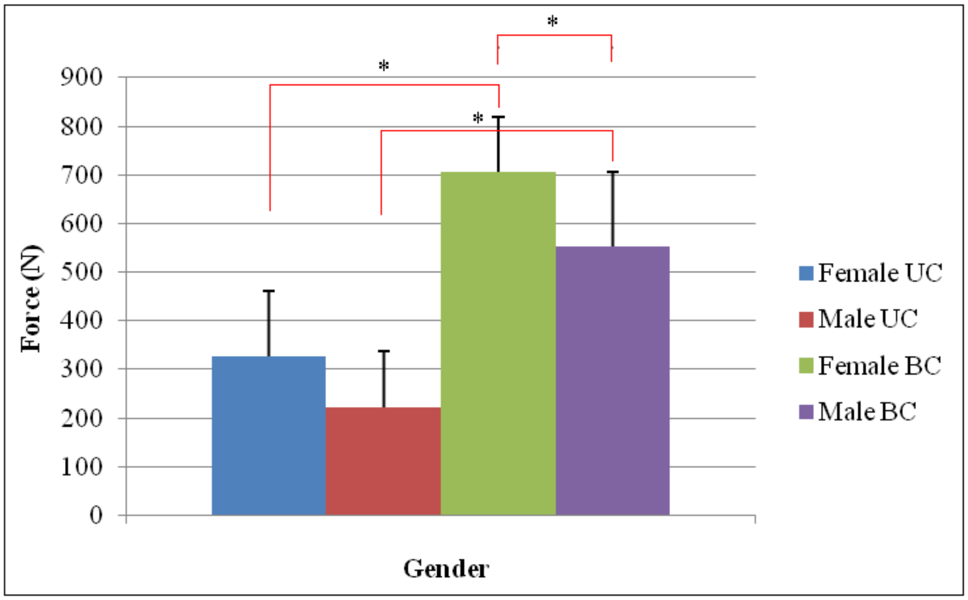

Figure 12: Failure strength data for gender.

Failure strength of the two anchor designs was analyzed with respect to age. A statistically significant correlation was found for both unicortical anchors and bicortical anchors with p values of 0.002 and 0.003. ANCOVA comparisons showed that failure strength of bicortical anchors was significantly higher than that of unicortical anchors with a p value of less than 0.0001. Figure 13 demonstrates these correlations.

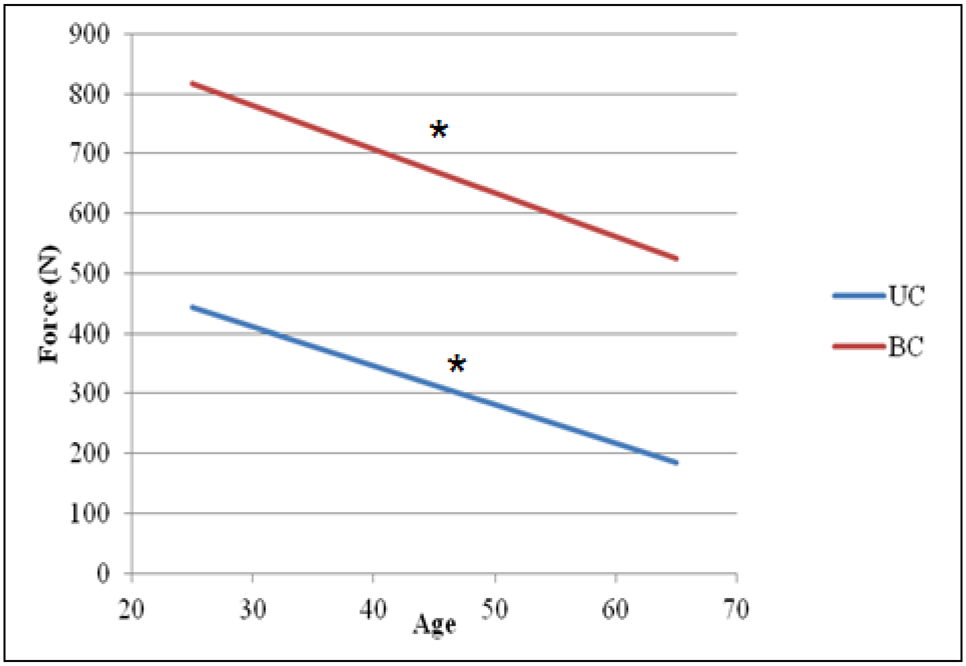

Figure 13: Predictive correlation between failure strength and age.

Comparisons of failure strength were analyzed between unicortical and bicortical anchors within the three diameters that were listed earlier. These comparisons are shown in Figure 14. Failure strength was significantly higher in bicortical anchors than unicortical anchors for all diameters with p values being less than 0.001 for the 4 and 6.5 mm diameter groups and 0.003 for the 5 mm anchor group. Comparisons were also made between the different diameters within unicortical and bicortical anchor groups. Failure strengths were not significantly different with respect to diameter in either unicortical or bicortical anchor designs. The difference in failure strength did approach statistical significance between the 4mm group and the 6.5 mm group within unicortical anchors. P values between groups are shown in Table 3. Comparisons were made using ANOVA.

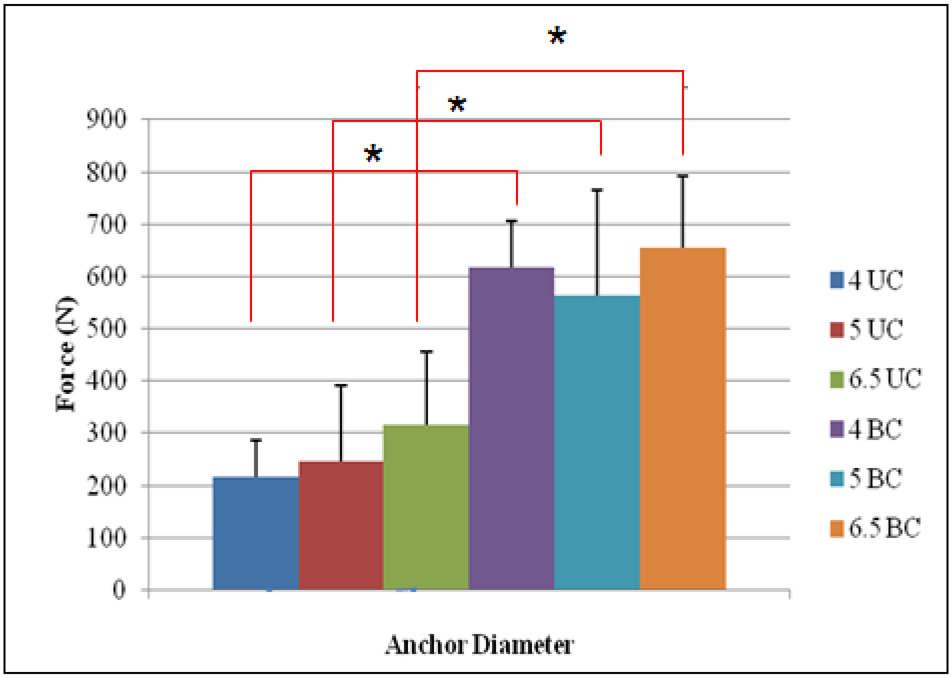

Figure 14: Failure strength for different anchor diameters.

Table 3: Statistical differences of failure strength between anchors grouped by diameter.

	4 mm vs 5 mm	4mm vs 6.5 mm	5mm vs 6.5mm
Unicortical Anchors P value	0.61	0.09	0.25
Bicortical Anchors P value	0.44	0.61	0.21

Because failure strength of anchors did not reach statistical significance between anchors of different diameter, data from all unicortical anchors was grouped and compared with grouped bicortical anchor data using a paired t test. Failure strengths of bicortical anchors were over two times higher than unicortical anchors as shown in

Figure 15. The difference between the groups was highly significant with a P value of less than 0.001.

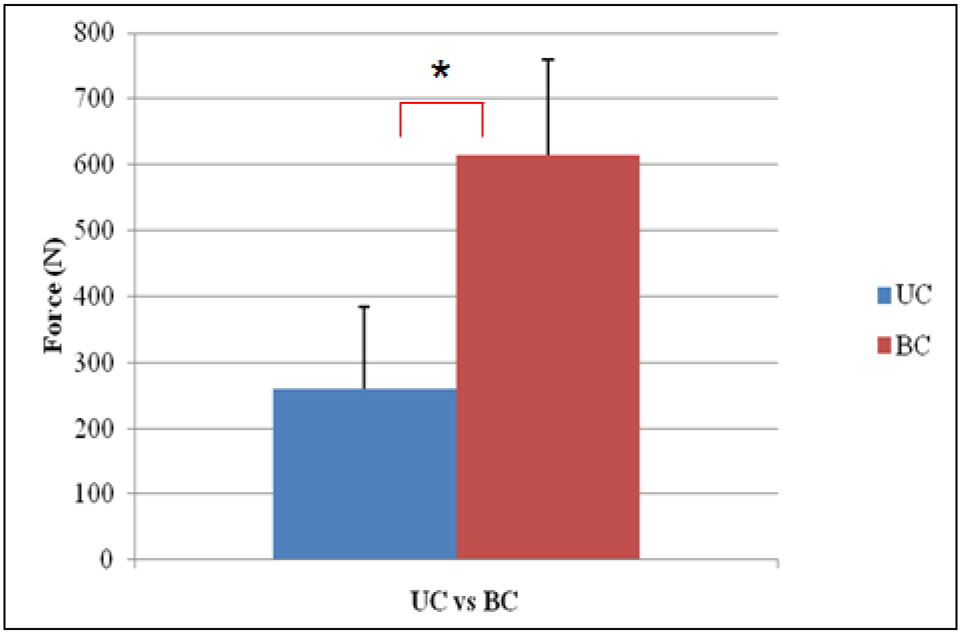

Figure 15: Failure strength of unicortical vs bicortical anchors.

Comparisons of failure strength were analyzed between unicortical and bicortical anchors within the three locations that were described earlier. These comparisons are shown in Figure 16. Failure strengths were significantly higher in bicortical anchors than unicortical anchors for all three anchor locations with a p value of less than 0.001. Comparisons were also made between the different locations within unicortical and bicortical anchor groups. Differences in failure strength were not statistically significant between locations in either unicortical or bicortical anchor groups. P values are shown in Table 4. Comparisons were made using ANOVA.

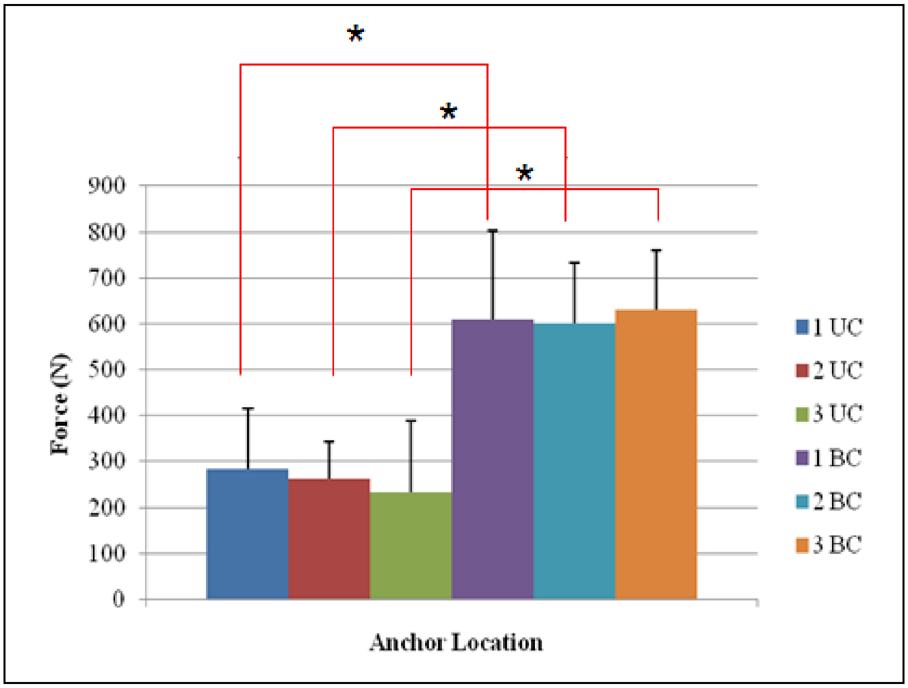

Figure 16: Failure strength data for different anchor locations.

Table 4: Statistical differences of failure strength between anchors grouped by location.

	Location 1 vs 2	Location 1 vs 3	Location 2 vs 3
Unicortical Anchors P value	0.72	0.41	0.66
Bicortical Anchors P value	0.91	0.79	0.69

Discussion

Success of RC repair using suture anchors is dependent upon variables such as but not limited to tendon tear size, tendon quality, suture to tendon binding technique, suture strength, eyelet geometry, eyelet strength, bone quality, and anchor design. This study focused on anchor design as well as taking bone quality and other factors into consideration for both cyclic and ramp loading scenarios.

The first set of tests incorporated a clinically used suture to link anchors to the linear actuator of the mechanical testing machine in order to mimic an RC repair construct. One of the 54 anchors failed during cyclic loading. This failure occurred by suture breakage as did the rest of the anchors which required ramp loading to reach failure. This insinuates that the suture was the limiting factor for failure and is supported by similarities in the failure loads of the unicortical and bicortical anchor groups during ramp loading (185.6 N and 204.4 N respectively). The second set of tests using steel wire was needed in order to identify the forces required to pull the anchors out of bone.

Comparisons of anchor performance between genders did not return the expected results. It is readily accepted that males consistently display higher bone strengths than females. Following this logic, one would expect cyclic elongation to be smaller and failure strength to be higher in males than in females. This study found the opposite to be true for elongation among unicortical anchors and for failure strength in both unicortical and bicortical anchors. Elongation for bicortical anchors was the same between males and females. This anomaly in the data is very misleading and may be attributed to an age discrepancy among the male and female specimens. The average age of male cadavers was 55.2 whereas the average age of female cadavers was 50. If the 26 year old male cadaver is removed from the calculation, the average age of the remaining four males is 62.5 which is above the threshold of 60 set in a previous study to identify decreased bone strength.[44] This age discrepancy, along with the small sample size of the test population may have created an artifact in the results comparing anchor fixation between genders.

Age was found to be a predictor of anchor performance. This was apparent in comparisons of cyclic elongation for unicortical anchors and in comparisons of failure strength for both unicortical and bicortical anchor goups. No correlation was found for age and elongation in bicortical anchors. This may be attributed to the small values found for cyclic elongation among bicortical anchors (average of 0.31 mm when grouped together) as it is difficult for trends to emerge with such small values; nonetheless, elongation of bicortical anchors was not dependent upon age. The correlation in age and anchor fixation is shown much more clearly in the failure strength data. Comparisons between anchor designs showed significantly better fixation of bicortical anchors than unicortical anchors for both elongation and failure strength with respect to age.

In the most recent suture anchor update from Barber et al it was noted that altering the diameter among similar anchor designs did not have an effect on pull out strength.[30] In the present study it was also found that diameter did not have a statistically significant effect on anchor performance. No trends were found in cyclic elongation with respect to diameter for either unicortical or bicortical anchor groups. Elongation values within bicortical anchors were nearly identical between diameters. Again, the reader should keep in mind that elongation values for both anchor designs were very small making it difficult for trends to emerge. Comparisons in failure strength did show a marginally significant trend in the unicortical anchor group with failure strength increasing with increasing diameter. In the bicortical anchor group, 6.5 mm anchors showed higher average failure strengths than the 4 or 5 mm anchors, though this did not reach statistical significance.

This study suggested that anterior anchor placement could result in improved anchor performance over posterior placement as was found in previous studies.[11,9] Trends to support this finding were seen in cyclic elongation data with the statistical difference between location 1 and 3 approaching significance in unicortical anchors (p=0.12) and reaching significance in bicortical anchors (p=0.04). No trends were found in either unicortical or bicortical anchors for failure strength data. Location of anchors may become less of a variable when using anchors of a bicortical design. This is because the portions of the proximal humerus that are responsible for the fixation of these elongated anchors are much different than that of unicortical designs.

Current anchor designs do not generally exceed approximately 2 cm in length. Therefore, all previous studies comparing differences in anchor performance with respect to location were focused on a 2 cm thick section of the superior/lateral portion of the proximal humerus when analyzing fixation. The bicortical anchors used in the present study were 5.5 cm in length, thus the area of bone involved for fixation was much different than in previous studies. These anchors were designed in such a way that the full width of the humeral head was utilized in fixation. This means much more trabecular bone is involved as well as both cortical surfaces. Because of this design, location may not be as relevant for bicortical anchor designs.

Bicortical anchors showed greater fixation than unicortical anchors in most cases when grouped by age, diameter or location for both cyclic elongation and failure strength.

Trends found between the anchor designs in these comparisons were evident and in many cases reached statistical significance, though no more telling data was found than the 2 comparisons made between anchor designs when grouped regardless of other factors. In these 2 comparisons, bicortical anchors showed significantly greater fixation for both cyclic elongation and failure strength.

This study showed that there are benefits in anchor to bone fixation with a bicortical metal screw type suture anchor design when compared to a similar unicortical anchor design, however, it did contain some limitations. The prototype anchors that were tested contained a design flaw in the geometry of the suture eyelet. The eyelets had sharp edges made of the same titanium material as the rest of the anchor. This caused suture breakage to be the mode of failure in 85% of failure tests in the first set of data in which tests were run using suture. A more rounded eyelet, possibly coated with a polymer, may have allowed more anchors to be pulled out in the first set of tests. Though improvements could have been made here, the second set of tests using steel wire accounted for the issue of suture breakage and allowed true failure data to be established.

The second limitation of the study was due to the uniformity in the length of the bicortical anchors when compared to the variety in size of the cadaver specimens. As was mentioned earlier, the bicortical anchors tested in this study were designed to penetrate both cortical layers of the humeral head. Two pairs of humeri used in the study were too large to achieve penetration of the second cortical layer which eliminated a key aspect of fixation in the bicortical anchor design.

Finally, the age of the test population varied considerably. Ages ranged from 26, to 65 with an average of 53.25, and five of the nine donors were under the age of 60. This population may not accurately represent the age range ideally suited for bicortical suture anchors as these anchors were designed for RC injury patients suffering from osteoporosis.

Future Studies

Future studies of bicortical anchor designs should address the aforementioned issues pertaining to the anchors themselves as well as the characteristics of the cadavers used. Anchors should be designed with a more advanced suture eyelet. These should incorporate a polymer lining to reduce suture breakage. Anchors should also be tailored to the size of the specific humeri in which they are being tested. This would ensure that the bicortical design was being realized in all tests. The clinical complication of a protrusion in the medial cortex is another area that should be addressed in future studies. Anchor design could be improved here to reduce abrasion with surrounding tissue in the glenoid area. Cadavers used in future studies should be older than those used in this study. A test population exclusively in post sixty age ranges would have given more clinically applicable results. The utility of the bicortical anchor design would be shown more clearly in older bone of lesser quality in which unicortical anchors do not provide adequate fixation.

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Appendix A - Cyclic Elongation Data

Specimen	Gender	Age	Side	Screw Size	Configuration	Failure Mode	Elongation
23279	M	64	R	4	1S	Eyelet Suture	0.492
23279	M	64	R	4	2L	Eyelet Suture	0.449
23279	M	64	R	4	3S	Eyelet Suture	0.614
23279	M	64	L	4	1L	Under Knot Suture	0.260
23279	M	64	L	4	2S	Eyelet Suture	2.236
23279	M	64	L	4	3L	Eyelet Suture	0.068
201016349	F	52	R	4	1L	Eyelet Suture	-0.055
201016349	F	52	R	4	2S	Eyelet Suture	0.116
201016349	F	52	R	4	3L	Eyelet Suture	0.727
201016349	F	52	L	4	1S	Eyelet Suture	0.167
201016349	F	52	L	4	2L	Eyelet Suture	0.081
201016349	F	52	L	4	3S	Eyelet Suture	0.447
Unmarked			R	4	1S	Eyelet Suture	0.817
Unmarked			R	4	2L	Eyelet Suture	0.652
Unmarked			R	4	3S	Eyelet Suture	0.457
Unmarked			L	4	1L	Eyelet Suture	0.051
Unmarked			L	4	2S	Cyclic	Failed
Unmarked			L	4	3L	Eyelet Suture	0.547
261100940	M	26	R	5	1L	Under Knot Suture	0.491
261100940	M	26	R	5	2S	Eyelet Suture	-0.005
261100940	M	26	R	5	3L	Under Knot Suture	0.387
261100940	M	26	L	5	1S	Eyelet Suture	0.380
261100940	M	26	L	5	2L	Eyelet Suture	-0.023
261100940	M	26	L	5	3S	Under Knot Suture	0.994
201101410	M	65	R	5	1S	Pull Out	1.687
201101410	M	65	R	5	2L	Eyelet Suture	0.322
201101410	M	65	R	5	3S	Pull Out	2.931
201101410	M	65	L	5	1L	Under Knot Suture	0.204
201101410	M	65	L	5	2S	Pull Out	2.546
201101410	M	65	L	5	3L	Eyelet Suture	0.719

6001	M	58	R	5		1L		Eyelet Suture		-0.073
6001	M	58	R	5		2S		Pull Out		3.978
6001	M	58	R	5		3L		Eyelet Suture		-0.134
6001	M	58	L	5		1S		Pull Out		0.531
6001	M	58	L	5		2L		Eyelet Suture		0.881
6001	M	58	L	5		3S		Pull Out		0.421
201101303	M	63	R	6.5		1S		Eyelet Suture		0.083
201101303	M	63	R	6.5		2L		Eyelet Suture		0.225
201101303	M	63	R	6.5		3S		Pull Out		4.465
201101303	M	63	L	6.5		1L		Eyelet Suture		-0.015
201101303	M	63	L	6.5		2S		Eyelet Suture		0.082
201101303	M	63	L	6.5		3L		Eyelet Suture		0.120
809	F	46	R	6.5		1L		Eyelet Suture		0.336
809	F	46	R	6.5		2S		Eyelet Suture		1.629
809	F	46	R	6.5		3L		Eyelet Suture		0.983
809	F	46	L	6.5		1S		Eyelet Suture		0.280
809	F	46	L	6.5		2L		Eyelet Suture		0.116
809	F	46	L	6.5		3S		Eyelet Suture		0.249
20109889	F	52	R	6.5		1S		Eyelet Suture		-0.308
20109889	F	52	R	6.5		2L		Eyelet Suture		0.040
20109889	F	52	R	6.5		3S		Pull Out		2.099
20109889	F	52	L	6.5		1L		Eyelet Suture		0.198
20109889	F	52	L	6.5		2S		Eyelet Suture		0.039
20109889	F	52	L	6.5		3L		Eyelet Suture		0.746

Appendix B - Failure Strength Data

Specimen	Gender	Age	Side	Screw Size		Configuration	Failure Mode	Failure Load
23279	M	64	R	4		1S	PO	130.119
23279	M	64	R	4		2L	U Bolts	583.621
23279	M	64	R	4		3S	PO	120.652
23279	M	64	L	4		1L	Eyelet	560.608
23279	M	64	L	4		2S	PO	232.542
23279	M	64	L	4		3L	PO	455.869
201016349	F	52	R	4		1L	Eyelet	646.213
201016349	F	52	R	4		2S	PO	335.368
201016349	F	52	R	4		3L	Eyelet	781.115
201016349	F	52	L	4		1S	PO	229.420
201016349	F	52	L	4		2L	Eyelet	663.938
201016349	F	52	L	4		3S	PO	175.036
Unmarked			R	4		1S	PO	309.133
Unmarked			R	4		2L	Eyelet	639.515
Unmarked			R	4		3S	PO	198.502
Unmarked			L	4		1L	Eyelet	646.666
Unmarked			L	4		2S	PO	206.810
Unmarked			L	4		3L	Wire Unwound	587.548
261100940	M	26	R	5		1L	U Bolts	723.609
261100940	M	26	R	5		2S	PO	356.114
261100940	M	26	R	5		3L	Wire Broke	708.502
261100940	M	26	L	5		1S	PO	535.330
261100940	M	26	L	5		2L	Wire Broke	670.887
261100940	M	26	L	5		3S	PO	262.151
201101410	M	65	R	5		1S	PO	198.149
201101410	M	65	R	5		2L	PO	297.098
201101410	M	65	R	5		3S	PO	254.447
201101410	M	65	L	5		1L	PO	199.055
201101410	M	65	L	5		2S	PO	134.449
201101410	M	65	L	5		3L	Head Ripped Off	532.711

6001	M	58	R	5		1L				
6001	M	58	R	5		2S				
6001	M	58	R	5		3L		Head Ripped Off		670.988
6001	M	58	L	5		1S		PO		125.083
6001	M	58	L	5		2L		U Bolts		694.957
6001	M	58	L	5		3S		PO		105.545
201101303	M	63	R	6.5		1S		PO		289.091
201101303	M	63	R	6.5		2L		PO		522.036
201101303	M	63	R	6.5		3S		PO		152.779
201101303	M	63	L	6.5		1L		Head Ripped Off		532.258
201101303	M	63	L	6.5		2S		PO		193.365
201101303	M	63	L	6.5		3L		U Bolts		575.765
809	F	46	R	6.5		1L		Wire Broke		846.728
809	F	46	R	6.5		2S		PO		343.223
809	F	46	R	6.5		3L		U Bolts		841.240
809	F	46	L	6.5		1S		PO		384.314
809	F	46	L	6.5		2L		Wire Broke		749.039
809	F	46	L	6.5		3S		PO		624.107
20109889	F	52	R	6.5		1S		PO		356.970
20109889	F	52	R	6.5		2L		PO		588.908
20109889	F	52	R	6.5		3S		PO		211.292
20109889	F	52	L	6.5		1L		PO		723.559
20109889	F	52	L	6.5		2S		PO		288.789
20109889	F	52	L	6.5		3L		PO		513.878