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A Comparison of Ultimate Pullout Strength of Four Bioabsorbable Tacks

Benjamin Bleess

University of North Dakota

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A COMPARISON OF ULTIMATE PULLOUT STRENGTH OF
FOUR BIOABSORBABLE TACKS

by

Benjamin Bleess
Bachelor of Science in Physical Therapy
University of North Dakota, 2000

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
2001
This Independent Study, submitted by Benjamin Bleess in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Susan Hend
(Faculty Preceptor)

Susan Hend
(Graduate School Advisor)

Thomas More
(Chairperson, Physical Therapy)
PERMISSION

Title A Comparison of Ultimate Pullout Strength of Four Bioabsorbable Tacks

Department Physical Therapy

Degree Master of Physical Therapy

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Most importantly, to an awesome God who created us all and loves us with an everlasting love. Thank you for the opportunity to study your greatest love and creation throughout physical therapy school. All of creation declares your handiwork. “For You formed my inward parts; You wove me in my mother’s womb. I will give thanks to You for I am fearfully and wonderfully made; Wonderful are Your works, And my soul knows it very well.” (Psalm 138:13-14 NAS)
ABSTRACT

The purpose of this study was to evaluate the pullout strength, both parallel and perpendicular to that tack shaft, of four different bioabsorbable tacks: Suretac A, Suretac B, Bionx A, and Bionx B. These tacks were fixated into a foam block and tension was placed on each tack until point of failure between the tack-foam interface. Results indicated that the Bionx B tack withstood the greatest mean ultimate parallel pullout strength at 292.04 N and failed at a force significantly higher than all other tack types (p=.000). The Bionx A failed at 150.25 N, Suretac B at 147.64 N, and Suretac A at 79.19 N. Suretac A failed at a force significantly lower than all other tack types (p=.01). Results indicated that Bionx B withstood the greatest ultimate perpendicular pullout strength at 468.47 N and failed at a force significantly higher than all other tack styles (p=.01). Suretac B failed at 354.02 N, Bionx A at 290.64 N, and Suretac A at 279.75 N. There was also a significant difference in mean ultimate perpendicular pullout strength between Suretac B and Suretac A (p = .000). The results indicate that Bionx B is the strongest tack in terms of pullout strength; however, failure modes were also assessed with the result of tack shaft breakage of the Bionx tacks and shaft bending of the Suretac designs.

The results of this study indicated that bioabsorbable tacks have qualities similar to other surgical fixation devices being used for surgical repair of the
supraspinatus tendon. It is crucial that the physical therapist have an appropriate amount of knowledge regarding surgical procedures when working with patients with rotator cuff repairs. This knowledge will assist the therapist in designing an appropriate rehabilitation program following the surgeon's guidelines or protocol and based on the needs of the individual patient.
CHAPTER I
INTRODUCTION

God's design of the human shoulder is indeed amazing when considering the extreme mobility and durability required for constant use during the many daily activities of a person's lifetime. As a person ages, degenerative changes occur in the tendons and muscles of the rotator cuff. These changes occur as a normal response to the aging process and include calcium deposition, fibrous thickening, diminished vascularity, tissue necrosis, and rending at the bone-tendon interface via Sharpey's fibers. Repetitive occurrences of minor strains during daily activities combine with these degenerative changes to cause chronic rotator cuff tears. Shoulder dysfunction and associated pain are often due to this type of chronic rotator cuff tear and predominantly affect males in their fifth and sixth decades of life. Traumatic rotator cuff injuries also occur but are less common than chronic rotator cuff injury. This type of injury occurs as a result of a single traumatic event and can happen in any age group. Damage to the rotator cuff tendons occurs when the load exceeds the cuff strength. The mode of injury is generally during sports when the shoulders are in forward flexion or an overhead position. In this position, a sudden overhead force could then overload cuff strength and cause an acute traumatic tear.
Conservative techniques as well as invasive surgical techniques have long been utilized to bring about restoration of proper function following a rotator cuff injury. The advent of arthroscopic surgery has further enabled surgeons to reduce post-surgical scar tissue from inhibiting the body’s intended free movement of tissue. Reduction of scar tissue and foreign bodies, such as metal or non-absorbable sutures, allows the original design of the shoulder to function as normally as possible.

Anatomy of the shoulder and specifically the supraspinatus will be reviewed in the proceeding chapters. This literature review will also discuss the failure of the supraspinatus tendon, standard surgical repair, and techniques using bioabsorbable fixation devices.
CHAPTER II

REVIEW OF LITERATURE

The “shoulder” is the generic term used to describe an extremely complex unit that provides stability and mobility for the upper extremities on the superior portion of the rib cage. The shoulder consists of five major articulating components: 4

1) Glenohumeral (GH) joint
2) Acromioclavicular (AC) joint
3) Sternoclavicular joint
4) Scapulothoracic joint
5) Suprathoracic (SH) joint (false joint).

Normal function of all components is essential for proper movement. Due to the complex nature of the entire shoulder complex, this anatomy review will be limited to the glenohumeral and suprathoracic joints along with the rotator cuff muscles.

Glenohumeral Joint

The GH joint appears to be like a golf ball on a tee. A little more than a third of the humeral head articulates on the glenoid fossa of the scapula at any one time.1 The two joint surfaces are somewhat incongruent and this requires a complex roll and spin of the humeral head simultaneously to stay within the
glenoid fossa during movement of the upper extremity. This extreme mobility allows for three degrees of freedom: internal/external rotation, flexion/extension, and abduction/adduction.

Stabilization of this joint is critical in order to keep the articulating surfaces in contact while the humeral head rolls and spins on the glenoid fossa. As the muscles that act as prime movers contract, providing the majority of force for movement of the upper extremity, the static and dynamic stabilizers of the GH joint function to restrain movement and stabilize the joint.

Static stabilizers include: 

1. Labrum - deepens the glenoid fossa
2. Coracohumeral ligament - thickening of the joint capsule which helps suspend the humerus, limit external and internal rotation of the humerus
3. Inferior, middle, and superior glenohumeral ligaments - thickenings of the joint capsule which limit external rotation, prevent excessive anterior translation and dislocation
4. Joint capsule - maintains synovial fluid in the glenohumeral joint; also helps to suspend humerus

Dynamic stabilization is performed by the rotator cuff muscles and the tendon of the long head of the biceps brachii. The rotator cuff consists of supraspinatus, infraspinatus, teres minor, and subscapularis (see Fig 2). Together, these muscles provide dynamic stabilization of the humeral head by acting as a force couple in all motions with the other muscles acting on the GH
Figure 1. Netter Plate 394 showing static and dynamic stabilizers of the glenohumeral joint. "Copyright 1999. ICON Learning Systems. Reprinted with permission from ICON Learning Systems, illustrated by Frank H. Netter, MD. All rights reserved."

Figure 2. Netter Plate 394 showing the rotator cuff muscles. "Copyright 1999. ICON Learning Systems. Reprinted with permission from ICON Learning Systems, illustrated by Frank H. Netter, MD. All rights reserved."
The rotator cuff muscles are extremely strong. In fact, Poppen and Walker found that between one-third and one-half of the shoulder power in abduction and 90% of shoulder power in external rotation is contributed by the rotator cuff. Another key function of the cuff is to act as a humeral depressor and prevent superior movement of the humeral head (see Fig 3). For example, when the deltoid contracts to abduct the humerus, the humeral head moves superiorly. Active contraction of the rotator cuff is required to prevent excessive superior humeral translation. The result of the function of this force couple is a spin and roll of the humeral head to maintain joint surface contact on the glenoid cavity without impinging structures in the subacromial space. Damage or weakness of the cuff results in loss of the force couple arrangement and excessive superior humeral movement. This movement allows structures in the subacromial space to be compressed under the coracoacromial arch. Undeniably, the most critical structure being damaged in the subacromial space is the supraspinatus tendon.

Suprahumeral Joint

The SH joint is actually a false joint but is a critical area due to the structures that lie within it. Understanding of this joint is essential in realizing the mechanism of impingement of the supraspinatus tendon within this space (see Fig 4).

The acromion forms a protective surface over the superior portion of the humeral head in order to prevent trauma from a superior direction. Immediately inferior to the acromion lies the coracoacromial ligament which forms the roof of
Figure 3. Deltoid and rotator cuff force couple. Although each of the muscles pull in different directions, the resultant force results in elevation of the humerus. Reprinted with permission from Tom Mohr, University of North Dakota.

Figure 4. Coronal section of shoulder showing subacromial structures. Reprinted with permission from Tom Mohr, University of North Dakota.
the SH joint. Within this space and inferior to this ligament lies the subacromial bursa, supraspinatus tendon, joint capsule, and biceps tendon respectively. The humeral head forms the floor of this joint. Structures within this area are most susceptible to impingement between the acromion and the humeral head.

Pathology of Supraspinaus Injury

The supraspinatus muscle function is critical for proper shoulder mechanics. Howell et al\(^7\) found that the supraspinatus and deltoid are equally responsible for the torque generated at the GH joint in forward flexion and elevation in the plane of the scapula.

Repetitive trauma, known as impingement, from the anterolateral edge of the acromion and the coracoacromial arch makes the supraspinatus the most susceptible muscle of the cuff to damage.\(^8,9\) This is consistent with evidence showing that a cuff tear almost always starts near the insertion of the supraspinatus tendon, under the acromion, and then slowly spreads to the other adjacent tendons of the cuff.\(^5,8,9\) A major source of damage for the supraspinatus tendon is a downward hooking acromion and/or osteophyte formation at the AC joint. The inferior side of the acromion process is usually shaped in one of three morphologies: flat or type I (17%), curved or type II (43%), and hooked or type III (39%).\(^11\) Hooking of the acromion and osteophytes at the AC joint were the reason Neer\(^8,12\) recommended an anterior acromioplasty be performed for all patients undergoing rotator cuff repairs in order to reduce further impingement damage. Peterson and Gentz\(^10\) found distally pointing osteophytes in 51% of 47 patients with a ruptured supraspinatus. Presence of
these osteophytes at the AC joint and hooking of the acromion was also consistent with Neer's\textsuperscript{12} experience with a majority of his patients with rotator cuff tears. He presumed because of this that tears of the cuff are initiated 95% of the time by impingement and not by a single traumatic incident or circulatory degeneration.

Sano et al\textsuperscript{13} found that degenerative changes that correlate with aging contribute significantly to supraspinatus tendon failure due to tensile strength reduction. Blevin et al\textsuperscript{14(\textsuperscript{p1})} stated, "Although the precise nature of this tendon degeneration is poorly understood, it most likely involves the biological response of the tendon to extrinsic loading as well as age-related alterations in tendon metabolism, vascularity, and structure." Alterations in vascularity may be compounded with the poor blood supply that is present in the supraspinatus tendon. Near the insertion of the supraspinatus tendon is an area of hypovascularity. This decrease in blood flow could possibly predispose this tendon to the need for longer healing times (see Fig 5). Blood tends to be wrung out in this region when the shoulder is fully adducted; when the shoulder is then abducted, the blood flow is restored to the tendon. Blevin\textsuperscript{14} also goes on to mention that due to the extreme resilience of healthy tendons, they must first degenerate before failure can be recognized clinically. A study by Neer and colleagues\textsuperscript{12} found that rotator cuff tears correlated to the presence of increasing age. Out of 233 patients with cuff tears studied, only eight patients were under 40 years of age. Normal tendon is extremely durable, and in order to find
Figure 5. Critical zone in supraspinatus tendon. Reprinted with permission from Tom Mohr, University of North Dakota.
damage clinically, there usually needs to be age related degeneration of the tissue combined with some trauma.

Damage to the rotator cuff that produces pain and/or dysfunction should be treated by conservative therapy because of the body's ability to heal itself within certain parameters. Surgical procedures are the next step when healing does not occur and the patient is not satisfied with their current condition.

Surgical Repair

Goals for rotator cuff repair have changed very little through the years. According to Kenter and Warren,\textsuperscript{15} goals continue to be: relief from pain due to surgery, restoration of function as fully as possible, avoidance of re-injury, and continuing with maintenance therapy. On the other hand, methods of surgery are always being researched to find a new “Gold” standard. Therefore, due to the comprehensive scope of surgical methods, this discussion will be general and will not include all variations of techniques.

The basic technique described by McLaughlin\textsuperscript{16} in 1944 continues to be the most commonly used surgical technique for rotator cuff repairs. There are many slight variations of materials and methods but the basic technique appears to be the present “Gold” standard for this type of surgery. This technique involves creating a bone trough adjacent to the articular cartilage just proximal to the original bone tendon interface. Holes are drilled in the bone of the lateral ridge of the trough previously formed and stitching is done through the distal portion of the supraspinatus tendon. This tendon is then pulled into the trough where it is secured by sutures to the bone trough.
A secure attachment for the supraspinatus tendon is extremely important. Wallace et al. estimated that the force generated through the supraspinatus tendon in an unloaded arm at 30° shoulder abduction to be approximately 300 N. This appears to be the minimum standard that fixation devices attempt to achieve in order to avoid as many complications as possible following rotator cuff surgical repair. Fixation devices have included transosseous sutures, metal staples, metal suture anchors, metal screws with plates or washers, polytetrafluoroethylene plates, polydioxanone bands, bioabsorbable rods, wedges or tacks, etc. Transosseous Sutures

Surgery utilizing transosseous suture fixation basically follows the McLaughlin technique and consists of a myriad of variations in materials and methods that offer a wide range of results. One constant of the basic technique is suturing through the greater tuberosity as an anchor site. As the most common patient is in his/her fifth and sixth decade of life, osteoporotic bone may be a risk factor for avulsion of the greater tuberosity. If an avulsion fracture occurs, a subsequent revision of this technique is made much more difficult as the strongest sites for fixation into the bone have failed and secondary sites must be used for fixation of the tendon. Bigliani et al. noted that secondary revisions are generally less favorable than the primary surgery and the need for revision is seen as one of the disadvantages of this technique.

Caldwell et al. evaluated the strength of transosseous sutures in cadaver. The standard technique with a braided non-absorbable suture was
used in all cadavera. The greatest strength was recorded when bone suturing was done 30 mm. distal to the greater tuberosity with a mean of 247 N ± 26 N (n=6). The weakest strength was recorded when the sutures were placed 10 mm distal to the greater tuberosity (x̄=69 N ± 22 N (n=8)).

Newer methods of surgical repair utilizing transosseous sutures were tested by Sward et al. on cadavera shoulders. The repair was performed as described by Matsen and Arntz with additional non-absorbable mattress sutures at the bone tendon interface. A non-absorbable patch made of ultra-high molecular weight polyethylene was also used at the bone suture site to disperse forces and prevent fracture. Failure occurred at x̄=605 N ± 109 N (n = 10).

France et al. measured the ultimate load that the supraspinatus tendon could withstand to be x̄=601.85 N ± 169.05 N (n = 4). The ultimate goal was to see fixation strengths greater than the supraspinatus tendon's ultimate load which was achieved with the surgical technique employed by Sward et al. This was, however, at the expense of a substantial amount of non-absorbable material left permanently in the shoulder.

Metal Staples

France et al. studied the use of arthroscopic metal staples on nine cadaver shoulders to fixate the supraspinatus tendon. Their results showed frequent tearing of the tendon on the staple legs along with staple loosening. The pullout strength was x̄=78.8 N ± 41.0 N (n = 6). Fixation was so poor that use of this type of fixation was discouraged altogether.
Metal Suture Anchors

Suture anchors were first introduced by Goble et al\textsuperscript{18} in 1985 to fixate non-contractile tissue and are now being used to fixate contractile tissue. A cadaveric study by Rossouw et al\textsuperscript{19} evaluated the strength of suture anchors for rotator cuff repair of the supraspinatus in two methods using different locations on the humerus. Method one used the standard location for the bone trough used in the McLaughlin\textsuperscript{16} technique. Method two placed the bone trough in the lateral cortex of the humerus 25 mm distal to the greater tuberosity, perpendicular to the surface, with the sutures passing through the greater tuberosity. This second placement was studied to address the problem of the common occurrence of osteoporosis in the cancellous bone in the proximal humerus. Method one failed at $\bar{x}=147 \text{ N} \pm 74 \text{ N}$ and always resulted in the pullout of the suture anchor. Method two failed at $\bar{x}=363 \text{ N} \pm 120 \text{ N}$ with failure of the suture itself. The strength of $\bar{x}=363 \text{ N} \pm 120 \text{ N}$ slightly exceeds the estimated 300 N generated at 30° active abduction of the shoulder. Despite this strength, the metal anchor still has significant drawbacks when compared to bioabsorbable fixation due to their permanent presence in the bone.

Metal Inference Screws

Walton\textsuperscript{26} performed anterior cruciate ligament (ACL) reconstructions on 71 sheep using both absorbable polyglyconate screws and metal inference screws. It was concluded that both were equal in fixation value, but the absorbable screws fully absorbed after the graft had reached sufficient healing giving a distinct advantage to the absorbable screws.
Walton also noted five specific advantages to using absorbable materials as opposed to metal materials.

1. Metal bodies can obstruct joint imaging.
2. Metal bodies can compromise any further arthroplasty; whereas, it is common for the total absorption of polyglyconate screws at one year post-op.
3. Metal implants can be displaced many years after initial surgery and would require surgical removal to limit serious damage to surrounding structures.
4. Greater risk for infection at implant site when using metal materials over bioabsorbable materials.
5. Persisting metal objects could possibly be obstacles to the natural and free movement of surrounding tissues; whereas, bioabsorbable materials are gone in a relatively short time.

Absorbable Fixation Devices

The use of bioabsorbable tacks for fixation of rotator cuff muscles is currently in its infancy. Therefore, there is no published information of their use for the rotator cuff fixations or pullout strengths. Despite this, research is available for bioabsorbable tacks when used to fixate labrum after a Bankart tear. A Bankart tear is defined as a tear in the labral cartilage disrupting the labral attachment from the anterior inferior glenoid rim.

Shawl and Cawley evaluated the ultimate pullout strength of suture anchors, absorbable staples, and absorbable tacks using 20 cadaver shoulders.
The mean forces were as follows: suture anchor $\approx 224.73$ N, tack $\approx 120.11$ N, staple $\approx 114.19$ N. Materials used in this comparison were not the newest on the market at the time of the study. Whether or not these tacks have sufficient strength to fixate the supraspinatus is debatable because their fixation strength is generally around 200 to 300 N per tack. However, these tacks are continuing to be routinely used and further development is likely for better bioabsorbable materials. It is the goal of this study to evaluate the strength of some of these new materials and hypothesize their ability to fixate the supraspinatus tendon for accelerated rehabilitation protocols following repair of the rotator cuff.

**Purpose of the Study**

The purpose of this study was to compare and determine the ultimate pullout strength of four types of bioabsorbable tacks, both perpendicular to the tack shaft and parallel to the tack shaft. Mode of failure of each tack type was also assessed in this study.

**Significance of the Study**

The significance of this study was to determine the pullout force that bioabsorbable tacks can successfully withstand and if this had implications on rehabilitation. Bioabsorbable tacks have already been proven to be successful in repairing non-contractile tissue. Tendons, however, are contractile tissue which produce a force on the injured tendon as well as the fixation device if the muscle is actively contracted. In order to successfully repair a tendon, the surgical fixation device must be strong enough to resist active contraction as well as a stretch from passive range of motion. Otherwise, the joint must be
immobilized until the tissue has healed enough to withstand physiological force without failing.

It is also important to determine the mode of failure of the tack. If the tack does not exit the bone entirely upon ultimate pullout, excess tack fragments could cause irritation and damage to the shoulder joint until absorption or surgical removal.

Research Questions

Through this study, the researchers hoped to answer a few questions about biodegradable tacks being used for rotator cuff repairs: 1) What is the pullout strength of the different tack types analyzed in this study? 2) Is there a difference in pullout strength between the four tack types? 3) Is the ultimate pullout strength of the tack enough to withstand active contraction produced by the tendon? 4) What is the mechanism of failure if the repair should fail?

Hypotheses

The null hypotheses stated that: 1) There is no significant difference between tacks in pullout strength parallel to the tack shaft. 2) There is no significant difference between tacks in pullout strength perpendicular to the tack shaft.

The alternate hypotheses stated that: 1) There is a significant difference between tacks in pullout strength parallel to the tack shaft. 2) There is a significant difference between tacks in pullout strength perpendicular to the tack shaft.
With this study, the goal was to increase the amount of knowledge regarding the use of bioabsorbable tacks in repair of contractile tissue of the shoulder and to have a better understanding of the strength factor of these tacks, and to ascertain whether an accelerated rehabilitation program would have detrimental effects on the repair. Assessing the mode of tack failure were also considered along with the implications that must be deliberated on a per patient basis due to the characteristics of the tacks and the surgical fixation.
CHAPTER III

METHODS

Materials

Four different types of bioabsorbable tacks with two different biochemical compositions were used for this study. They included 1) Suretac A; 2) Suretac B (Smith & Nephew Inc., 160 Dascomb Rd., Andover MA 01810 U.S.A), which are polyglyconate absorbable fixators, made from a copolymer of polyglycolic acid (PGA) and trimethylene carbonate; 3) Bionx tack A; 4) Bionx B (Bionx Implants Inc., 1777 Sentry Parkway W., Gwynedd Hall, Suite 400, Blue Bell, PA 19422 U.S.A) which are made of poly L-lactic acid (PLLA) (Figure 6). A total of 46 tacks were tested: Suretac A (n = 20), Suretac B (n = 10), Bionx A (n = 10), Bionx B (n = 6).

The Suretac tacks were separated into A and B categories due to the fact that the groups of tacks were received and tested at separate time intervals. There was no measurable difference in width or length between the two Suretac styles. The Suretac contains barbs along the outer rim of the undersurface of the head of the tack and ribs along the shaft.

The Bionx tacks were separated into A and B groups based on designs of the tacks. A measurable difference was noted in Bionx tack types and these tacks types contain different barb designs on the undersurface and on the tack.
Figure 6. Comparison of Suretac and Bionx tack types: A) Suretac A & B; B) Bionx A; C) Bionx B.
shaft. The barbs on the undersurface of the head of Bionx A were smaller and rounded in comparison to the longer, more pointed barbs on the Bionx B tack. Barbs on the shaft of Bionx A were staggered and less flared out from the surface of the shaft in comparison to the evenly placed barbs, which were more flared on the Bionx B tack. Table 1 illustrates the difference in tack dimension designs between the Suretac and Bionx tack styles.

Table 1. Dimensions of Different Tack Styles Measured in Inches

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Suretac (A &amp; B)</th>
<th>Bionx A</th>
<th>Bionx B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of tack</td>
<td>.707</td>
<td>.822</td>
<td>.787</td>
</tr>
<tr>
<td>Length of top of tack head to start of rib/barb</td>
<td>.247</td>
<td>.384</td>
<td>.387</td>
</tr>
<tr>
<td>Diameter of tack shaft just under tack head</td>
<td>.144</td>
<td>.144</td>
<td>.141</td>
</tr>
<tr>
<td>Diameter of tack shaft at tip of shaft</td>
<td>.112</td>
<td>.138</td>
<td>.137</td>
</tr>
<tr>
<td>Diameter of tack head</td>
<td>.294</td>
<td>.280</td>
<td>.276</td>
</tr>
<tr>
<td>Thickness of tack head</td>
<td>.071</td>
<td>.062</td>
<td>.076</td>
</tr>
</tbody>
</table>

A piece of high-density, polyurethane foam (Pacific Research Labs Inc., 10221 S.W. 188th St., Yashon, WA 98070 U.S.A) was used to simulate human bone (density of 30 lbs/cubic ft). A preliminary ultimate parallel pullout strength test was done to assess 10 lb., 15 lb., 20 lb., and 30 lb. densities of the foam board as compared to a porcine humeral head. This revealed an equivalent comparison between the 30 lb. foam board and the bone.
Instrumentation

An Omega model LC101 'S' Beam Load Cell was used to measure the force placed on each tack during testing procedures. The load cell was attached to a computer and a 'Strawberry Tree' analog input card, model ACPC-12-8, was used to record the data in mV transmitted from the load cell. The data were later converted to N for analysis. A custom-made fixation device (Airlift Technology, 6520 Lake Dr., Grand Forks, ND 58201) was used to secure the test setup (Figure 7).

Procedure

Force measurements were recorded under two different test conditions: 1) force applied parallel to and 2) force applied perpendicular to the shaft of each tack. Tacks were implanted into a foam board following the manufacturer's instructions which entailed pre-drilling a hole into the foam board, placement of tack on guide-wire into the hole, pounding tack with cannulated driver to secure tack into foam board. A single researcher implanted each tack to ensure consistency of placement and to decrease error. Tacks pulled parallel to the tack shaft were inserted into an aluminum collar/bracket (Northern Valley Machine, 1510 Gateway Dr. NE, East Grand Forks, MN 56721) prior to implantation into the foam board. This collar was used to ensure well-distributed pull on the entire tack (Figure 8). Tacks pulled perpendicular to the tack shaft were implanted directly into the foam board securing a Kevlar tendon between the tack head and foam. The Kevlar tendon was composed of 12 strands of Hexcel's #710 Farric and was used to simulate the supraspinatus tendon.
Figure 7. Setup of device used for testing pullout strength.
Figure 8. Bracket used to apply equal force upon parallel pullout.
Force was continually applied to the system until the tack pulled free of the foam board. Force data were measured by the load cell and recorded on the computer.

Data Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS)\(^2\) using a one-way, independent measures Analysis of Variance (ANOVA) and Kruska-Wallis which is a non-parametric test. Comparisons of the four tacks were analyzed to assess mean ultimate pullout strength, standard deviation, and to determine if a significant difference existed between any of the four tack types.

When using a one-way ANOVA to analyze data, three assumptions must be met: 1) homogeneity of variance, 2) normal distribution, and 3) interval ratio data. When analyzing assumptions of parallel pullout strength, homogeneity of variance was not met; for perpendicular pullout strength, normal distribution was not met. This required the use of the non-parametric Kruskal-Wallis test. The calculated \(p\) value was less than alpha (for parallel pullout \(p = .001\), for perpendicular pullout \(p = .007\)) on the Kruskal-Wallis indicating that there was a significant difference of parallel pullout strength between tacks. According to Linquist,\(^3\) because a significant difference was noted in both Kruskal-Wallis and ANOVA, the ANOVA results can be reported utilizing a higher significance level. Therefore, the alpha level of \(p = .025\) was considered significant.
CHAPTER IV

RESULTS

Parallel Pullout

Table 2 summarizes the mean pullout strength, standard deviation, maximum and minimum scores for each tack. The results indicate that the Bionx B tack withstood the greatest mean ultimate pullout strength at 292.04 N ± 18.31 N compared to the Suretac A which produced the lowest mean ultimate pullout strength at 79.19 N ± 14.87 N. Bionx A produced the largest standard deviation of 55.64 N compared to Suretac A which produced the lowest standard deviation of 14.87 N. Suretac B and Bionx A produced remarkably similar mean ultimate pullout strengths (147.64 N and 150.25 N, respectively).

Table 2. Comparison of Tack Pullout Strength Parallel to Tack Shaft

<table>
<thead>
<tr>
<th>Tack</th>
<th>n</th>
<th>Mean (N)</th>
<th>Standard Deviation</th>
<th>High Score (N)</th>
<th>Low Score (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suretac (A)</td>
<td>10</td>
<td>79.19</td>
<td>14.87</td>
<td>97.50</td>
<td>50.79</td>
</tr>
<tr>
<td>Suretac (B)</td>
<td>5</td>
<td>147.64</td>
<td>18.16</td>
<td>171.95</td>
<td>120.85</td>
</tr>
<tr>
<td>Bionx (A)</td>
<td>7</td>
<td>150.25</td>
<td>55.64</td>
<td>223.92</td>
<td>75.26</td>
</tr>
<tr>
<td>Bionx (B)</td>
<td>3</td>
<td>292.04</td>
<td>18.31</td>
<td>312.96</td>
<td>278.89</td>
</tr>
</tbody>
</table>

Analysis of the one-way ANOVA indicated a significant difference between tack types pulled parallel to the tack shaft where F(3,21)=33.30, p=.000. Scheffe's test was used for post hoc analysis at a significance level of α=.025.

Table 3 summarizes pairwise comparison of the pullout strengths. Results
indicate that Suretac A had a significantly lower mean pullout strength than all other tack styles. Bionx A and Suretac B did not have a significantly different mean pullout strength, although the standard deviation of Bionx A was quite different from Suretac B (55.64 N compared to 18.16 N respectively). Bionx B had a significantly higher mean pullout strength than all other tack styles.

Table 3. Pairwise Comparison Between Tacks When Pulled Parallel to Tack Shaft

<table>
<thead>
<tr>
<th>(I) Tacks</th>
<th>(J) Tacks</th>
<th>Mean Difference (I-J)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suretac A</td>
<td>Suretac B*</td>
<td>-68.45</td>
<td>.010</td>
</tr>
<tr>
<td></td>
<td>Bionx A*</td>
<td>-71.07</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-212.86</td>
<td>.000</td>
</tr>
<tr>
<td>Suretac B</td>
<td>Suretac A*</td>
<td>68.45</td>
<td>.010</td>
</tr>
<tr>
<td></td>
<td>Bionx A</td>
<td>-2.61</td>
<td>.999</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-144.41</td>
<td>.000</td>
</tr>
<tr>
<td>Bionx A</td>
<td>Suretac A*</td>
<td>71.07</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Suretac B</td>
<td>2.61</td>
<td>.999</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-141.79</td>
<td>.000</td>
</tr>
<tr>
<td>Bionx B</td>
<td>Suretac A*</td>
<td>212.86</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Suretac B*</td>
<td>144.41</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Bionx A*</td>
<td>141.79</td>
<td>.000</td>
</tr>
</tbody>
</table>

* Mean difference is significant at $p < .025$.

Failure modes of both Suretac styles occurred by intact and complete pullout from the foam. All Bionx A tacks pulled out intact with the exception of one which failed by complete breakage of the shaft leaving part of the shaft in the foam. Bionx B tacks tested had different modes of failure. Failure occurred by complete shaft breakage, intact pullout, and avulsion of the foam with the tack (Figures 9, 10).
Figure 9. Failure modes of Bionx tack types. A) Avulsion of the foam; B) Partial fracture of the tack shaft; C) Complete fracture of tack shaft; D) Intact tack for reference.

Figure 10. Failure mode of Suretac. A) Bending of tack shaft; B) Intact tack for reference.
Perpendicular Pullout

Table 4 summarizes the mean ultimate pullout strength, standard deviation, maximum and minimum scores for each tack. Our results indicated that Bionx B withstood the greatest mean ultimate pullout strength at 468.47 N ± 4.21 N compared to Suretac A which withstood the lowest mean ultimate pullout strength at 279.75 N ± 40.46 N. Suretac B produced the largest standard deviation of 46.33 N compared to Bionx B which produced the lowest standard deviation of 4.21 N. Standard deviations were similar for all tacks with the exception of Bionx B which was much lower.

Table 4. Comparison of Tack Pullout Strength Perpendicular to Tack Shaft

<table>
<thead>
<tr>
<th>Tack</th>
<th>n</th>
<th>Mean (N)</th>
<th>Standard Deviation</th>
<th>High Score (N)</th>
<th>Low Score (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suretac (A)</td>
<td>10</td>
<td>279.75</td>
<td>40.46</td>
<td>377.76</td>
<td>245.05</td>
</tr>
<tr>
<td>Suretac (B)</td>
<td>5</td>
<td>354.02</td>
<td>46.33</td>
<td>413.83</td>
<td>285.32</td>
</tr>
<tr>
<td>Bionx (A)</td>
<td>3</td>
<td>290.64</td>
<td>37.91</td>
<td>314.00</td>
<td>246.90</td>
</tr>
<tr>
<td>Bionx (B)</td>
<td>3</td>
<td>468.47</td>
<td>4.21</td>
<td>472.84</td>
<td>464.45</td>
</tr>
</tbody>
</table>

Analysis of the one-way ANOVA indicated a significant difference between tack types pulled parallel to the tack shaft F(3,21)=19.44, p=.000. Scheffe’s test was used for post hoc analysis at a significance level of α= .025. Table 5 summarizes pairwise comparison of the pullout strengths. Results indicate that Bionx B had a significantly higher mean pullout strength than all other tack styles. Bionx A did not have a significantly higher mean pullout strength than either Suretac styles.

Failure mode of both Suretac styles was intact and complete pullout of the tack from the foam; however, bending of the tack shaft did occur (Figure 10). All
Table 5. Pairwise Comparison Between Tacks When Pulled Perpendicular to Tack Shaft

<table>
<thead>
<tr>
<th>(I) Tacks</th>
<th>(J) Tacks</th>
<th>Mean Difference (I-J)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suretac A</td>
<td>Suretac B*</td>
<td>-74.28</td>
<td>.026</td>
</tr>
<tr>
<td></td>
<td>Bionx A</td>
<td>-10.90</td>
<td>.980</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-188.73</td>
<td>.000</td>
</tr>
<tr>
<td>Suretac B</td>
<td>Suretac A*</td>
<td>74.28</td>
<td>.026</td>
</tr>
<tr>
<td></td>
<td>Bionx A</td>
<td>63.38</td>
<td>.220</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-114.45</td>
<td>.009</td>
</tr>
<tr>
<td>Bionx A</td>
<td>Suretac A</td>
<td>10.90</td>
<td>.980</td>
</tr>
<tr>
<td></td>
<td>Suretac B</td>
<td>-63.38</td>
<td>.220</td>
</tr>
<tr>
<td></td>
<td>Bionx B*</td>
<td>-177.83</td>
<td>.000</td>
</tr>
<tr>
<td>Bionx B</td>
<td>Suretac A*</td>
<td>188.73</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Suretac B*</td>
<td>114.45</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Bionx A*</td>
<td>177.83</td>
<td>.009</td>
</tr>
</tbody>
</table>

*Mean difference is significant at the .05 level.

Bionx A tacks failed by breakage of the tack shaft leaving part of the tack shaft in the foam. Bionx B failed in two different modes. Failure occurred once by intact and complete tack pullout and twice by fracturing the tack shaft with complete pullout (Figure 9).

Figures 11 and 12 summarize the mean, standard deviation, and significance level for parallel and perpendicular pullout.
Figure 11. Mean ultimate pullout strength of bioabsorbable tacks pulled parallel to tack shaft. A) Suretac A; B) Suretac B; C) Bionx A; D) Bionx B.

Figure 12. Mean ultimate pullout strength of bioabsorbable tacks pulled perpendicular to the tack shaft. A) Suretac A; B) Suretac B; C) Bionx A; D) Bionx B.
Bionx B showed significantly stronger mean ultimate pullout strength both parallel (292.04 N) and perpendicular (468.47 N) to the tack shaft than the other three styles as summarized in Tables 3 and 5. These differences between Bionx B and the both Suretac styles could be attributed to several factors. Tack design characteristics were different for the two tack styles. They included a greater overall tack length (.787 and .707 inches, for Bionx B versus the Suretac styles) and diameter of tack shaft at tip (.137 and .112 inches, for the Bionx B versus the Suretac styles). Bionx B also had 15 small, flared barbs along the shaft, while the Suretac styles had four ribs along the shaft. Any of these design changes could make a difference in the fixation quality of the Bionx B over both Suretac styles.

Chemical composition may also have given the tacks unique physical characteristics, such as rigidity. The Suretac styles composed of PGA did not break during any trial whether parallel or perpendicular pullout. This may be a favorable situation due to the ease of removal by the surgeon if failure were to occur and a second surgery for removal was necessary. However, pullout strength is significantly less than that of Bionx B in both testing conditions. The Bionx styles composed of PLLA frequently broke or fractured during parallel
pullout and always broke during perpendicular pullout, except in one instance where there was avulsion of foam from the block (Figure 9). Both Bionx styles showed a propensity towards breakage at the tack head or shaft, consequently leaving part of the shaft in the foam block. In one specimen, the remainder of the shaft protruded out of the foam block. This type of failure may be an unfavorable situation due to the increased difficulty for surgical removal of tack fragments. This type of failure in a patient could also result in trauma to structures in the subacromial space during glenohumeral movement. It appears as though both Suretac styles were less rigid when compared to both Bionx styles. This was demonstrated by their bent appearance after perpendicular pullout (Figure 10). These characteristics must be considered by the individual surgeon along with their pullout strengths to evaluate which tack type is appropriate for the individual patient, surgical technique, and the recommended rehabilitation program.

Differences between Bionx A (PLLA) and Bionx B (PLLA) must be contributed to tack design and dimensions rather than chemical makeup due to their similar composition. Tack bars present in Bionx B were smaller, more flared, and more numerous than those present in Bionx A. Smaller bars cut from the tack shaft could result in less damage to the integrity of the shaft and overall greater fixation strength present in Bionx B tack. During testing of Bionx A, the failure of the tack shaft was typically at the site where bars were cut in the shaft; whereas, the instances of failure of Bionx B occurred at the tack head. This evidence agrees with the previously stated benefit of the smaller bars.
Wallace et al\textsuperscript{17} estimated that the force generated through the supraspinatus tendon in an unloaded arm to be 300 N at 30° shoulder abduction. This appears to be the minimum strength that fixation techniques must offer in order to be viable surgical options. Only Bionx B exceeded this guideline of 300 N during both parallel and perpendicular pullout with a single tack. It should also be noted that a stronger repair could be possible if multiple tacks were used to fixate which is often the case during rotator cuff and labral\textsuperscript{29} repairs.

No other research was available on the pullout strength for any of these bioabsorbable tack styles so comparison of other studies is not possible.

Limitations of the Study

Using a foam board substitute gave the researchers a consistent material and reduced the variability that would be present in individual bones. It was realized that the foam board was a dissimilar environment than that of human humeral head, which offered benefits as well as disadvantages. By eliminating the variability of bone, the foam board allowed for an evaluation of each tack style in a consistent environment allowing for more accurate comparison between trials which was the ultimate goal.

Porcine humeri are generally considered similar to human humeri; thus, this study tested two porcine humeri and used a foam board with similar straight pullout strength. Testing of more porcine humeri could have been done to find an even more similar substitute.
The custom-made device used to manually test pullout strength could have placed different forces on each tack. A constant rate of pullout was attempted by researchers but was difficult to achieve due to the test set-up. As the researcher manually turned the nut on the shaft, the rate of turning varied from trial to trial. This variance changed the amount of time each tack was under force and had the potential to produce creep and weakening of different magnitude, thus influencing results of the fixation strength. Based on the miniscule standard deviation of BionX B perpendicular pullout, this factor may be minimal. Despite this, it would be beneficial in future studies to reproduce the same rate for each tack pullout to eliminate creep variation and the possible effects on ultimate pullout strength.

The use of the Kevlar tendon eliminates further variables but allows the researchers to test only the pullout strength of the tack itself. Whether or not the tack can hold a supraspinatus tendon as well as the Kevlar tendon is unknown and prevents us from knowing the actual fixation strength of a rotator cuff repair. This information is needed in order to apply our current data to the physical therapy environment.

Clinical Implications of this Study

Care must be taken to limit clinical generalization of this study beyond initial fixation strength due to changes in fixation strength as healing occurs in the tissues. Walton\textsuperscript{26} tested bioabsorbable and metal fixation screws in 71 anterior cruciate ligament reconstructions in sheep. Initial fixation strength testing for bioabsorbable and metal screws was $\bar{x}=184 \pm 84$ N and $\bar{x}=233 \pm$
35 N, respectively. At six weeks, it was $\approx 192 \pm 64$ N and $\approx 133 \pm 68$ N, respectively. At twelve weeks, it was $\approx 377 \pm 183$ N and $\approx 355 \pm 139$ N, respectively. It is likely that these tacks would perform similarly when using human bone and tendon, but further testing of these situations must be done in order to make that claim. This also implies that bioabsorbable materials do offer a competition to their metal counterparts in regard to strength.

Recommendations for Further Research

Recommendations for further research include the use of human bone and tendon to evaluate the fixation strength of the tack in a more realistic environment. Since these data show how the tack itself will react to pullout force, this next step is only logical. This will allow a comparison of fixation strengths for bioabsorbable materials and to the traditional methods reported in the literature. Another option could be to use the foam board along with human tendon or porcine tendon to evaluate the fixation strength on the tendon itself. Likewise, human bone could be used along with the Kevlar tendon to evaluate the fixation strength of the tack into bone. Using a testing device such as the Instron would provide testing at the same rate for each tack, will resolve the discrepancy in creep variation, and will ensure that each tack is stressed at nearly the same rate. Lastly, testing of different tack styles should include using a varying number of tacks as is done during any rotator cuff fixation, depending on the size of tear, to assess fixation strength using multiple tacks.
Conclusion

This pilot study has been beneficial to demonstrate the different qualities offered by these four tack styles. Bionx B clearly shows greater pullout strength in all cases, but it is unclear as to how these tacks will perform with variables of human bone and tendon. More research would be beneficial to evaluate if the bone, tendon, or tack show a pattern as the weakest component of the fixation. This information will give knowledge needed to assess whether these tacks can meet the apparent minimum requirements in vivo for surgical fixation to effectively hold the supraspinatus tendon to withstand a force greater than 300 Newtons.

Further, recommendation for use of accelerated protocols is premature in light of the absence of information regarding tack performance in human tissues. It is also recommended that individual surgeons critically evaluate the current information to decide their immediate use for accelerated rehabilitation protocols.
APPENDIX A
September 25, 2000

Mr. Benjamin T. Bleess
Student
University of North Dakota
570 Carleton Ct. #105
Grand Forks, ND 56711

Dear Mr. Bleess:

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