

The fixable suture anchor plate: a mechanical comparison to other devices commonly used for tendon anchorage to bone during rotator cuff repair surgery

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ABSTRACT

Background: A fixable suture anchor plate is a new device which has been designed with the intention of improving anchorage-to-bone strength during tendon-to-bone repair in patients with compromised bone quality. In this *in vitro* study we compare the load-to-failure and mode-of-failure results of a fixable suture anchor plate to that of other devices that are commonly used during rotator cuff repair surgery, including: a buttress plate, metal suture anchors, bioabsorbable suture anchors, and suture through simple tunnels without any augmenting device. We hypothesized that the fixable suture anchor plate would provide higher load-to-failure measurements compared to the other devices.

Methods: Each device was implanted into solid rigid polyurethane foam blocks with densities representing varying degrees of osteoporosis, and then tested to failure. ANOVA and post-hoc analysis tests were used to determine statistical significance.

Results: The fixable suture anchor plate demonstrated superior anchorage strength in low and medium density foam blocks compared to the other devices that were tested in this study ($p < 0.01$). The greatest difference in magnitude was seen in low density blocks (5pcf), where the fixable suture anchor plate failed at 278 ± 53 N (mean \pm standard deviation), about double the value of the next highest failure at 133 ± 11 N for the buttress plate.

Conclusions: In the foam blocks that simulated greater degrees of osteopenia (low and medium density blocks), the average load to failure for the fixable suture anchor plate was significantly greater compared to the other devices tested. Further studies are needed to determine whether clinical use of a fixable suture anchor plate will translate into a higher rotator-cuff-repair success rate *in vivo*.

LEVEL OF EVIDENCE

Basic Science Study

KEYWORDS

suture anchor plate; cuff repair plate; fixable; rotator cuff repair; osteopenia; osteoporosis; greater tuberosity; load to failure

INTRODUCTION

The integrity of the rotator cuff at the time of follow-up is the major determinant of the outcome of an operative repair of a rotator cuff tear.²² Reported cuff repair failure rates have ranged from 6% to 94%.^{2; 14; 15; 18; 19; 22; 26; 34}

While it has been shown that bone quality, anchor type, and anchor placement location have a significant impact on failure loads for rotator cuff repair,³¹ the ideal means of securing the tendon to bone has not yet been identified. This is evidenced by the fact that the most common complication of rotator cuff repair is structural failure at the repair site.³⁵

Various devices, including sutures alone, suture anchors, screws, staples, tacks, wedges, plugs, posts and plates have been used to secure tendon to bone, and repair failures involving each device have been reported.^{1; 3; 4; 7; 9; 17; 20; 21; 24; 25; 27; 33}

Failure at the repair site may result in component malposition or migration,^{24; 27} which in turn can lead to persistent pain, decreased range of motion, failure of the rotator cuff repair, and even destruction of the glenohumeral joint. Because of this, the importance of choosing an implant or technique that will provide sufficient mechanical strength, especially in patients with osteoporotic bone, has been emphasized, yet there is little consensus regarding the superiority of any particular device or technique for tendon-to-bone fixation.²⁷

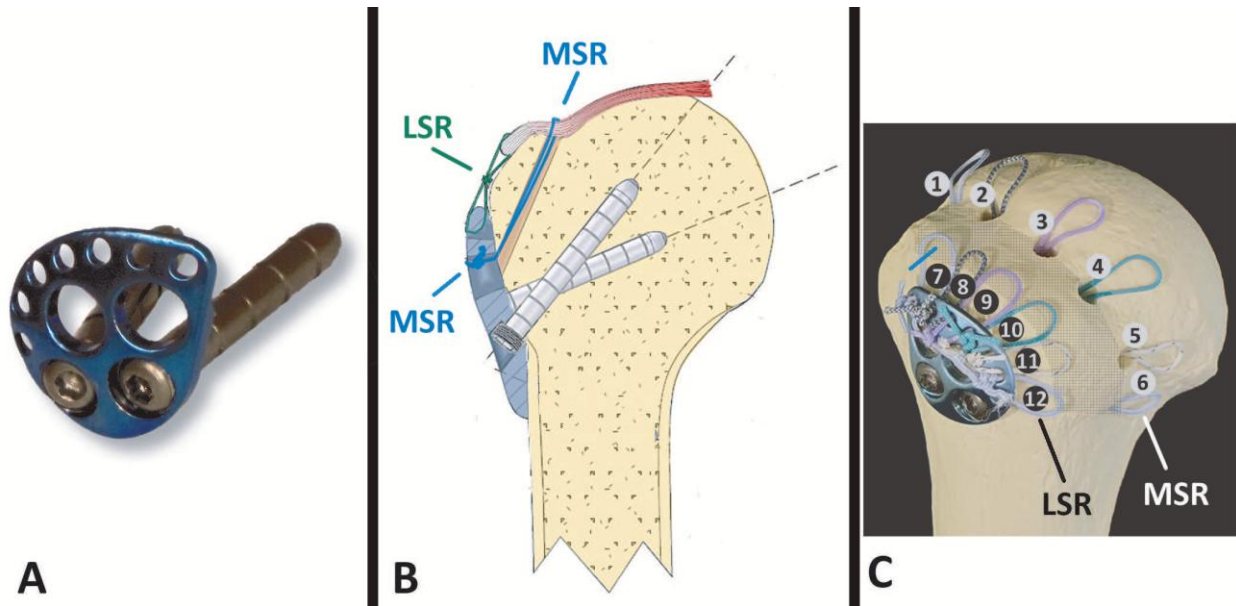


Figure 1 A, A fixable suture anchor plate (Cuff Repair Plate (CRP), Shoulder Options, Inc. Boise, ID). The device consists of a contoured plate (blue) and two anchor bolts (gray) that lock into the plate and diverge from one another. The plate has several holes which serve as tying points for suture. **B**, An illustration of a cuff repair utilizing a “double row” suture technique. The medial suture row (MSR) is placed through the bone, while the lateral suture row (LSR) runs over the bone. **C**, An example of how a fixable suture anchor plate could be used to provide multiple points of fixation for repair of a massive rotator cuff tear. A medial row of sutures (numbered 1-6) runs through the bone, and the lateral row of sutures (numbered 7-12) sits on the surface of the bone.

A fixable suture anchor plate is a new device that has been designed with the intention of improving anchorage-to-bone strength during rotator cuff repair in patients with compromised greater tuberosity bone quality. Like a buttress plate,^{13;20} a fixable suture anchor plate may be used to augment weak bone at the lateral metaphysis of the proximal humerus to prevent suture from cutting through the bone during or after a rotator-cuff-repair surgery. The difference between a buttress plate and a fixable suture anchor plate is that a buttress plate is held in place against the lateral metaphyseal bone by suture material alone, while the fixable suture anchor plate is also coupled to the bone by anchor bolts that lock into the plate (Figure 1A). The purpose of

coupling the plate to the bone with additional hardware is to distribute the forces of the newly repaired rotator cuff tendon over a larger area of bone in hopes of minimizing the risk of bony fixation failure.

The fixable suture anchor plate device has yet to be compared to other established devices and techniques for anchorage to bone. Our in vitro study compares the load-to-failure and mode-of-failure results of a fixable suture anchor plate (Cuff Repair Plate (CRP), Shoulder Options, Inc., Boise, ID) to that of four other devices/constructs that are commonly used during rotator cuff repair surgery, including: 1) a buttress plate (7-hole titanium button-plate (7HTBP), Synthes, Monument, CO); 2) 5.5mm metal suture anchors (Fastin RC, DePuy Mitek,

Raynham, MA); 3) 5.5mm bioabsorbable suture anchors (Spiralok, DePuy Mitek, Raynham, MA); and, 4) suture through tunnels without any fixation-augmenting device. We hypothesized that the load to failure for the fixable suture anchor plate repair construct would be greater than that of other devices.

MATERIALS AND METHODS

A bone model using solid rigid polyurethane foam blocks (Sawbones, Pacific Research Laboratories, Inc., Vashon, Washington) was created to simulate the proximal humerus. Foam blocks of three different densities (5, 10, and 15 pounds per cubic foot (pcf)) were used to represent varying degrees of osteopenia, with lower pcf values representing greater degrees of osteopenia. The foam blocks complied with American Society for Testing and Materials (ASTM) standard.¹⁶ The edges of each foam block were contoured with a router with a ¼" roundover bit to approximate the shape of the greater tuberosity (Figures 2 and 3).

The devices were implanted into the humeral models by an orthopedic surgeon (CSH). Each device (fixable suture anchor plate, buttress plate, metal suture anchor, bioabsorbable suture anchor, and suture without any fixation-augmenting device) was implanted and tested five times for each of the three polyurethane block densities. Every construct utilized #2 FiberWire® (Arthrex, Inc., Naples, FL) suture for consistency in suture strength between the devices. 35mm anchor bolts were used when testing the CRP device (Figure 1A) since they represented the midrange of the sizes available for that device. Each device was joined to the foam block by a double loop of suture, which was in turn coupled to metal S-hooks used for loading of the construct (Figure 4). The S-hooks were secured to the construct by tying a surgeon's knot followed by 5 half hitches in every case.

Suture anchors were loaded with #2 FiberWire sutures prior to implantation. The 5.5mm metal and bioabsorbable suture anchors were implanted at an angle 45 degrees from the long axis of the foam block (Figure 3) in a manner similar to what has been previously described.^{8;}⁹ As recommended by the manufacturer, an awl and tap were used when placing the bioabsorbable anchors.

When testing the other repair constructs (fixable suture anchor plate, buttress plate, and suture without any fixation-augmenting device) two tunnels, spaced 1 cm apart, were made in the polyurethane blocks in a manner similar to what has been described in previous studies (Figure 4).^{10; 20; 28; 29} Tunnels were created in the 5 and 10pcf blocks by passing a heavy, size 7 surgical needle through the polyurethane blocks adjacent to the metal plate such that it exited approximately 1.7cm distally (Figure 2). A curved awl was used in place of a needle when using 15pcf foam blocks because the higher density of these blocks tended to cause the needle to break. Two suture strands were then passed through the tunnels and tied as shown in Figure 4.

The blocks were positioned in a custom testing jig designed to simulate the forces seen after a supraspinatus repair (Figures 2, 3, and 5). Each construct was then tested to failure in tension using a materials testing machine (Model SFM-30, United Calibration Corporation, Huntington Beach, CA). After application of a 5 Newton preload, an applied load was directed 135 degrees from the long axis of the block at a rate of 20mm/minute until failure occurred. The ultimate failure loads and the modes of failure for each test were recorded.

To compare anchor constructs, a one-way ANOVA was conducted. Upon significance of the one-way ANOVA, a Levene Statistic was calculated to determine if the variance of the

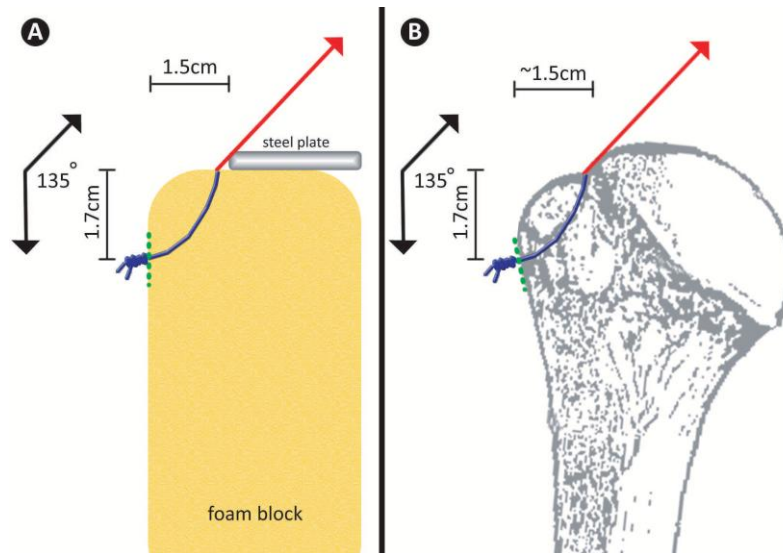


Figure 2 A, Illustration of our model for simulating the proximal humerus. Tunnels were created for passing suture (blue) through the foam block as shown. When utilized, the buttress plate and the fixable suture anchor plate were positioned to augment the foam in the region represented by the dashed green line. Tensile force (red arrow) was applied to the sutures in a direction corresponding to 135° from the long axis of the block. **B**, This illustration corresponds to what our model is meant to represent.

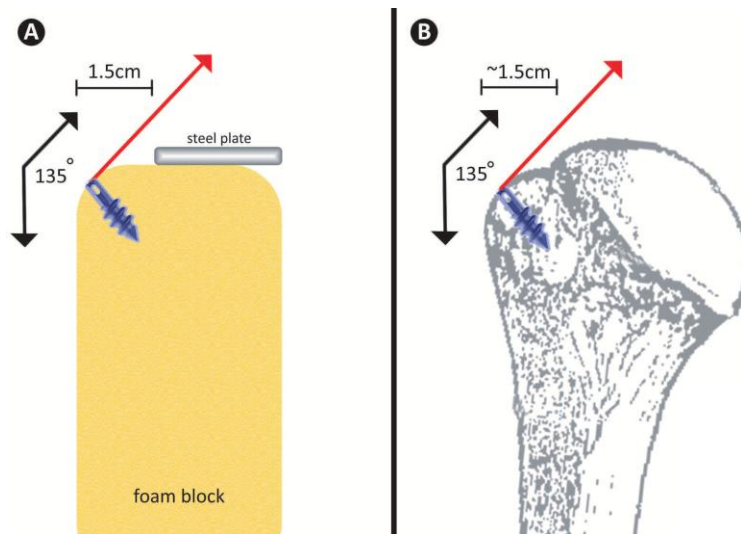


Figure 3 A, Illustration of our model for simulating the proximal humerus. Suture anchors were placed into the foam block at a 45° angle from the long axis of the block. Tensile force (red arrow) was applied to the sutures in a direction corresponding to 135° from the long axis of the block. **B**, This illustration corresponds to what our model is meant to represent.

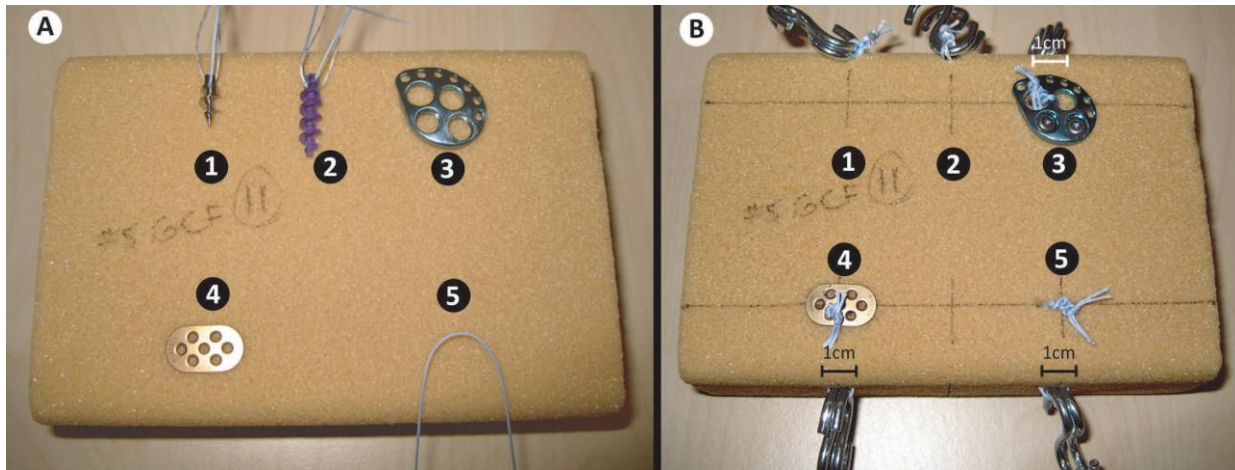


Figure 4: A, Five constructs were tested in a foam block, including: **1**, a metallic suture anchor (Mitek Fastin RC), **2**, a bioabsorbable suture anchor (Mitek Spiralok), **3**, a fixable suture anchor plate (Shoulder Options Cuff Repair Plate (CRP)), **4**, a buttress plate (Synthes 7-hole titanium button plate (7HTBP)), and **5**, suture through tunnels without any augmenting device. B, S-hooks have been secured to a foam block using a double loop of #2 FiberWire for each construct. The suture was passed through two tunnels 1cm apart from one another when testing the CRP, 7HTBP, and suture through tunnels without any augmenting device.

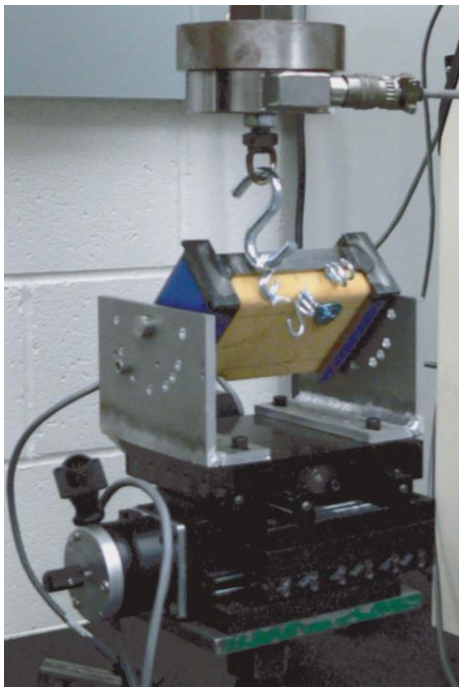


Figure 5 A foam block has been inserted into the custom testing jig and materials testing machine.

anchor constructs was equal. With a significant Levene Statistic showing unequal variance among anchor constructs, a Games-Howell post hoc analysis was conducted to determine pairwise differences among bone-anchorage constructs. The significance cutoff was set at 0.05.

RESULTS

The load-to-failure results varied significantly depending upon device type and block density. The load-to-failure and mode-of-failure results are summarized in Tables I and II.

In foam blocks that simulated greater degrees of osteopenia (5 and 10pcf blocks), the average load to failure for the fixable suture anchor plate was significantly greater ($p \leq 0.01$) compared to the other devices tested. The greatest difference in load-to-failure magnitude was seen in the low density blocks (5pcf), where

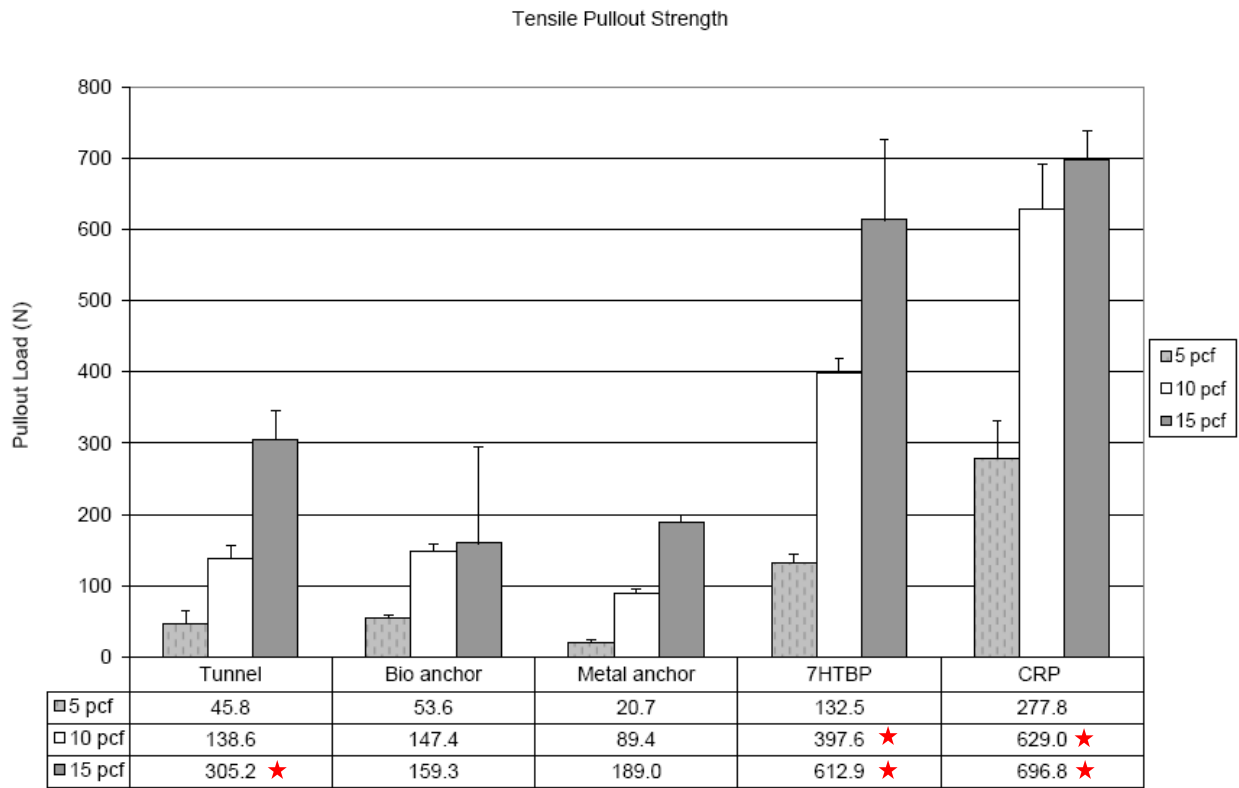


Table I Average load-to-failure measurements in Newtons for the constructs implanted into foam blocks of low (5pcf), medium (10pcf), and high (15pcf) densities. **Table key:** *Tunnel* = suture placed through tunnels in the foam block without any augmenting device; *Bio anchor* = bioabsorbable suture anchor; *Metal anchor* = metal suture anchor; *7HTBP* = buttress plate (7-hole titanium button plate); *CRP* = fixable suture anchor plate (Cuff Repair Plate); ★ = measurement above 302N.

the fixable suture anchor plate failed at 278 ± 53 N (mean \pm standard deviation), about double the value of the next highest failure at 133 ± 11 N for the buttress plate. Under these conditions, the load to failure for the fixable suture anchor plate measured 13X greater than that of the metal suture anchor. In general, the magnitude of the difference between the fixable suture anchor plate and the other devices decreased as the density of the testing block material increased.

In high density blocks (15pcf), both the fixable suture anchor plate and the buttress plate outperformed the other devices ($p \leq 0.01$). The mode of failure for these two devices in high density blocks was suture breakage. The load-to-failure measurements for these two devices when

placed in high density blocks were therefore similar because the results simply reflected the strength of the suture.

The bioabsorbable anchors were the only devices that broke during our testing. Mechanical failure of the device did not occur when testing metal suture anchors, the buttress plate, or the fixable suture anchor plate. Failure of the device was not seen when bioabsorbable anchors were tested in blocks of low and medium density (5 and 10pcf). However, mechanical failure of the bioabsorbable anchors was seen in 5 of 5 cases when tested in high density (15pcf) foam blocks. In one case, the eyelet of the bioabsorbable anchor broke off upon insertion prior to load testing. Of the 4 bioabsorbable anchors that could still be

Construct	Foam block density (pcf)	Suture gauge	Mode of Failure (n=5)			Load to failure (N)	
			foam block failure	device failure	suture failure	average	standard deviation
Tunnel	5	#2	5			46.1	±10.9
CRP	5	#2	5			277.8	±52.9
7HTBP	5	#2	5			132.5	±10.8
Bio anchor	5	#2	5			53.6	±5.7
Metal anchor	5	#2	5			20.7	±2.6
Tunnel	10	#2	5			138.6	±17.9
CRP	10	#2			5	629	62.7
7HTBP	10	#2	5			397.6	±20.8
Bio anchor	10	#2	5			147.4	±10.6
Metal anchor	10	#2	5			89.4	±6.8
Tunnel	15	#2	5			305.2	±40.4
CRP	15	#2			5	696.8	±41.1
7HTBP	15	#2	1		4	612.9	±112.4
Bio anchor	15	#2		5		159.3	±135.2
Metal anchor	15	#2	5			189	±9.8

Table II The modes and loads of failure. **Table key:** *Tunnel* = suture placed through tunnels in the foam block without any augmenting device; *CRP* = fixable suture anchor plate (Cuff Repair Plate); *7HTBP* = buttress plate (7-hole titanium button plate); *Bio anchor* = bioabsorbable suture anchor; *Metal anchor* = metal suture anchor.

implanted, all failed at the eyelet upon load testing.

DISCUSSION

This is the first study to introduce the concept of a fixable suture anchor plate for rotator cuff repair surgery. The goal of this study was to compare the load-to-failure and mode-of-failure results of a fixable suture anchor plate to those of other devices that are commonly used to repair a torn rotator cuff. The results presented here represent preliminary biomechanical testing of a new device, and our study must be interpreted with caution as our results do not reflect the strength of an actual

tendon-to-bone rotator cuff repair. Rather, our results show the load that is required to either: 1) displace any of these devices from a foam block ("foam block failure"; Table II), 2) cause a device itself to fail ("device failure"; Table II), or 3) cause the suture material to break ("suture failure"; Table II).

Burkhart et al¹¹ estimated a total supraspinatus/infraspinatus force of 302 N based on measurements of muscle cross-sectional area and a force production constant. None of the devices tested in our study provided sufficient fixation strength to withstand a force of this magnitude irrespective

of foam block density. The constructs utilizing the fixable suture anchor plate, the buttress plate, and suture through tunnels without any fixation-augmenting device could achieve a load-to-failure measurement above the 302 N “threshold” in some cases (Table I), depending upon the density of the foam blocks. The bioabsorbable and metal suture anchor devices all failed at loads much lower than this regardless of foam block density.

Compromised greater tuberosity bone quality (Figure 6) has been shown to be associated with rotator cuff tear chronicity,¹² and several authors have indicated that greater tuberosity osteopenia may affect anchor pullout strength.^{12; 23; 31; 32} In fact, insufficient bone quality is considered a contraindication to

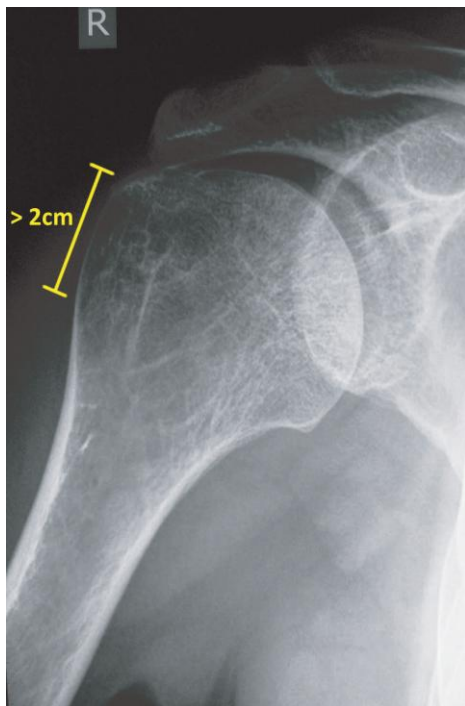


Figure 6 A radiograph of a patient with a chronic rotator cuff tear showing osteopenia of the greater tuberosity and a paucity of cortical bone at the lateral metaphyseal region. An increase in cortical bone thickness is seen about 2cm distal to the lateral edge of the greater tuberosity.

suture anchor use according to some device manufacturers.^{5; 6; 30} Failure at the rotator cuff repair site may result in component malposition or migration,^{24; 27} which in turn can lead to persistent pain, decreased range of motion, failure of the rotator cuff repair, and even destruction of the glenohumeral joint.

Guidelines regarding the degree of osteopenia at which device implantation becomes unsafe are currently lacking, and at this point in time this decision is ultimately in the hands of the treating surgeon. The fixable suture anchor plate achieved the highest load-to-failure measurements in low and medium density foam blocks. Based on these results, we believe that use of a fixable suture anchor plate might help to minimize the risk of component migration and its associated complications in patients with osteopenic bone compared to the other devices that were tested in this study, but further studies are needed to prove this.

A criticism of this study could be that it was conducted using foam blocks rather than cadaveric bone. The bony structure of the greater tuberosity bone is complex, and we admit that this complexity is not represented by our foam block model. Despite this, we did find that some of our results were consistent with those from previously published cadaveric studies. Specifically, in our study the buttress plate increased the load to failure by 2-3X compared to suture through tunnels without any augmenting device. This is consistent with the results of Gerber et al²⁰ as well as those by Caldwell et al,¹³ both of whom tested similar devices in cadaveric specimens.

Despite the limitations of our synthetic bone model, there were advantages to using it over cadaveric humeri. Regional variability of the density of trabecular bone within the greater tuberosity in cadaveric humeri has been documented,³¹ and by using foam blocks the density of the material was known as well as

consistent throughout the specimen regardless of the location of the anchor/device placement. This eliminated density variability between separate bone specimens and within an individual bone specimen as confounding factors in our study.

In conclusion, this is the first paper to introduce the concept of the fixable suture anchor plate for rotator cuff repair. This new device demonstrated superior anchorage strength in the foam blocks that simulated greater degrees of osteopenia (low and medium density blocks) compared to the other devices that were tested in this study. Based on these results, we believe that use of a fixable suture anchor plate might help to minimize the risk of component migration and its associated complications

during rotator cuff repair in patients with osteopenic bone. Further studies are needed to prove this, however, and to know whether use of a fixable suture anchor plate will translate into a higher rotator-cuff-repair success rate in vivo.

CONFLICT OF INTEREST STATEMENT

C. Scott Humphrey is the founder of Shoulder Options, Inc., and the designer of the Cuff Repair Plate (CRP) device.

Tyler C Brown, Seth Kuhlman, and Michelle B Sabick received no direct compensation for this study. Shoulder Options, Inc. provided an unrestricted donation to the Boise State University Center for Orthopaedic & Biomechanical Research (a research foundation with which these authors are affiliated) to help fund studies such as this one.

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