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Research Article

Effect of Subchondral Bone Needling on Suture Anchor Pull Out Strength: A Cadaveric Study

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Received: November 21, 2016; **Published:** December 02, 2016

Abstract

Purpose: Multiple studies have evaluated methods to enhance rotator cuff healing to the footprint, including techniques to stimulate the repair site by bringing biologic factors and stem cells into the site. The purpose of this study was to determine if subchondral bone needling to the rotator cuff footprint would compromise the pull-out strength of standard suture anchors and thus possibly compromise clinical outcomes.

Methods: A single row of three 5.5 x 18 mm suture anchors were placed into the greater tuberosity of eight fresh-frozen matched-pair cadaveric shoulders (ages 59-64; 1M, 3 F) which had been inspected to ensure normal humeral head anatomy void of any apparent humeral head deformities. They were then randomly divided into two groups: One side served as the Control Group with suture anchors alone; the contralateral side shoulder, the suture anchors were augmented with two rows of subchondral bone needling of the rotator cuff footprint with 1.0 mm wide channels spaced 2.5 mm apart (Augment Group).

Each suture anchor underwent biomechanical testing using a 45 degree pull angle. Anchors were pre-loaded with 50 N for 10 seconds and then loaded to failure (304 mm/second).

Results: There was no significant difference in the average pull-out strength between the two groups ($p = 0.43$). The mean pull-out strength for the Augment Group (12 anchors) was 236.8 N (range: 166 - 303) and 234.3 N (range: 124 - 333) for the Control Group (12 anchors). Position specific anchor analysis showed no statistically significant differences for anterior, superior, and posterior ($p = 0.2128$) placement nor between the control group and each location.

Conclusions: The ultimate load-to-failure of medially inserted suture anchors augmented with subchondral needling showed no difference compared with the control group.

Keywords: *Suture Anchors; Rotator Cuff; Pull Out*

Abbreviations

N: Newtons; M: Male; F: Female; RCR: Rotator Cuff Repair; A: Anterior; M: Middle; P: Posterior; µct: Micro Computed Tomography; Kv: Kilovolts; µa: Microampere; Ms: Milliseconds; µm: Micrometer; ANOVA: Analysis of Variance; Mm: Millimeter; BMS: Bone Marrow Stimulating; K-Wire: Kirschner Wire; Nanofx: Nanofracture

Introduction

Despite relatively high rates of clinical success for arthroscopic rotator cuff repair [1,2] and improved repair techniques, tendon healing to bone remains a challenge [3]. Retear rates after rotator cuff repair (RCR) increase as the tear size becomes larger and have been

shown to be as high as 57% for massive tears [4], with some estimates in the radiology literature approaching 95% [3,5]. While short term clinical outcomes appear acceptable, the long-term effects of these high failure rates remain unclear.

The recruitment of mesenchymal stem cells to a repair site is crucial to the process of tendon repair [6]. Bone marrow has been shown to be an excellent source of such cells [7], and multiple techniques to produce cancellous bleeding at the site of RCR have been investigated [8-17]. One such described technique is performing acromioplasty at the time of RCR, which has shown to be a potential source of growth factor release [8]. However, Snyder and Burns in their review article [9] theorized that techniques with deeper penetration into the bone marrow are necessary to produce adequate access to stem cells and other cellular components.

Based on the available literature, marrow stimulating techniques are potential adjuvants to RCR to decrease re-tear rates. Microfracture to the rotator cuff footprint has been used to obtain deeper penetration, with multiple studies showing a decrease in retear rates [18], particularly in massive tears [19], at short term follow-up. However, since the channels created by the microfracture awl can be up to 2.5 mm wide [20], multiple perforations in the greater tuberosity raise the concern for tuberosity fracture and anchor pull-out.

The purpose of this controlled biomechanical study was to determine if subchondral bone needling of the rotator cuff footprint would compromise the pull-out strength of standard suture anchors and thus possibly compromise the repair. Our hypothesis was that augmentation with subchondral needling would have no significant effect on ultimate load to failure of suture anchors in the proximal humerus.

Methods

Eight fresh-frozen matched-pair cadaveric shoulder (ages 59 - 64, 1 male and 3 female) specimens were inspected to ensure normal humeral head anatomy void of any apparent humeral head deformities. Each specimen was marked to retain matched-pair control throughout the investigation. The soft tissue envelope was removed including all rotator cuff tendons.

Surgical Technique

Suture Anchors

Commercially available suture anchors were obtained from the manufacturer for testing (5.5 x 18 -mm Healix Advance, PEEK, DePuy Mitek Inc., Raynham, MA). All shoulders were treated with a single row of suture anchors (three per shoulder) placed adjacent to the articular cartilage margin in the anterior, superior, and posterior position (Figure1) according to the manufacturers' instructions. To prepare the bone for anchor insertion, the awl was tapped gently with a mallet to the laser line. Sutures were loaded into the threader and the tab is pulled back to incorporate the sutures into the anchor. The anchor was zip-lined down to the bone hole for insertion. To individually tension each suture, the nose of the anchor was dropped to the first thread and tension was applied on each suture. The sutures were then docked in the cleats in the ring to maintain tension in each stitch. Once the sutures were tensioned, the sutures were removed from the cleats, and with downward force the anchor was screwed in perpendicular until the laser line was flush with the cortex of the bone. Anchors were separated by 1cm to limit fracture propagation between the insertion sites during testing.

The four shoulder pairs were then randomly divided into two treatment groups: Suture anchor placement alone on one side (Control) (2 left, 2 right); suture anchor placement plus the addition of subchondral bone needling with a double row of 1 mm wide channels spaced 2.5 mm apart using a custom template, which was created specifically for this study, on the contralateral side (Augment) (2 left, 2 right).

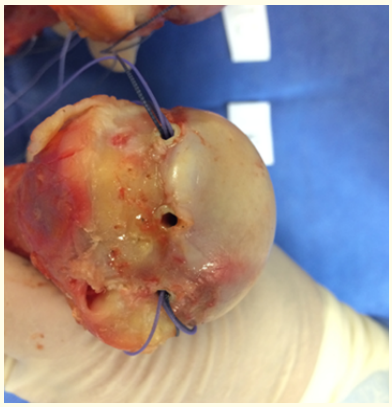

Figure 1: *Humeral head specimens with anchors placed lateral to the articular margin at anterior, superior, and posterior positions.*

Subchondral Bone Needling

Once all suture anchors were deployed, the Augment Group was treated with a commercially available augmentation technique (Nanofracture, Arthrosurface, Franklin, MA). The 1 mm thick needle (Nitinol) is threaded through the lever and inserted into the lumen of the cannulated awl. The tip of the awl is placed onto the rotator cuff footprint and the needle tip is advanced into the subchondral bone at a consistent, stop controlled depth of 9 mm using light taps on the proximal end of the needle. Light pressure on the lever using the thumb retracts the needle and allows for repositioning of the awl tip onto the next channel marker. Following the custom template, each perforation is placed 2.5 mm apart providing an even pattern (Figure 2). The number of channels delivered depended on the area available in each shoulder, therefore the number of channels varied from specimen to specimen.

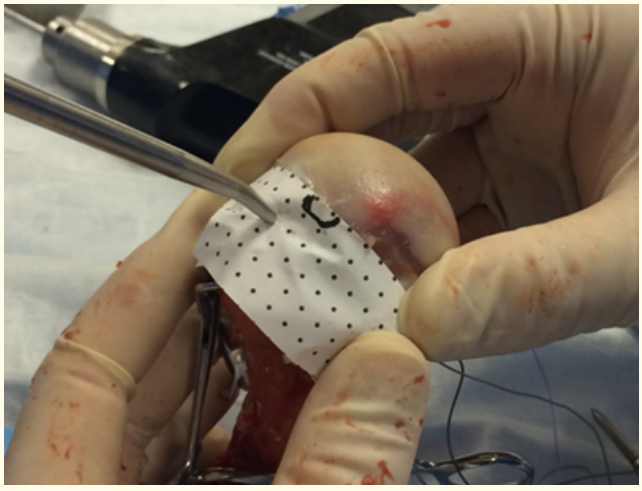

Figure 2: *Template being used to perform standardized augmentation to the footprint.*

Biomechanical Testing

Each specimen was mounted onto a machine (Instron 5980, Norwood, Massachusetts, US). Using a 45 degree pull angle to replicate the force vector direction of the rotator cuff, each anchor was pre-loaded with 50 N for 10 seconds and then loaded until failure occurred

at 304mm/second on the Instron machine. Ultimate load to failure which was the primary outcome measure, was then recorded for each anchor.

MicroCT Imaging

After testing was concluded, microfracture was performed on 2 of the Augment Group specimens to show the differ-ence in penetration of the 2 procedures (Figure 3a, VIDEO 3b). These 2 specimens then underwent MicroCT imaging (Department of Anatomy and Cell Biology, Rush University Medical Center, Chicago, IL). Imaging was not intended to quantify the mechanical testing, but to provide visual representation for anchor failure, channel integrity, bone bridge preservation, and the penetration differentiation between the historical microfracture and novel subchondral bone needling procedure.

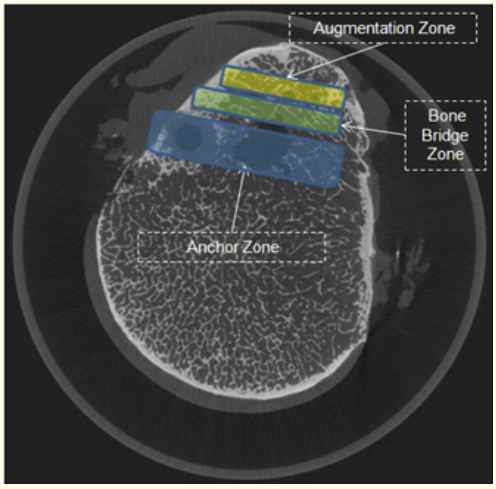

Figure 3a: *MicroCT image showing placement of anchors and augmentation channels with preservation of bone bridges between them.*

The imaging sequence was conducted with the following settings on a µCT 50 (Scanco Medical, Scanco USA, Inc, Wayne, PA): Tube voltage 55 kV, current 145 µA, integration time 500 ms, and voxel size / resolution 24.2 µm. Imaging was done with 2048 samples and 1000 projections per 180 degrees.

Statistical Analysis

Statistical analysis was performed using a 2-way repeated ANOVA as well as a chi square test. The significance level was set at 0.5 a priori.

Results and Discussion

Biomechanical Results

Biomechanical results of the two groups are shown in Table 1. The average anchor pull-out strength was 242.67 +/- 50.2 N for the Augment Group and 229 +/- 61.9 N for the Control Group. No statistical significance was present between the ultimate load to failure in the two groups ($p = 0.56$). The overall average pull-out for anterior (A) anchors in both groups was 215 +/- 58.3, for middle (M) anchors was 250.1 +/- 67.2 and posterior anchors (P) 242.4 +/- 8.1 (Table 2). No significant difference in pull out strength (N) was seen based on anchor location (A/M $p = 0.28$; A/P $p = 0.29$; M/P $p = 0.78$). Also, no difference was seen in the number of pull outs between the Control group and Augment group for anchors in any location (A $p = 0.7$; M $p = 0.9$; P $p = 0.7$). The most common mode of anchor failure was suture breakage -13, followed by anchor pull-out -8 and anchor eyelet breakage -3 (Table 1).

Specimen #	Group	Extremity Side	Anchor Location (Anterior, Middle, Posterior)	Pull-Out Strength (N)	Failure Mode
1	NanoFx	L	A	170	Anchor pull out
			M	166	Anchor pull out
			P	212	Suture broke
			average	183 +/- 25.5	
1	Control	R	A	177	Anchor pull out
			M	124	Anchor pull out
			P	181	Anchor pull out
			average	161 +/- 31.8	
2	NanoFx	R	A	183	Anchor pull out
			M	303	Suture broke
			P	215	Anchor pull out
			average	234 +/- 62.1	
2	Control	L	A	179	Anchor pull out
			M	283	Suture broke
			P	243	Anchor broke
			average	235 +/- 52.5	
3	NanoFx	L	A	274	Eyelet broke
			M	286	Suture broke
			P	292	Suture broke
			average	284 +/- 9.2	
3	Control	R	A	307	Suture broke
			M	302	Eyelet broke
			P	244	Suture broke
			average	284 +/- 35.0	
4	NanoFx	R	A	270	Anchor pull out
			M	263	Anchor pull out
			P	278	Suture broke
			average	270 +/- 7.5	
4	Control	L	A	160	Anchor pull out
			M	274	Anchor pull out
			P	274	Suture broke
			average	236 +/- 65.8	

Table 1: *Anchor Data.*

Group	Anterior	Middle	Posterior
Control	205.8 +/- 68.0	245.8 +/- 82.0	235.5 +/-39.1
Nanofx	224.3 +/- 55.4	254.5 +/- 61.2	249.3 +/- 41.7
Overall	215.0 +/- 58.3	250.1 +/-67.2	242.4 +/- 38.1

Table 2: *Average Pull-out by Location.*

Micro CT Imaging

The Micro-Ct scans showed subchondral needling when compared to conventional microfracture, creates smaller diameter channels (1 mm vs. 2.5 mm), penetrates deeper (9 mm vs. 3 mm), and gives greater access to trabecular channels (Figures 4a, b) [20]. Anchor failure, and bone bridge preservation can be seen in Figure 3a and video 3b.

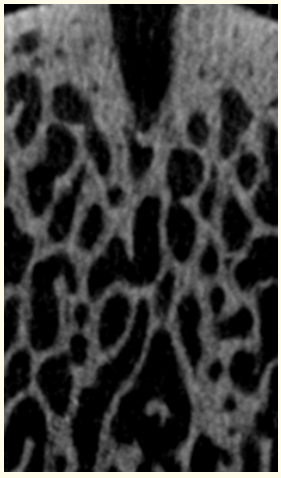

Figure 4a: *Close-up micro-CT image of microfracture technique performed with a standard awl showing lack of penetration into trabecular channels.*

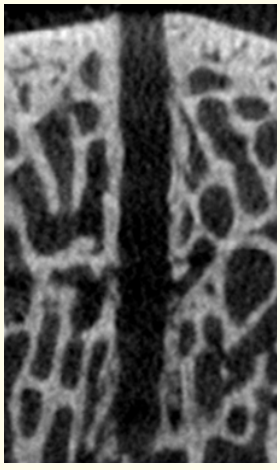

Figure 4b: *Subchondral bone needling showing deeper penetration and patent trabecular channels. (Images courtesy of William Walsh, PhD, Surgical & Orthopaedic Research Laboratories (SORL), Prince of Wales Clinical School - The University of New South Wales, Level 1, Clinical Science Bldg, Prince of Wales Hospital Gate 6, Avoca Street, Sydney, Australia).*

Discussion

Our study showed that in bone with decent quality, augmentation with subchondral needling did not weaken the bone/suture anchor interface nor decrease the ultimate load to failure of suture anchors for rotator cuff repair and that the suture is much more likely to break than the anchor pulling out. Also, no difference was found for different anchor locations (Anterior, Medial, Posterior).

Despite the advancements in surgical techniques and ability, healing after rotator cuff repair remains a problem. Recent studies have estimated an 11% - 57% retear rate after repair [5,21,22]. Although patients with retears have been shown to still receive a clinical benefit, outcome scores are inferior to those of intact repairs [23,24].

Much of the focus in the recent literature has been dedicated to potential augmentations for rotator cuff repairs. Acromioplasty is one potential augment, the benefit of which has been debated [10-12]. While acromioplasty has been shown to be a possible source of growth factor release [9], its clinical benefit remains lacking in the current literature [10,11]. Familiari., *et al*. [12] observed that in some instances, performing acromioplasty and coracoacromial ligament resection caused anterior escape and worsening symptoms.

In an attempt to further enhance healing, the use of biologics has been increasing in orthopedic surgery and holds great promise in RTC repair given the high retear rates observed to date [4]. Significantly lower retear rates have been observed with the addition of Platelet-rich-plasma (PRP) [13], Making the assumption that structurally intact tendons produce better long-term outcomes [25,26], Jo., *et al*. [13] supports using PRP as an adjunct to rotator repair. In contrast, however, a systematic review [14] found no difference in overall retear rates or in clinical outcomes, including function, pain, and quality of life following PRP treatment. Despite many recent studies [15,27,28] reporting on the effects of PRP on rotator cuff repair, the outcomes and recommendations remain controversial and no clear advantage to using PRP has been shown [29].

In 2009, Snyder and Burns published an innovative article describing the "Crimson duvet" and their technique to create it [9]. The Crimson duvet is a "super clot" resulting from blood flowing out of the bone marrow after creating channels through the rotator cuff footprint (microfracture) with a bone tamp or awl. The clot is known to contain a significant number of mesenchymal stem cells, platelets, growth factors, and vascular components, all of which contribute to tendon healing. Since their publication, several studies have attempted to validate this theory. Milano., *et al*. performed a prospective, randomized trial (Level I) comparing arthroscopic rotator cuff repair groups with and without microfracture [16]. While the overall result showed no significant difference in clinical outcomes or healing rates, a subgroup analysis of tear size showed a significantly higher healing rate in large tears when microfracture was performed. In a 2013 study by Osti., *et al*. rotator cuff repair groups were once again compared with and without microfracture of the footprint [17]. At the 3 month, post-op mark, the visual analogue scale, range of motion, UCLA and Constant scores were all significantly better in the microfracture group. However, these results equalized by the 2-year mark, where there was no significant difference between groups across all results. They concluded that microfracture, which is safe and low cost, may be worthwhile to decrease pain and improve function in the short term post-op period.

Techniques for stem cell augmentation of rotator cuff repair are being investigated. Using bone marrow derived MSCs to augment rotator cuff repair in rats, Gulotta., *et al*. found that the addition of the MSCs did not improve the structure, composition, or strength of the healing tendon attachment site [3]. In contrast, Kida., *et al*. in 2013 created bilateral supraspinatus tears in a rat model [31]. These tears were then repaired, with one group receiving drilling of the greater tuberosity and a control group with no drilling. A higher number of mesenchymal cells were observed infiltrating the repair site in the drilling group with significantly higher ultimate force-to-failure. In a human case control study of 45 patients, Hernigou., *et al*. [32] found that the addition of bone marrow concentrate containing MSC significantly improved healing outcomes on standard rotator cuff repair. One hundred percent of the repairs treated with MSCs were healed by 6 months where only 67% of the untreated repairs were healed. At 10 years 87% of the treated repairs were intact vs only 44% of the untreated group. In a similar study, Haylas., *et al*. [33] applied a suspension of MSCs to the sutures at the end of the procedure. At 6 months, all the repairs were fully healed as confirmed by MRI. Gomes., *et al.* [34] also found promising results in their small number of

patients undergoing bone marrow mononuclear cell implantation in the sutures for rotator cuff repair when compared with historical data available for patients undergoing the same procedure without the addition of stem cells.

In a Japanese study by Taniguchi., *et al.* [35], 67 patients had their repairs augmented with drilling and 44 did not. At 13.7 months, the augmented group had an overall retear rate of 9.1% vs. 23.9 % for the non-augmented group. Large to massive tears had a retear rate of 4.5% for the augmented group vs. 28.6% for those who did not have augmentation. He also suggested that 4-6 large holes (3 mm in diameter) drilled 3-5 mm apart creates the risk of anchor pull out as they are too close to the anchor holes. To avoid this complication, they attempted to drill holes relatively far from the anchors. This may cause the MSC cells to not thoroughly invade the repair.

Microfracture is a technique with well proven results in cartilage regeneration (fibrocartilage) of the knee, ankle and shoulder. As mentioned above, it has been shown to recruit mesenchymal cells to the site of rotator cuff repair. However, microfracture has also been shown to produce fractured and compacted bone inside the channels, essentially sealing them off from viable bone marrow and potentially impeding repair [20,36]. Chen reported that drilling deeper than 2 mm induced a larger volume of remodeling subchondral bone and improves cartilage repair [37,38]. Min., *et al*. [39] took this one step further with his study measuring the effects of different bone stimulating techniques on the number of mesenchymal stem cells (MSC) drained from the bone marrow. He concluded that the larger the exposed area, the more MSCs are obtained. He suggested that the current microfracture method cannot drain the most MSCs and therefore a more improved surgery technique is needed. Eldracher., *et al*. [40] found that the smaller drill holes (1 mm) taken to a depth of 10mm allowed improved osteochondral repair more efficiently than larger holes (1.8 mm). The larger holes negatively affected the osteochondral repair by showing significantly less and thicker trabecular bone with fewer conjunctions. They felt that the smaller holes induced less subchondral damage. In a recently published paper by Gianakos., *et al.* [41], 3 types of Bone Marrow Stimulating (BMS) techniques were compared in the talus of cadavers in 9 different zones: a 1.00-mm microfracture awl, a 2.00-mm standard microfracture awl, or a 1.25-mm Kirschner wire (K-wire). They concluded that BMS techniques using K-wire and the 2.00-mm standard microfracture awl resulted in increased trabecular compaction and sclerosis in areas adjacent to the defect. The larger diameter instruments also resulted in less open communicating bone marrow channels, denoting a reduction in bone marrow access and causing greater microarchitecture disturbances.

Subchondral bone needling is similar to microfracture, but creates a narrower channel (1 mm vs. 2.5 mm), which eliminates the concern for greater tuberosity fracture when placing multiple holes [21]. Additionally, the needle penetrates 3x deeper (9 mm) than the standard awl (2 - 3 mm) potentially accessing the richest bone marrow within the humeral canal and not just within the metaphyseal bone and thereby has the potential to be a promising augmentation technique.

There is a paucity of literature available testing augmentation of rotator cuff repair and pull-out strength of the suture anchors. In a cadaver study by Braunstein., *et al*. [42], the pull-out strength of suture anchors augmented with polymethylmethacrylate in osteoporotic humeral heads was compared to anchors without the augmentation. They found that the augmented anchors increased the pull out to 332 N compared to 226 in the anchors without the augmentation.

It is estimated that in normal activities, the force transmitted through the cuff tendon is in the range 140 to 200 N [43-46]. We chose a very conservative load of 50 N to load the specimens with the ultimate load to failure of 236 and 234 N being well above the force for normal tendons.

The strength of our study included the innovative technique being tested, as very little has been reported in the literature to date. In addition, MicroCT imaging was added which enabled us to observe the vast difference in the penetration depth between subchondral bone needling and microfracture. It also allowed us to observe the bone bridge preservation between augmentation channels in the tested samples.

The limitations of the study are the relatively small number of specimens (n = 8). A power analysis was performed and given the small number of specimens there exists the possibility of a Type 2 Error. Secondly, performing the technique in a cadaveric model does

not replicate the in-vivo conditions of patients Finally, due to the lack of available literature on this device, any clinical benefit of its use is extrapolated from those obtained by similar techniques. Randomized clinical trials are needed to reconfirm clinically relevant effects.

This study was designed to test the effect of multiple needle augmentation channels and the footprint on the ultimate load to failure of suture anchors used during rotator repair. Our hypothesis, that augmentation would not have a significant effect on the load to failure, was proven correct. Since the completion of this study we have treated our patients with subchondral needling following rotator cuff repair. To date we have not observed any retears. However, details will be part of future publication. Further randomized studies to compare Nanofracture to Microfracture in a human model should also be undertaken.

Conclusions

Subchondral bone needling may be an excellent augment to rotator cuff repair with no adverse effect on ultimate load to failure of surrounding suture anchors. The ultimate load-to-failure of medially inserted suture anchors augmented with subchondral needling showed no difference compared with the control group. This technique is a potential enhancement of healing rates by bringing more biologic healing factors to the repair site without compromising anchor fixation strength.

Conflict of Interest

The investigation was supported by an institutional grant from Arthrosurface. No personal conflict of interest exists by any of the authors.

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