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Significant Improvement in Pain and ASES Scores After Partial Thickness Rotator Cuff Repair with Augmentation Using a Xenograft Collagen Bioinductive Implant

Rodenhouse P* and Bishai SK

Department of Orthopaedic Surgery, Henry Ford Macomb Hospital, Nineteen Mile Rd, Clinton Township, USA

Abstract

Introduction: Rotator cuff tears (RCT) range from partial thickness to full thickness and are common problems creating pain and morbidity among sufferers. Even with the increasing prevalence of partial thickness RCTs, much of the literature focuses on full-thickness RCTs. Partial thickness RCTs are unique and affect a wide range of patients. Furthermore, a significant percentage of partial thickness RCT's, up to 35%, propagate to full-thickness tears. Accepted treatments for partial thickness RCT's include arthroscopic debridement, conversion repairs, and *in-situ* trans tendon repairs. Due to the lack of literature on partial thickness RCTs and the fact that one treatment option has not proven itself superior to the others, we looked at the treatment of partial thickness RCTs with augmentation using a xenograft collagen bio-inductive implant.

Case study: Using data collected from a single surgeon, we evaluated both Visual Analog Scale (VAS) pain scores as well as American Shoulder and Elbow Surgeons (ASES) functional scores pre-operatively and at 6 weeks, 3 months, and 6 months post rotator cuff repair using a xenograft collagen implant.

Results: Pre-operative VAS scores averaged 6.03 and followed a nearly linear decline to 2.08 at the 6-month post-operative visit. ASES functional scores pre-operatively averaged 35.49 and followed a linear progression to reach 69.49 at 6 months post-op, a 95% improvement.

Conclusion: Using the xenograft collagen implant is a novel treatment option for the management of partial thickness rotator cuff tears. It provides a buttress to the rotator cuff which dissipates strain at the injury site allowing time for healing while incorporating into the tendon itself creating more robust rotator cuff tissue.

Keywords: Rotator cuff tear; Visual analog scale (VAS); Xenograft; Bioinductive

Introduction

Partial thickness RCTs are unique and affect a wide range of patients from sedentary individuals to elite athletes.1 Despite their high prevalence, the diagnosis and treatment remain controversial due to the literature focus on full-thickness tears [1]. Sher et al., reported a 20% prevalence of partial-thickness tears on MRI in 96 asymptomatic shoulders [2]. Based on cadaveric and imaging studies, partial thickness tears have been shown to affect approximately 13% to 32% of people with a strong correlation to age [1]. Milgrom et al., showed a linear increase in prevalence after the 5th decade of life [3]. Demonstrating that no age group or population is immune to partial thickness RCTs, Conner et al., performed shoulder MRIs of asymptomatic elite overhead athletes and 40% had partial or full-thickness tears. Accepted treatments for partial thickness RCT's include arthroscopic debridement, conversion repairs, and *in-situ* trans tendon repairs. While all have been shown to benefit some patients, none has shown significant outcome benefits over the others. Due to the lack of literature on management of partial thickness RCTs and the fact that one treatment option has not proven itself superior to the others, we looked at the treatment of partial thickness RCT with augmentation using a xenograft collagen bio inductive implant.

Etiology

The etiology of partial thickness RCTs is multifactorial. The intrinsic factors leading to tears include hypocellularity, fascicular thinning, and the formation of granulation tissue. All of these can decrease the vascularity of tissue which in turn predisposes the tendon to degenerative tearing [1]. The extrinsic factors include subacromial impingement, glenohumeral instability, and internal impingement [1]. These lead to tensile overload and can cause the rotator cuff tendon fibres to tear. Increases in tendon strain due to presence of a tear lead to propagation and increases in tear size over time [2-4]. Often partial thickness tears progress to full-thickness tears [4]. One study of 40 patients with partial thickness cuff tears followed for a mean of 13.5 months showed 80% of lesions enlarged or progressed to full-thickness lesions [4].

Background research rationale

A finite-element study demonstrated increasing the thickness of the bursal side of supraspinatus by 2mm can decrease intra-tendinous strain by 47% in bursal sided tears and 40% on articular sided tears [4]. The bio-inductive xenograft implant decreases local tendon strain and provides a scaffold for new tendon tissue to grow. Boker et al., showed a mean increase in tendon thickness of 2.2 mm at 3 months post-op which persisted for 24 months and was indistinguishable from normal cuff tissue by MRI. Arnoczky et al., published in 2016 that biopsies of the collagen implants retrieved from 7 patients on second look arthroscopies showed cellular incorporation, tissue maturation, implant resorption and biocompatibility to that of normal rotator cuff tissue (Figure 1).

Case Study

This was a retrospective review of patient reported outcomes

***Corresponding author:** Rodenhouse P, Department of Orthopaedic Surgery, Henry Ford Macomb Hospital, Nineteen Mile Rd, Clinton Township, USA, Tel: (734) 323-9193; E-mail: prodenh1@hfhs.org

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following rotator cuff repair using a Bio-inductive implant. The data collection period was from October 2014 through March 2017. All patients were operated on by a single surgeon. The VAS and ASES scores were collected on 75 patients in the office with the help of the nursing staff. All patients had rotator cuff tears measuring 50% or less on MRI and were confirmed intra-operatively by the surgeon. Each patient had failed conservative treatment consisting of oral anti-inflammatory, corticosteroid injections, activity modifications, and physical therapy prior to having surgery (Figures 2 and 3). All cases were primary partial thickness rotator cuff repairs. Revision procedures as well as procedures with anchor fixation of the rotator cuff were excluded from data collection.

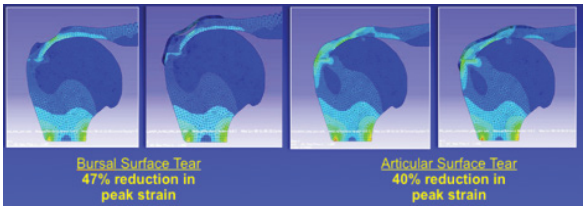

Figure 1: Demonstrates the effects of both bursal and articular sided tears and the peak strain on the supraspinatus tendon, courtesy of rotation medical.

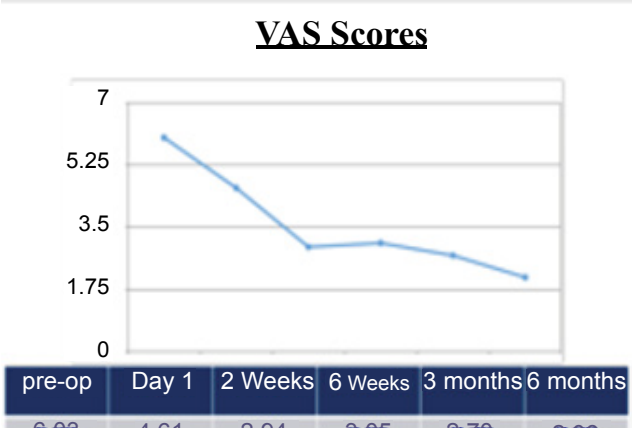

Figure 2: Average VAS scores of patients at the given time points, Scale is 0-10.

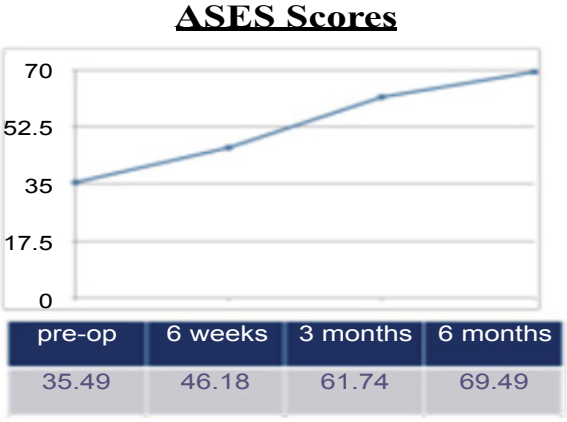

Figure 3: Average ASES functional scores of the patients at the given time points, Scale is 0-100.

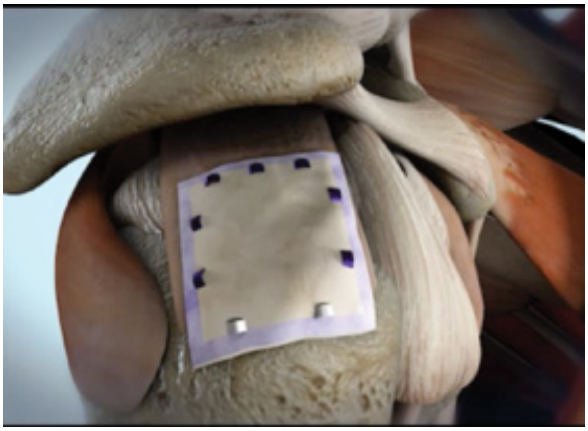

Figure 4: An illustration of the bio inductive xenograft implant, courtesy of rotation medical.

Results and Discussion

The average pre-operative VAS and ASES scores for the included patients were 6.03 and 35.49, respectively. The average 6-month post-operative VAS and ASES scores were 2.08 and 69.49, respectively. There was a near linear decrease in VAS scores overtime from pre-op to 6 months. The VAS scores decreased on average 3.95 points by 6 months compared to pre-op, a 66% reduction. The ASES scores also followed a linear improvement. The ASES scores improved 34 points at the 6 months visit for a 95% improvement in patient perceived function.

Conclusion

We believe that the xenograft collagen implant is a novel treatment option for the management of partial thickness rotator cuff tears. It provides a buttress to the rotator cuff and dissipates strain at the injury site allowing time for healing while incorporating into the tendon itself creating more robust rotator cuff tissue. This study from a single surgeon using the xenograft implant for repair of partial thickness rotator cuff tears shows significant improvement in VAS and ASES scores at 6 months post-operatively. Weaknesses of the study include the retrospective nature of the study. Given resources, this was the only way to feasibly complete the study at this time. Another weakness is the limited follow-up of 6 months. However, many patients no longer return for follow-up appointments in the sports clinic unless they are having problems. Strengths of the study include one single surgeon with significant experience which will limit the variability in how the implant was applied surgically (Figure 4). Another strength is the power of the study including 75 patients over a two-and-a-half-year period given us an abundance of data.

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