Augmenting rotator cuff repairs with ArthroFLEX® can improve clinical outcomes.

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INTRODUCTION

Rotator cuff tears are the primary cause of shoulder discomfort and dysfunction, with an estimated 621,500 surgical repairs expected to be performed in 2014. In general, rotator cuff tears are categorized based on size, ranging from small (<1 cm) to massive (> 5 cm). If surgery is warranted, the type of procedure may depend on the severity of the tear. Physicians may choose a minimally invasive arthroscopic operation for smaller tears, or a mini-open or open technique for larger tears. Approximately 70% of surgeries are performed arthroscopically.[1]

Unfortunately, reports in the literature demonstrate a 20-90% failure rate for rotator cuff repairs.[2] Failure of these tears is common and occurs most frequently at the suture-tendon interface due to poor tissue quality. One study that investigated mode of failures at time of revision, showed 19/22 repairs failed due to tendon pulling through the sutures.[3] In addition to the financial burden of failed rotator cuff repairs, the associated complications, including loss of function, pain, and decreased strength, can significantly affect the patient. Taken together, the avoidance of such issues is paramount to both the surgeon and patient.[4]

In some cases, the repair may require additional strength to avoid potential failure of the reconstruction or worsening of the initial tear. Reinforcing the suture-tendon interface with an acellular dermal matrix (ADM) has been proposed as a means to improve rotator cuff repairs and therefore decrease failure rates. In recent publications, the use of ADM's in rotator cuff repair have demonstrated a higher rate of intact repairs clinically, as well as improved strength of the rotator cuff tendon in biomechanical testing.[5-7] Augmentation of a rotator cuff repair with an ADM has been shown to reduce the high failure rates that typically require an additional revision repair. In a level II study of rotator cuff tears of at least 3 cm, the added strength provided by an ADM in the augmented group attributed to the higher frequency of intact repairs at 85%, compared to 40% in the non-augmented group.[5] This higher rate of intact repairs may significantly reduce the risk of revision surgery.

ARTHROFLEX

ArthroFLEX (LifeNet Health, Virginia Beach, VA), is a uniquely processed ADM, prepared utilizing MatrACELL® technology. This proprietary and patented decellularization process results in at least 97% DNA removal, which may decrease the risk of an inflammatory response and resultant delayed healing. It is provided as medical-device grade sterile, with a sterility assurance level (SAL) of 10^{-6}. ArthroFLEX is also treated with Preservon®, a proprietary and patented preservation technology that allows the graft to be stored fully hydrated at room temperature, so it is immediately ready to use out of the packaging. The graft is biocompatible with its native preserved collagen matrix that facilitates cell proliferation and demonstrates excellent suture strength. ArthroFLEX has also demonstrated the ability to resist infection in a rat model compared to the control.[9] Patients receiving augmented repairs with ArthroFLEX have reported improved function, range of motion, and reduced pain.[8]

PUBLISHED RESULTS

- A recent biomechanical report by Ely et al in 2014 demonstrates that the use of ArthroFLEX to augment large rotator cuff repairs decreased gap formation by 21% and increased load to failure by 29% versus the non-augmented controls. Results suggest that ArthroFLEX can protect the repair site during early healing.[13]
- A report by Levenda et al. in 2012 describes an augmentation method for rotator cuff repair using ArthroFLEX and reports nine out of ten patients have shown decreased pain as well as improved motion and function. In the one failure due to a fall, the initial repair was found to be still intact during the follow-up surgery.[8]
- A biomechanical study using ArthroFLEX by Van der Meijden et al in 2013 reports that augmented double-row repairs provide a more consistent repair. Also states that augmented repairs are strong and the application

of the ADM "could provide the needed strength to withstand the initial loading so that biological healing and remodeling can occur."[7]

- A biomechanical study by Beitzel et al in 2012 evaluating the strength of a repair with an ADM (ArthroFLEX) placed on top of the rotator cuff repair demonstrated a 65% higher ultimate load to failure than the non-augmented repair. Gap formation was also improved by 25%.[10]
- A level II study by Barber et al in 2012, found better ASES and Constant scores reported by patients, and more frequent intact cuffs at an average follow-up of 24 months post-operative in the augmented group (85%) compared to the non-augmented control group (40%).[5]
- A retrospective case series by Agrawal et al. in 2012 evaluated 14 patients with large, massive, or previously repaired rotator cuff tears and found that the use of an ADM in their surgical technique demonstrated favorable structural healing rates and statistically improved functional outcome in the near term.[11]
- A clinical evaluation by Wong et al in 2010 examined 45 patients with massive rotator cuff tears treated arthroscopically with an ADM and found significant clinical improvement.[12]
- A biomechanical study by Barber et al. from 2008 evaluated the failure mode of supraspinatus tendon repairs with and without a human ADM. They concluded that an ADM significantly increases the strength of a repaired tendon by 19% and can be expected to significantly increase the initial strength of a rotator cuff repair.[6]

CONCLUSION

Rotator cuff tears are a common injury with the majority requiring surgical repair. Reports of high failure rates necessitate a need to improve the repair and address the suture-tendon interface, the weakest link of the surgical repair. Several published surgical techniques and biomechanical studies show that augmenting the repair with an ADM can increase the strength of the repair and thus potentially reduce the amount of failures, which require a more extensive surgery with a worse prognosis. ArthroFLEX is a commercially available ADM that can be used to augment these tendon repairs with the demonstrated ability to improve the strength of the tendon-suture interface.

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