Allograft Materials for Rotator Cuff Augmentation

Arthrex Research and Development

Introduction

Partial and complete tears of the rotator cuff (RC) are common, especially in athletic patients, and can result in impaired shoulder function. A patch that can connect rotator cuff back to the muscle and bone while retaining strength would be ideal. The RC Allograft is exactly what the product name indicates – it is human freeze-dried and sterilized rotator cuff tissue. Other products on the market, as indicated in Table 1 below, are made from animal-derived collagen or human allograft made from other tissue forms, which do not have the same mechanical characteristics as native rotator cuff tissue. The RC Allograft has properties comparable or superior to other rotator cuff augmentation products on the market, including biocompatibility, mechanical properties, and tissue response.

Table 1: Products and composition of materials used for RC augmentation patches

Distributor	Product Name	Material Source
AlloSource/LifeNet	**RC Allograft**	***Human freeze-dried rotator cuff allograft***
DePuy	Restore	Porcine small intestine submuscosal type I collagen
Biomet	CuffPatch SportMesh	Porcine small intestine submuscosal type I collagen Artelon® poly(urethane urea)
Wright Medical	GraftJacket	Human decellularized dermis
Stryker	TissueMend	Fetal bovine decellularized dermis
Zimmer	Collagen Repair Patch	Porcine dermis-derived tissue
MTF	AlloPatch	Human fascia lata from iliotibial band
Tornier	Conexa	Porcine decellularized dermis
Pegasus Biologics	OrthADAPT	Equine dermis-derived type I collagen

In Vitro Testing

Cell culture studies conducted at the Department of Orthopaedics at the University of Connecticut Medical Center [1] showed varied amounts of human tenocyte adhesion after 24 hours (Figure 1) and proliferation after 48 hours (Figure 2) on various rotator cuff augmentation materials. Human tenocytes were seeded onto all surfaces, including tissue culture polystyrene (TCP) as a control, at a density of 20,000 cells/cm2. Adhesion after 24 hours was determined by counting in a Coulter counter, while proliferation at 48 hours was determined by measuring thymidine incorporation. In some cases, materials with higher amounts of initial adhesion had lower amounts of proliferation. Some materials, notably the Collagen Repair Patch and Conexa, behaved in the opposite manner, with low amounts of initial adhesion and higher amounts of proliferation. However, RC Allograft had high amounts of both adhesion and proliferation, indicating that cells initially found the RC Allograft substrate suitable for growth, and were able to spread and proliferate.

Selected samples of all materials were seeded with tenocytes and cultured for 4 weeks, embedded in polymethylmethacrylate (PMMA), and stained with Masson's trichrome stain. Representative histological images are shown in Figure 3. The RC Allograft material contained generous porosity, allowing for cell infiltration during healing. Many other materials contain little to no porosity for cell infiltration.

Figure 1: Adhesion of tenocytes after 24 hours on RC augmentation materials

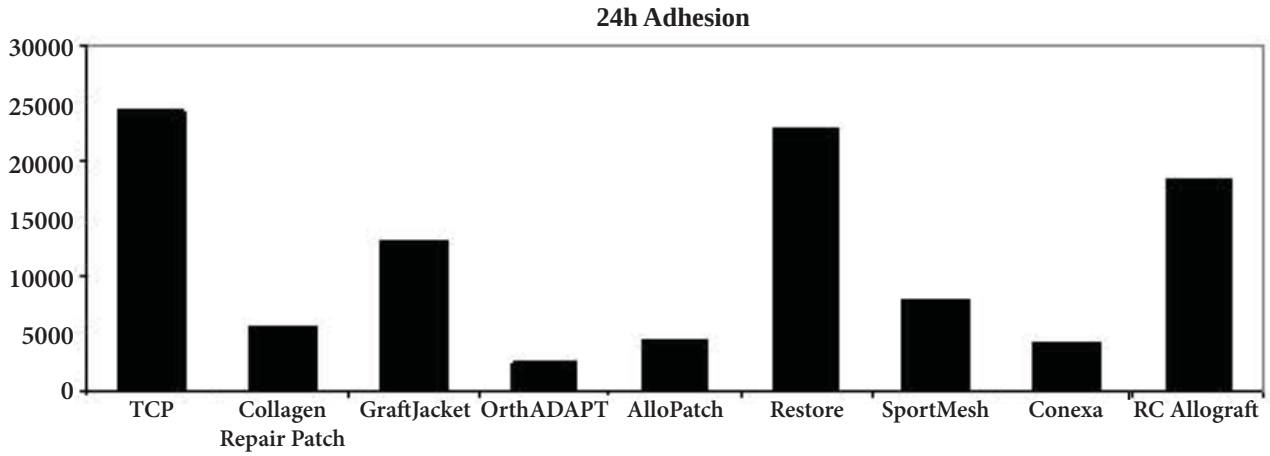


Figure 2: Proliferation of tenocytes after 48 hours on RC augmentation materials

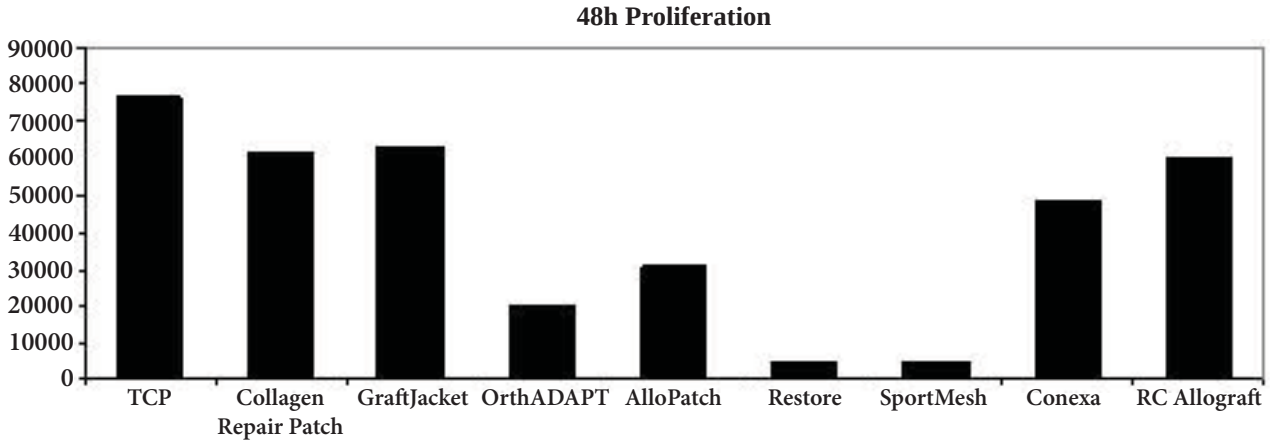
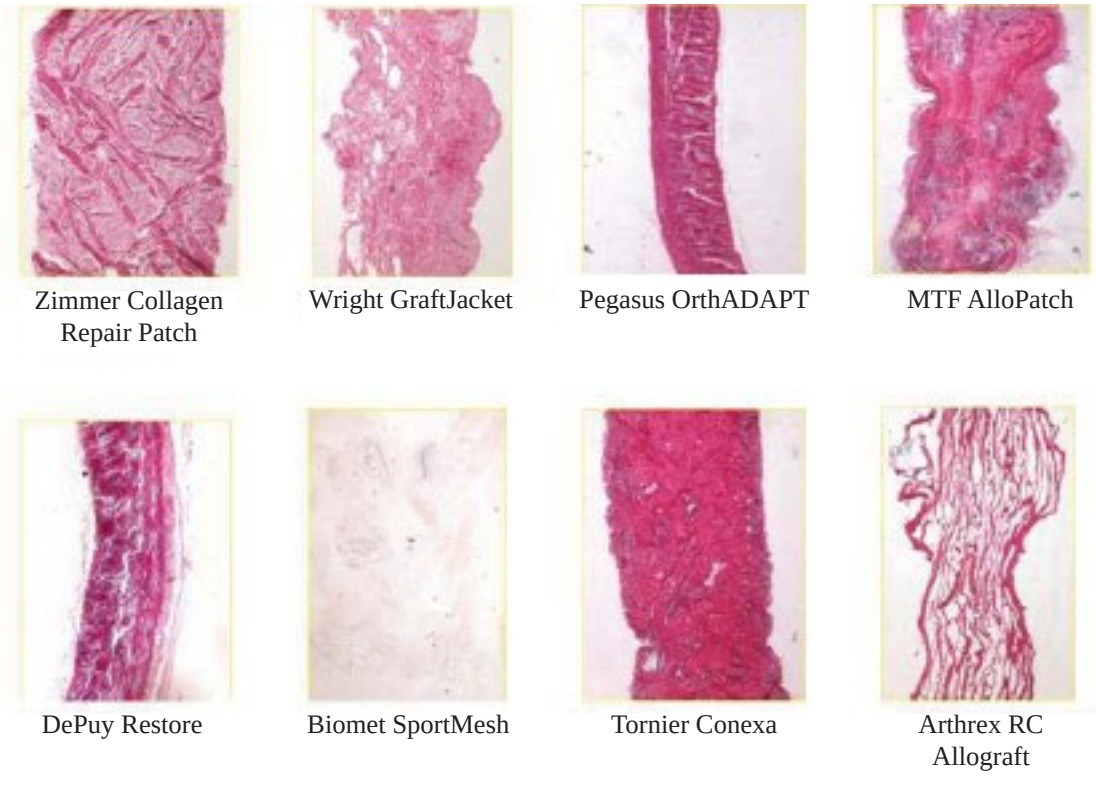


Figure 3: Histology of RC augmentation products. All images at 4X magnification.



Mechanical Testing

Suture retention is important for the rotator cuff augmentation procedure, as the material has to be sutured securely without pulling through into the surrounding tissues. This feature determines the fate of the material and, therefore, the subsequent healing profile of the shoulder. Figure 4 shows the suture retention strength of the RC Allograft compared to other rotator cuff augmentation materials. Some were tested in-house, while others were identified in a review article from Dr. Alan Barber [2]. As seen in Figure 4, RC Allograft has comparable suture retention strength to GraftJacket.

Linear stiffness measures the augmentation material's ability to transfer and maintain load, as well as the amount of elongation per given load. Figure 5 shows the linear stiffness of the RC Allograft compared to other rotator cuff augmentation materials. Again, some were tested in-house, and others were identified in review articles from Dr. Kathleen Derwin [3,4]. Figure 5 shows that RC Allograft's linear stiffness is superior to all other augmentation devices with the exception of AlloPatch [3,4] which is human-derived fascia lata.

Figure 4: Suture retention of RC augmentation materials tested in-house (black) and from a review article (gray) using #2 FiberWire suture in a mattress stitch configuration.

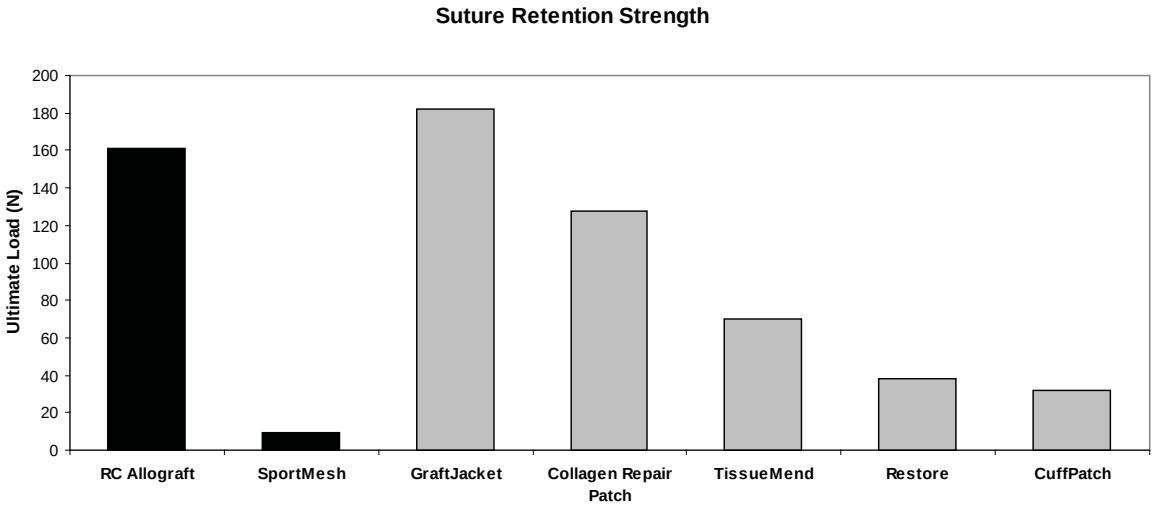
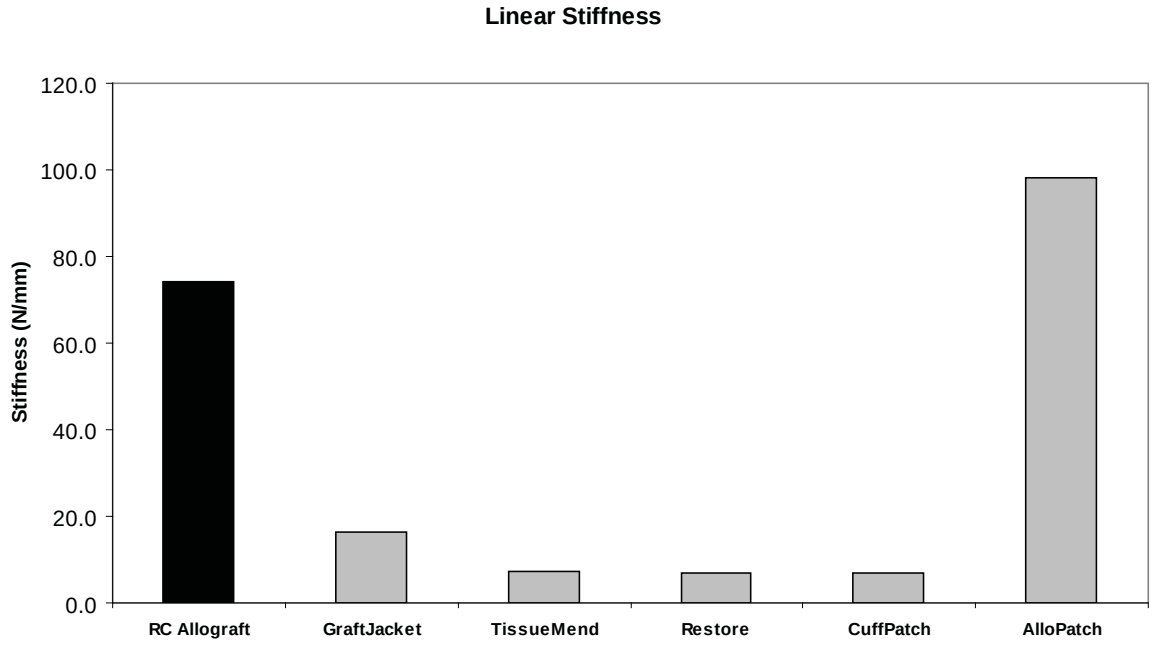


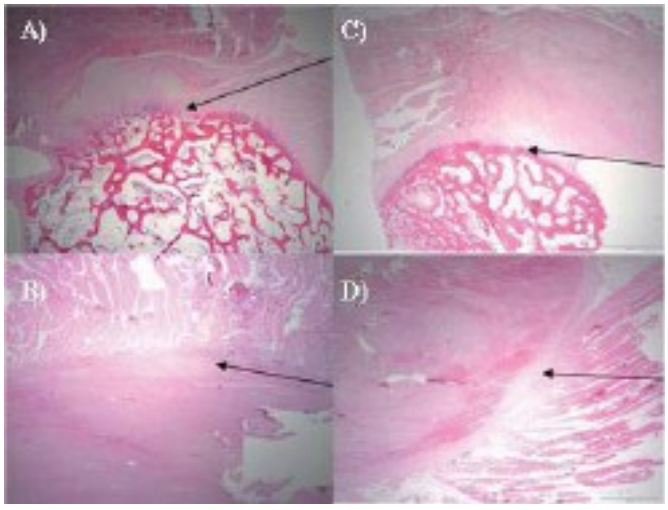
Figure 5: Linear stiffness of RC augmentation materials tested in-house (black) and from review articles (gray) [3,4].



In Vivo Testing

The Comparative Orthopaedic Laboratory at the University of Missouri [5] implanted canine allograft tendons processed the same way as RC Allograft as span grafts in surgically created defects in the rotator cuffs (infraspinatus tendons) of purpose-bred dogs; isotopic bone-tendon autografts were used as controls. After 12 weeks, functional, imaging, biomechanical testing, and histologic assessments showed favorable outcomes for both groups. No forelimb lameness was noted and all dogs had full shoulder range of motion with no clinically apparent muscle atrophy. Radiographs and ultrasound revealed evidence for good bone-bone, bone-tendon, and tendon-muscle healing and architecture. Repair tissue stiffness, as well as displacement at the bone-tendon and tendon-muscle interfaces, for canine allograft tendons and controls were similar and within desired ranges for tissue healing and function. However, both treatment groups had significantly lower stiffness and higher displacements than normal shoulders at the bone-tendon interface. Histologically, canine allograft tendons showed excellent cellular repopulation and revascularization, good bone-tendon integration, no gap formation at either interface, and no evidence of untoward immune or inflammatory responses (Figures 6A and 6B). Controls showed normal bone-tendon integration and maintenance of tendon and muscle architecture (Figures 6C and 6D).

Figure 6: Canine allograft tendons show good integration without any gaps (arrows) at both the bone-tendon interface (A) and tendon-muscle interface (B). Bone-tendon autograft controls show comparable integration (arrows) at the bone-tendon interface (C) and tendon-muscle interface (D).



Sterility/Safety

The RC Allograft is sterilized using AlloSource's validated Sterile R sterilization process that includes rigorous donor screening, tissue recovery using aseptic techniques in a controlled environment, extensive donor testing in accordance with AATB and FDA guidelines, the AlloWash™ cleansing process to reduce or eliminate bacteria, marrow elements, and lipids, and low dose gamma irradiation. This process enables the RC Allograft to achieve sterility without impairing the biomechanical integrity of the graft.

Conclusion

The RC Allograft is an affordable option that offers advantages over many of the current patches available for rotator cuff augmentation. The biocompatibility, mechanical properties, tissue response, and safety of the allograft make it desirable for use in shoulder surgery.

References

1. Mazzocca AD, McCarthy MB. Unpublished data, Department of Orthopaedics, University of Connecticut Medical Center, 2008.
2. Barber et al, Arthroscopy, 2006 May; 22(5):534-8.
3. Derwin et al, J Bone Joint Surg Am. 2006 Dec; 88(12):2665-72.
4. Aurora et al, J Shoulder Elbow Surg. 2007 Sep-Oct; 16(5 Suppl):S171-8.
5. Cook JL, Jayabalan P, Kuroki K, Cook CR. Unpublished data, Comparative Orthopaedic Laboratory, University of Missouri, 2008.