Biomechanical Properties of Tendon Augmentation Materials

Arthrex Research and Development

Introduction

Decellularized human skin has been used for a variety of medical applications such as wound healing, soft tissue reconstruction, and sports medicine applications. One such clinical application is rotator cuff tear repair[1-3]. During this procedure, the dermal matrix is used to augment the repair to provide biomechanical strength and to support directed healing. Achilles and quadriceps tendon augmentation procedures using decellularized human skin have also been reported[4-5]. A variety of methods exist to prepare acellular dermal matrices and are available under such tradenames as GraftJacket® (Wright Medical Technology, Arlington, TN), ArthroFlex™ (LifeNet Health, Virginia Beach, VA), and DermaSpanTM (Biomet Sports Medicine, Warsaw, IN). Other materials for tendon augmentation include synthetics such as SportMesh® (Biomet Sports Medicine, Warsaw, IN) and equine pericardium, distributed as OrthADAPT™ (Synovis Orthopedic and Wound Care, Irvine, CA). Key biomechanical properties of tendon augmentation materials, namely suture retention and ultimate load-to-failure, were tested and are presented here.

Materials

GraftJacket is a human acellular dermal matrix treated by a process that attempts to remove cells, while retaining matrix proteins to provide a scaffold for ingrowth. The product is aseptically processed and not sterilized and requires rehydration, prior to use. Two versions that are discussed here are GraftJacket MaxForce (average thickness 1.5 mm) and GraftJacket MaxForce Extreme (average thickness 2 mm). SportMesh (average thickness 0.8 mm) is a knitted fabric device made from Artelon, a resorbable polyurethane urea polymer, and is sterilized with a 25 kGy dose of electron beam irradiation. OrthADAPT (average thickness 0.5 mm) is a xenograft made from equine pericardium that is aseptically processed and terminally sterilized using a proprietary chemical sterilization method. It contains 90% collagen I and 10% collagen III and is crosslinked for added strength. Finally, ArthroFlex is human dermis rendered acellular to a ≥97% reduction of DNA content through patented MatrACELL technology[6]. The bio-implant is provided hydrated at room temperature and terminally sterilized with validated low temperature, low dose (<20 kGy) gamma irradiation to yield a Sterility Assurance Level (SAL) of 10-6. It is available in two average thicknesses —1.5 mm and 2 mm.

Mechanical Testing

ArthroFlex samples were tested exactly as described in Barber and Aziz-Jacobo[7]. In Figures 1 and 2, the ArthroFlex data is shown graphically with the data from the Barber paper for GraftJacket MaxForce, GraftJacket MaxForce Extreme, SportMesh, and OrthADAPT samples, since the same methodologies and testing equipment were used. Suture retention (Figure 1) was measured as the force needed to pull out a simple vertical stitch of Arthrex #2 FiberWire passed through the tissue 5 mm from the edge. Ultimate load-to-failure (Figure 2) was measured by pressure-clamping two ends of a single layer of material and elongating to failure after a cyclic preload. Statistical analysis was performed using a one-way ANOVA and pairwise comparison using the Holm-Sidak method. Significance was found when $p < 0.05$.

Results

ArthroFlex 1.5 mm suture retention (Figure 1) was similar to GraftJacket MaxForce ($p = 0.80$) and SportMesh ($p = 0.42$), but significantly stronger than OrthADAPT ($p < 0.001$). Ultimate load-to-failure (Figure 2) for ArthroFlex 1.5 mm was significantly stronger than for GraftJacket MaxForce, SportMesh, and OrthADAPT ($p < 0.015$). ArthroFlex 2 mm suture retention was very close to being significantly stronger compared to GraftJacket MaxForce Extreme ($p = 0.054$) and was significantly stronger than SportMesh and OrthADAPT ($p < 0.05$). Ultimate load-to-failure for ArthroFlex 2 mm was similar to GraftJacket MaxForce Extreme ($p = 0.18$), but significantly stronger than SportMesh and OrthADAPT ($p < 0.001$).

Figure 1.

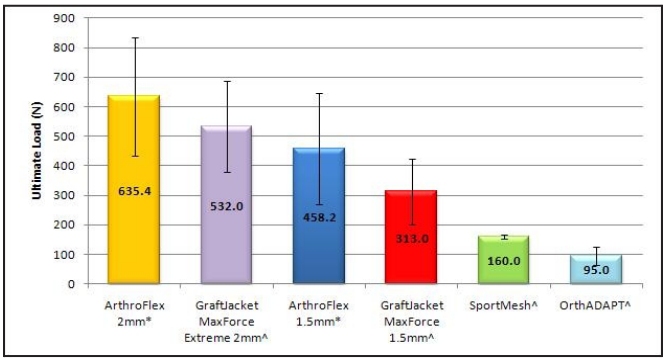
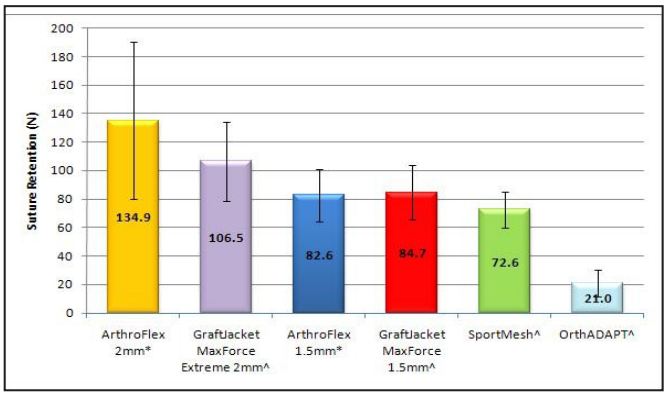


Figure 2.



* Data on file at Arthrex

^ Barber and Aziz-Jacobo. Arthroscopy 2009;25(11):1233-9. Selected data was derived from Figure 3 (Suture Pullout) and Table 1 (Ultimate Tensile Strength) of this reference. The two studies were performed at different points in time; however, the exact same methods, fixtures, material testing machine, and facility were used for both studies.

Conclusion

A variety of materials are being used for tendon repair augmentation. These include human allograft dermis, xenograft pericardium, and synthetic materials. The key biomechanical properties of suture retention and ultimate load to failure for these materials were compared here. For the materials tested, the acellular human dermis products ArthroFlex and GraftJacket performed just as well or better than OrthADAPT equine pericardium and SportMesh synthetic matrix.

References

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