



# ArthroFLEX® Dermal Allograft Scientific Update

Nonclinical and Biomechanical Studies

ArthroFlex dermal allograft is a biohospitable graft that supports cellular repopulation,<sup>1</sup> provides biomechanical strength,<sup>2</sup> and enhances suture retention.<sup>3</sup> It is intended as supplemental support and covering for soft-tissue repairs. Matracell technology, a patented and validated process, renders the ArthroFlex allograft dermis acellular without compromising biomechanical or biochemical properties. The following published studies present nonclinical and biomechanical outcomes and benefits of using ArthroFlex dermal allograft.

## Animal<sup>1</sup> and Nonclinical Reports on ArthroFLEX® Dermal Allograft

[Comparison of biologic scaffolds for augmentation of partial rotator cuff tears in a canine model.](#) *J Shoulder Elbow Surg.* 2020;29(8):1573-1583. doi:10.1016/j.jse.2019.11.028

**Takeaway:** This study tested the hypothesis that biologic scaffold augmentation of articular-sided, partial-thickness supraspinatus tendon tears would be associated with superior functional, imaging, biomechanical, and histologic properties compared with untreated tears in a preclinical canine model. The studied defects were treated with debridement, Arthrex Amnion™ matrix, ArthroFlex dermal allograft, and bovine collagen patches. Results showed that canines treated with allograft had more positive outcomes for pain, shoulder range of motion, tendon thickness, structure and architecture, and biceps tendon pathology, followed by those treated with amnion matrix. Those treated with a bovine graft had significantly higher pain and lower comfortable shoulder range of motion (CROM) at 6 months.

[Evaluation of host tissue integration, revascularization, and cellular infiltration within various dermal substrates.](#) *Ann Plast Surg.* 2012;68(5):495-500. doi:10.1097/SAP.0b013e31823b6b01

**Takeaway:** This study compared the properties of four different acellular dermal matrices—AlloDerm®, DermACELL®+, DermaMatrix™, and Integra®—in an in vivo rat model. Researchers obtained tissue specimens at various time points and used histology and immunohistologic assays to quantify the cellular infiltration and revascularization of each matrix. DermACELL showed the highest level of cellular infiltration, while AlloDerm showed the lowest. Angiogenesis was evident by day seven.

[In vivo assessment of bacteria infection clearance of an acellular dermal matrix and a synthetic mesh.](#) Paper presented at: Symposium on Advanced Wound Care and Wound Healing Society Annual Meeting. April Apr 23-27, 2014; Orlando, FL.

**Takeaway:** In a rat model, acellular dermal matrices (ADM) treated with the Matracell process demonstrated resistance to infection, while a polyester mesh matrix did not. Researchers seeded both graft types with *S. aureus* and implanted them into the abdominal wall of a rat. After 28 days, they removed and analyzed the implants. “H&E staining showed complete fibroblast infiltration and minimum neutrophil infiltration in the implanted ADM, while there was a significant quantity of neutrophil appearance around the polyester mesh and bacteria.” The ADM was able to resist the infection and showed “better implant tissue incorporation compared to the synthetic polyester mesh.”

Smith MJ,  
Bozynski CC,  
Kuroki K,  
Cook CR,  
Stoker AM,  
Cook JL

Capito AE,  
Tholpady SS,  
Agrawal H,  
Drake DB,  
Katz AJ

Rosines E,  
Qin X,  
Chen S

<sup>1</sup>Animal results are not necessarily indicative of human clinical outcomes  
<sup>2</sup>ArthroFlex dermal allograft is also marketed under the name Dermacell



Rosines E,  
Lin Q

[Analysis of the acellular matrix, growth factors, and cytokines present in ArthroFlex®.](#) LifeNet Health. Data on file (68-20-048.00). Virginia Beach, VA; 2012.

**Takeaway:** This study examined ArthroFlex extracellular matrix (ECM), a minimally manipulated human skin product, to ensure that it retains the components of healthy human skin relevant to the structural support of damaged soft tissue. “Findings suggest that ArthroFlex retains a broad array of extracellular matrix components, matrikines, growth factors, and cytokines present in healthy human skin and provides structural ECM components that can help prevent re-tearing of surgically attached tendons.” In addition, the study found that ArthroFlex matrix contains the collagens that provide supplemental structural integrity and mechanical strength to surgically attached tendons, “aiding in the prevention of a re-tear.”

Moore MA,  
Samsell B,  
Wallis G,  
et al

[Decellularization of human dermis using non-denaturing anionic detergent and endonuclease: a review.](#) *Cell Tissue Bank.* 2015;16(2):249-259. doi:10.1007/s10561-014-9467-4

**Takeaway:** The study found that the Matracell process effectively removes cellular material including DNA and immunogenic components. The resulting acellular dermis is biocompatible and retains biomechanical strength. Both preclinical and clinical results “support the use of this allograft tissue in a myriad of clinical applications.”

Agrawal H,  
Tholpady SS,  
Capito AE,  
Drake DB,  
Katz AJ

[Macrophage phenotypes correspond with remodeling outcomes of various acellular dermal matrices.](#) *J Regen Med.* 2012;1(3):51-59. doi:10.4236/ojrm.2012.13008

**Takeaway:** This study demonstrates that acellular dermal matrices with a higher ratio of M2 macrophages than M1 macrophages, such as DermACELLS<sup>+</sup>, were associated with a more constructive tissue remodeling response. Researchers concluded that a greater M2 response promoted cell proliferation and tissue repair while a greater M1 response produced more inflammatory tissue remodeling, which inhibits cell proliferation and causes tissue damage.

## Biomechanical Reports Using ArthroFLEX® Dermal Allograft

Ely EE,  
Figueroa NM,  
Gilot GJ

[Biomechanical analysis of rotator cuff repairs with extracellular matrix graft augmentation.](#) *Orthopedics.* 2014;37(9):608-614. doi:10.3928/01477447-20140825-05

**Takeaway:** Authors performed a biomechanical study to evaluate gap formation and ultimate tensile failure load of a rotator cuff tear (RTC) repair augmented with ArthroFlex dermal allograft. The study found that “RTC repair with human dermal allograft ECM increased ultimate load to failure by 29% and decreased gap formation by 21% compared with non-augmented controls.”

Conroy C,  
Sethi P,  
Macken C,  
et al

[Augmentation of distal biceps repair with an acellular dermal graft restores native biomechanical properties in a tendon-deficient model.](#) *Am J Sports Med.* 2017;45(9):2028-2033. doi:10.1177/0363546517701426

**Takeaway:** Investigators evaluated if augmentation with a dermal graft would improve load to failure of distal biceps tendon repair compared to a nonaugmented control. In a model of a tendon-deficient, complete distal biceps rupture, “acellular dermal allograft augmentation restored the native tendon’s biomechanical properties at time zero.” In addition, researchers found that, in comparison to the nonaugmented model, augmentation of the tendon repair with a dermal allograft increased the load to failure and stiffness and decreased displacement. Finally, researchers concluded that augmentation of the distal biceps with dermal allograft “is a biomechanically feasible option for patients with an attritionally thinned-out tendon.”



van der Meijden OA,  
Wijdicks CA,  
Gaskill TR,  
Jansson KS,  
Millett PJ

[Biomechanical analysis of two tendon posterolateral rotator cuff tear repairs: extended linked repairs and augmented repairs.](#) *Arthroscopy*. 2013;29(1):37-45. doi:10.1016/j.arthro.2012.07.012

**Takeaway:** Investigators compared single-row; extended double-row; and augmented, extended double row RCT repairs in 20 cadaveric shoulders. ArthroFlex dermal allograft was used for the augmented, extended double row group. The authors concluded that while augmentation with ArthroFlex allograft did not have an impact on biomechanical properties in their model, its use “did result in less variability in failure load and more consistency in the mode of failure.”

Beitzel K,  
Chowaniec DM,  
McCarthy MB,  
et al

[Stability of double-row rotator cuff repair is not adversely affected by scaffold interposition between tendon and bone.](#) *Am J Sports Med*. 2012;40(5):1148-1154. doi:10.1177/0363546512437835

**Takeaway:** Investigators used 25 cadaveric shoulders, divided amongst five randomized groups, to evaluate the strength of RCT repairs with and without augmentation using Visco-gel fibrin matrix, Mucograft® collagen matrix, and ArthroFlex dermal allograft interpositionally, as well as with augmentation on top of repair (five groups). The authors conclude that two of the augmentation methods—the collagen matrix placed interpositionally and the ArthroFlex allograft on top of the reconstruction—increased ultimate load to failure compared with the nonaugmented repair.

Curtis DM,  
Lee CS,  
Qin C,  
et al

[Superior capsule reconstruction with subacromial allograft spacer: biomechanical cadaveric study of subacromial contact pressure and superior humeral head translation.](#) *Arthroscopy*. 2020;36(3):680-686. doi:10.1016/j.arthro.2019.09.047

**Takeaway:** This biomechanical study of eight cadaveric shoulders investigates the superior capsule reconstruction (SCR) using ArthroFlex dermal allograft as a subacromial spacer on superior humeral head translation and subacromial contact pressure. SCR with subacromial resurfacing resulted in significantly decreased superior humeral head translation when compared to SCR without resurfacing. This pilot study supports the use of human acellular dermal allograft for acromial resurfacing in SCR, which may improve patient outcomes.

Morikawa D,  
Mazzocca AD,  
Obopilwe E,  
et al

[Reconstruction of the acromioclavicular ligament complex using dermal allograft: a biomechanical analysis.](#) *Arthroscopy*. 2020;36(1):108-115. doi:10.1016/j.arthro.2019.07.021

**Takeaway:** The authors used six cadaveric shoulders to evaluate resistance force against posterior translation and torque against posterior rotation after reconstruction of the superior acromioclavicular ligament complex using a dermal allograft. For both measurements, anatomic coracoclavicular reconstruction with a dermal allograft was the closest to restoring the percentage of normal posterior translational and rotational stability.



Altintas B,  
Scibetta AC,  
Storaci HW,  
Lacheta L,  
Anderson NL,  
Millett PJ

[Biomechanical and histopathological analysis of a retrieved dermal allograft after superior capsule reconstruction: a case report.](#) *Arthroscopy*. 2019;35(10):2959-2965. doi:10.1016/j.arthro.2019.07.006

**Takeaway:** This case study examined the biomechanical and histopathological properties of an acellular human dermal allograft explanted after a failed SCR. The graft did not fail structurally, and intraoperative evaluation revealed the graft had completely healed. Histopathology demonstrated that the graft had recellularized and was forming new collagen, which is characteristic of tendon morphology. These results do not represent failed grafts, but do provide insight to the fate of acellular human dermal allografts after implantation.

Mirzayan R,  
Andelman SM,  
Sethi PM,  
et al

[Acellular dermal matrix augmentation significantly increases ultimate load to failure of pectoralis major tendon repair: a biomechanical study.](#) *J Shoulder Elbow Surg*. 2020;29(4):728-735. doi:10.1016/j.jse.2019.09.020

**Takeaway:** This study examined the cyclic elongation, linear stiffness, load to 5 mm displacement, maximum load to failure, and method of failure in cadaveric shoulders following pectoralis major tendon (PMT) repair. Three groups were tested: standard repair, repair augmented with an acellular dermal matrix, and intact native tendon. Repairs augmented with acellular dermal matrix significantly increased the ultimate load to failure and were equivalent to the native tendon. Additionally, the mode of failure was noted as fracture of the humerus rather than pullout from the PMT repair.

## References

1. Moore MA, Samsell B, Wallis G, et al. Decellularization of human dermis using non-denaturing anionic detergent and endonuclease: a review. *Cell Tissue Bank*. 2015;16(2):249-259. doi:10.1007/s10561-014-9467-4
2. Ely EE, Figueroa NM, Gilot GJ. Biomechanical analysis of rotator cuff repairs with extracellular matrix graft augmentation. *Orthopedics*. 2014;37(9):608-614. doi:10.3928/01477447-20140825-05
3. Arthrex, Inc. Data on file (LA0822-EN, TR-4926). Naples, FL; 2011.

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