



REPRESENTATIVE REPORTS USING ARTHROFLEX®

LifeNet Health has distributed more than 40,000 ArthroFlex grafts. We understand that the safety and quality of your allograft implants are critical to you and your patients. We provide high-quality allograft implants with the biomechanical specifications you need to perform successful sports medicine surgeries. LifeNet Health offers a variety of safe and clinically proven decellularized dermal matrix implants, ArthroFlex, to provide soft tissue support and covering soft tissue repairs. The list of articles below demonstrates the efficacy of our ArthroFlex acellular dermal matrix (ADM) implants.

Clinical Reports Using ArthroFLEX

Gilot GJ, Alvarez AM, Barcksdale L, Westerdahl D, Krill M, Peck E. Outcome of Large to Massive Rotator Cuff Tears With and Without Extracellular Matrix Augmentation: A Prospective Comparative Study. Arthroscopy. 2015 Aug;31(8):1459-65.

- This prospective study compares the results of 35 large and massive rotator cuff repairs with and without augmentation using ArthroFlex at two years post-operative. The control group (non-augmented) had a 26% re-tear rate compared to only 10% in the augmented group. Researchers conclude that using ArthroFlex to augment “large to massive rotator cuff reduces the incidence of re-tears, improves patient outcome scores, and is a viable option during complicated cases in which a significant failure rate is anticipated.” [Click here for link.](#) Reprint available upon request.

Hirahara AM, Andersen WJ, Panero AJ. Superior Capsular Reconstruction: Clinical Outcomes After Minimum 2-Year Follow-Up. AJO. 2017 Nov;46(6): 266-272, 278.

- Authors discuss a series of patients undergoing Superior Capsular Reconstruction with ArthroFlex that have a minimum of two year follow up. After two years post-operatively, “mean ASES score improved significantly...and mean VAS pain score decreased significantly.” “Our data showed SCR with dermal allograft effectively restored the superior restraints in the glenohumeral joint and yielded outstanding clinical outcomes even after 2 years, making it an excellent viable alternative to RTSA.” [Click here for link](#)

Denard PJ, Brady PC, Adams CR, Tokish JM, Burkhart SS. Preliminary Results of Arthroscopic Superior Capsule Reconstruction with Dermal Allograft. Arthroscopy. 2018;34(1):93-9.

- This multicenter, prospective study evaluates the short-term outcomes of arthroscopic SCR with a dermal allograft, ArthroFLEX. The investigators measured range of motion and functional outcome scores of 59 patients pre-operatively and 1 year at final follow-up. The VAS, ASES, and SSV scores all showed statistically significant improvements. The investigators conclude that their “preliminary results are encouraging in this difficult to manage patient population.” [Click here for link.](#)

Pennington WT, Bartz BA, Pauli JM, Walker CE, Schmidt W. Arthroscopic Superior Capsular Reconstruction with Acellular Dermal Allograft for the Treatment of Massive Irreparable Rotator Cuff Tears: Short-Term Clinical Outcomes and the Radiographic Parameter of Superior Capsular Distance. Arthroscopy 2018.

- In a retrospective review, the authors analyzed 88 patients with irreparable rotator cuff tears treated with arthroscopic SCR using an acellular dermal allograft. Patients underwent a minimum 12-month follow-up. The authors used radiography, VAS, and ASES scores to analyze patient outcomes. At 1 year follow-up, VAS and ASES scores improved, 4.0-1.5 and 52-82, respectively. The analysis concludes that arthroscopic SCR with acellular dermal allograft is successful in decreasing pain and improving patient function. [Click here for link.](#)

Hartzler RU and Burkhart SS. Superior Capsular Reconstruction. Orthopedics. 2017 Oct; 40(5): 271-280.

- Authors discuss clinical indication for Superior Capsular Reconstruction as well as some tips for the surgical technique. The senior author (SSB) also discusses his own personal outcomes utilizing ArthroFlex. In 97 patients, 34 have minimum one year follow up. "Only two patients (6%) have had further surgery, both after traumatic reinjury...The remaining 32 patients have all reported satisfaction with the surgery, and there have been no complications." Authors conclude "Superior Capsular Reconstruction is technically demanding, but early adopters of the procedure are supported by its excellent anatomical, biomechanical, and short-term clinical results."

Petri M, Warth RJ, Horan MP, Greenspoon JA, Millet PJ. Outcomes After Open Revision of Massive Rotator Cuff Tears With Biologic Patch Augmentation. Arthroscopy. 2016 Sept; 32(9): 1752-1760.

- This study evaluates the outcomes of 13 massive rotator cuff revision augmentations using ArthroFlex. MRIs showed intact repairs at a mean 9.9 months post-operative and 1 patient (7.7%) had a documented re-tear at 2 months postoperatively. "Although the pain component of the ASES score and the total ASES did not improve significantly, the function component of the ASES improved significantly when compared with its preoperative baseline." Researchers conclude using ArthroFlex was "a safe and effective treatment method for patients with massive rotator cuff re-tears with deficient posterolateral rotator cuff tendons in the presence of healthy rotator cuff muscles." [Click here for link.](#)

Burkhart SS, Denard PJ, Adams CR, Brady PC and Hartzler RU. Arthroscopic Superior Capsular Reconstruction for Massive Irreparable Rotator Cuff Repair. Arthrosc Tech. 2016 Dec; 5(6): e1407-18.

- Authors describe their SCR technique using acellular dermal allograft that they have been performing for 2 years. They have collectively performed more than 100 SCRs using dermal allograft in patients with massive irreparable cuff tears. They state "our early results give us reason to be optimistic that SCR with dermal allograft may be a joint-preserving alternative that is preferable to rTSA for patients with massive irreparable rotator cuff tears." [Click here for link.](#)

Adams CR, Denard PJ, Brady PC, Hartzler RU and Burkhart SS. The Arthroscopic Superior Capsular Reconstruction. American Journal of Orthopedics. 2016;45(5):320-4.

- Authors describe their surgical technique for superior capsular reconstruction using ArthroFlex and "believe SCR is as a viable alternative" to reverse shoulder arthroplasty. They discuss that "reconstruction of the superior capsule has been shown to restore the normal restraint to superior translation of the humeral head and reestablish a stable fulcrum at the glenohumeral joint." "The short-term results of this novel procedure have been encouraging, including our own series of patients, in which most patients have had a significant reduction in pain, improvement in function, and very few complications." [Click here for link.](#)

Sanchez G, Chahla J, Moatshe G, Ferrari MB, Kennedy NI, Provencher MT. Superior Capsular Reconstruction With Superimposition of Rotator Cuff Repair for Massive Rotator Cuff Tear. Arthroscopy Techniques. 2017 Oct;6(5):e1775-9.

- Authors describe their technique of Superior Capsular Reconstruction with Rotator Cuff Repair and rehabilitation protocol. They conclude this "may be a reasonable treatment options for irreparable rotator cuff tears in patients wishing to avoid tendon transfer or reverse total shoulder arthroplasty or for whom these treatments are contraindicated." [Click here for link.](#)

Noyes MP, Denard PJ. Arthroscopic Superior Capsular Reconstruction: Indications and Outcomes. Operative Techniques in Sports Medicine. 2018;26(1):29-34.

- The authors discuss the indications and outcomes of superior capsule reconstruction using ArthroFLEX for irreparable rotator cuff tears. The authors state "this construct has demonstrated satisfactory outcomes with low complication risks." Furthermore, they conclude that SCR offers an alternative to joint preservation in younger patients with irreparable rotator cuff tears. [Click here for link.](#)

Kwapisz A, Tokish JM. Anterior Capsule Reconstruction Technique With an Acellular Dermal Allograft. Arthrosc Tech. 2017;6(5):e1945-e52.

- The authors describe their technique of arthroscopic anterior capsule reconstruction for irreparable subscapularis tears using ArthroFLEX. The authors discuss several advantages of the technique such as, no donor site morbidity, no time loss for harvesting, no remnant tissue needed, and possible delay or prevention of shoulder arthroplasty revision. The authors suggest promising short-term results, however longer follow-up is necessary to fully evaluate the technique. [Click here for link.](#)

Mirzayan R, Sethi PM. Distal Biceps Repair With Acellular Dermal Graft Augmentation. Operative Techniques in Sports Medicine. 2018.

- In this article, the authors describe a technique for distal bicep tears by augmenting the primary repair with ArthroFLEX. The authors report no re-tears, no synostosis, no infections, no inflammatory reactions, and no reoperations for previous repairs following this technique. They found this technique reduces the repair site interface, normalizes tendon stiffness, and reduces the risk of tendon elongation. [Click here for link.](#)

Rogers JP, Kwapisz A, Tokish JM. Anterior Capsule Reconstruction for Irreparable Subscapularis Tears. Arthroscopy Techniques. 2017 Dec;6(6):e2241-7.

- Authors describe a technique to repair the anterior shoulder capsule following irreparable tear of the subscapularis tendon using ArthroFlex. “Early promising results of SCR for irreparable rotator cuff tears have prompted us to adapt this technique for the anterior capsule reconstruction.” “We have employed this technique for irreparable SSC in the setting of chronic lesions, revision instability cases, as well as in patients with symptomatic subscapularis insufficiency after total shoulder replacement.” [Click here for link.](#)

Sanchez G, Rossy WH, Lavery KP, McHale KJ, Ferrari MB, Sanchez A, Provencher MT. Arthroscopic Superior Capsule Reconstruction Technique in the Setting of a Massive, Irreparable Rotator Cuff Tear. Arthrosc Tech. 2017;6(4):e1399-e404.

- In this technical note, the authors discuss their preferred technique for arthroscopic superior capsule reconstruction using a dermal allograft from Arthrex®. The authors highlight the pearls and pitfalls of their technique. They conclude “Although short-term results have been shown to significantly improve overall forward elevation and strength, future long-term studies with larger samples are needed to assess durability of patient reported outcomes.” [Click here for link.](#)

Sloan M Kamath AF. Capsular augmentation in Colonna arthroplasty for the management of chronic hip dislocation. J Hip Preserv Surg. 2018 Jan;5(1):34-38.

- Authors describe the use of ArthroFlex to augment the hip capsule in a 27-year-old female who presented with left hip pain and chronic high femoral head dislocation. “The patient continues to do well at 8 months post-operatively, with maintenance of reduction and the femoral head centered.” “Capsular arthroplasty, in conjunction with modern hip preservation techniques, may offer a viable option for chronic hip dislocation, and allograft capsular augmentation may help to address capsular deficiency.” [Click here for link.](#)

Neumann JA, Klein CM, van Eck CF, Rahmi H, Itamura JM. Outcomes After Dermal Allograft Reconstruction of Chronic or Subacute Pectoralis Major Tendon Ruptures. Orthop J Sports Med. 2018 Jan;6(1).

- Authors perform a retrospective review of patients with augmented pectoralis major tendon rupture repairs. 19 patients were reviewed at an average 26.4 months post-operative. They conclude that “PM tendon reconstruction with dermal allografts resulted in good objective and improved patient-reported outcomes.” [Click here for link.](#)

Chahla J, Dean Cs, Soares E, Mook WR, Phillippon MJ. Hip Capsular Reconstruction Using Dermal Allograft. Arthrosc Tech. 2016 Apr;5(2):e365-9.

- Authors describe their surgical technique of augmenting hip capsule repairs with ArthroFlex. “Given our promising early clinical results, we will continue to perform arthroscopic hip capsular reconstruction using dermal allograft in the setting of capsular deficiency.” [Click here for link.](#)

Cole W, Samsell B, Moore M. Achilles tendon augmented repair using human acellular dermal matrix: a case series. J Foot ankle Surg. 2018.

- Authors present a series of nine patient undergoing Achilles tendon repair augmented with ArthroFlex. After an average follow-up period of 14.4 months, the mean Foot Function Index-Revised long form showed improved scores and there were no cases of rerupture or complication during the observation period. [Click here for link.](#)

Sutter GE, Godin JA and Garrigues GE. All-Arthroscopic Superior Shoulder Capsule Reconstruction with Partial Rotator Cuff Repair. Orthopedics. 2017 July/Aug; 40(4): e735-8.

- The authors describe a technique for arthroscopic superior capsular reconstruction with a dermal allograft (ArthroFlex) with a concomitant partial rotator cuff repair. “The authors believe that the described SCR and partial repair work in concert to restore the mechanics of the glenohumeral joint. This is a reproducible technique that improves pain and strength while potentially delaying shoulder arthroplasty.” [Click here for link.](#)

Pogorzelski J, Hussain ZB, Lebus GF, Fritz EM, Millett PJ. Anterior Capsular Reconstruction of Irreparable Subscapularis Tears. Arthrosc Tech. 2017 Jul 3; 6(4): e951-e958.

- The authors discuss their surgical technique using an ADM, ArthroFlex, for the treatment of irreparable subscapularis tears in anterior capsular reconstruction. The pearls and pitfalls of the technique are discussed. The authors acknowledged several advantages of using ArthroFlex, such as faster recovery, more anatomic reconstruction, lower risk of neurovascular injury, and better cosmetic outcomes. The authors concluded that using ArthroFlex “may be a reasonable treatment option in younger patients with irreparable subscapularis tears”; however, further clinical trials are needed in determining the long-term benefit of the technique. [Click here for link.](#)

Petri M, Greenspoon JA, Millet PJ. Arthroscopic Superior Capsule Reconstruction for Irreparable Rotator Cuff Tears. Arthroscopy. 2015 Nov 30; 4(6):e751-5.

- Authors describe their surgical technique using ArthroFlex, highlighting pitfalls and pearls to the technique. They summarize that SCR “may be a reasonable treatment option in younger patients with irreparable posterosuperior rotator cuff tears wishing to avoid tendon transfer or reverse total shoulder arthroplasty.” [Click here for link.](#)

Bertasi G, Cole W, Samsell B, Qin X, Moore M. Biological incorporation of human acellular dermal matrix used in Achilles tendon repair. Cell Tissue Bank. 2017; 18(3):403-411.

- Authors evaluated the biological incorporation of a Matracell treated ADM [ArthroFlex] after a patient re-ruptured an Achilles tendon repair at 2 months post-operative and performed a literature review to determine the mechanism of ADM integration into the tendon structure. “The histology analysis demonstrated that the healing process during a tendon reconstruction process is similar to that of wound healing. Furthermore, the literature review showed that differences exist in the mechanism for integration among various human ADMs and that these differences may be due to variances in the methods and technologies that manufacturers use to process human ADMs.” [Click here for link.](#)

Hirahara AM, Adams CR. Arthroscopic Superior Capsular Reconstruction for Treatment of Massive Irreparable Rotator Cuff Tears. Arthrosc Tech., 2015 Dec; 4(6):e637-641.

- This article describes an arthroscopic reconstruction of the superior capsule using ArthroFlex. The authors discuss advantages of SCR which include easy graft passage, reliable suture placement, and very strong repairs. They found this technique using a strong, thick dermal graft “allows for faster mobilization postoperatively” and “more accurate measurement and placement of the graft.” [Click here for link.](#)

Tokish JM, Beicker C. Superior Capsule Reconstruction Technique Using an Acellular Dermal Allograft. Arthrosc Tech. 2015 Dec; 4(6): e833 – 839.

- Authors present their surgical technique for superior capsule reconstruction using ArthroFlex, as well as describe “an advantage of SCR is that it provides an option to restore and rebalance the force couples necessary for dynamic shoulder function and does not sacrifice any future treatment options.” “The clinical outcomes at our institution are relatively short-term but have shown early promising results.” [Click here for link.](#)

Millet PJ, Hussain ZB, Fritz EM, Warth RJ, Katthagen JC, Pogorzelski J. Rotator Cuff Tears at the Musculotendinous Junction: Classification and Surgical Options for Repair and Reconstruction. Arthrosc Tech. 2017 Jul 24; 6(4): e1075-e1085.9090i

- In this article the authors define the major medial tear patterns of the rotator cuff at the musculotendinous junction (MTJ) and describe their preferred repair techniques. Type B tears are identified when the medial torn rotator cuff tendon length is insufficient, yet the muscle remains healthy. The authors propose tendon augmentation with an acellular dermal matrix (ArthroFlex). Type C tears are identified as tears in which muscle quality is poor in addition to fatty infiltration and deficient medial tendon. Authors state that SCR with allograft augmentation (ArthroFlex) is their preferred technique for type C repairs. The authors discuss the importance of recognizing the tear patterns to avoid more revision surgeries. [Click here for link.](#)

Perets I, Hartigan DE, Walsh JP, Chaharbakshi E, Close MR, Domb BG. Arthroscopic Capsular Reconstruction of the Hip With Acellular Dermal Extracellular Matrix: Surgical Technique. Arthroscopy Techniques 2016. DOI: <http://dx.doi.org/10.1016/j.eats.2016.05.002>

- Authors from the American Hip Institute describe a capsular reconstruction surgical technique of the hip using ArthroFlex to regain joint stability. “Current literature suggests that microinstability may play a role in the development of labral tears and ultimately arthritis. It is vital to treat the hip capsule appropriately because of its key role in instability.” [Click here for link.](#)

Petri M, Greenspoon JA, Bhatia S, Millet PJ. Patch-Augmented Latissimus Dorsi Transfer and Open Reduction — Internal Fixation of Unstable Os Acromiale for Irreparable Massive Posterosuperior Rotator Cuff Tear. Arthrosc Tech. 2015 Sep 28;4(5):e487-92.

- Authors describe a patch augmented latissimus dorsi tendon transfer with the use of ArthroFlex for the treatment of an irreparable massive posterosuperior rotator cuff tear. The authors suggest this technique “is reasonable for younger patients with previous failed repairs, and without glenohumeral osteoarthritis.” They conclude that this treatment option allows for “improved biomechanical stability, coverage of the rotator cuff defect, and stability to the os acromiale.” [Click here for link.](#)

Levenda AC & Sanders NR. A Simplified Approach for Arthroscopic Repair of Rotator Cuff Tear with Dermal patch Augmentation. Advances in Orthopedic Surgery. 2015, Article ID 423949

- This article describes a surgical technique to arthroscopically augment a standard rotator cuff tear with ArthroFlex. Authors also present an informal case series of the technique used on 12 patients with 2-4 cm large tears. Patients showed both an increased range of motion and increased strength” and have “experienced a significant decrease in pain.” Of the 12 patients, 2 patients suffered re-tears due to falls. However, upon second look during arthroplasty, the graft and repair were still intact. [Click here for link.](#)

Katthagen JC, Tahal DS, Millett PJ. Arthroscopic Capsule Reconstruction for Irreparable Rotator Cuff Tears. Orthopedics Today. 2016 Mar;36(3):13-15.

- Authors describe surgical technique using ArthroFlex and comment on their early results that are “18 months from surgery with excellent clinical and structural results.” Postoperative radiographs show cases of re-centering of the humeral head. Patients note pain relief and return of function by 3 months post-op. Authors also report “no complications or adverse events.” [Click here for link.](#)

Petri M, Greenspoon JA, Moulton SG and Millett PJ. Patch-Augmented Rotator Cuff Repair and Superior Capsule Reconstruction. The Open Orthopaedics Journal, 2016, 10, (Suppl 1: M7) 315-323.

- Authors report on their personal surgical experience and selective literature search for rotator cuff repair and superior capsule reconstruction. “Several case studies have reported promising clinical outcomes for patch-augmented rotator cuff repair.” “Superior capsule reconstruction appears to be an emerging solution when even a partial repair and patch-augmentation are no longer feasible. This technique has been reported biomechanically to restore almost normal glenohumeral kinematics.” [Click here for link.](#)

Lederman E, Softic D, Qin X, Samsell B, and Dorfman A. Biological Incorporation of ArthroFlex in Superior Capsular Reconstruction for Irreparable Rotator Cuff Repair. LifeNet Health White Paper 68-20-168. 2016.

- Investigators performed histological analysis of an explanted ArthroFlex SCR that had failed as a result of a fall at 10 weeks post-operative. Recellularization and blood vessel formation was observed in addition to tendon-like remodeling on the medial aspect of the graft and fibrocartilage on the inferior surface. “The fibroblast infiltration, neovascularization and tissue remodeling seen here demonstrated that ArthroFlex can adapt to the local environment and have good incorporation following SCR.” White Paper available upon request.

Gilot GJ, Attia AK, Alvarez AM. “Arthroscopic Repair of Rotator Cuff Tears using Extra-Cellular Matrix (ECM) graft.” Arthrosc Tech.. 2014 Aug; 3(4):e487-9.

- This technique article demonstrates the use of ADM augmentation using ArthroFlex in the arthroscopic repair of large to massive rotator cuffs. ECM scaffold grafts can decrease failure of the repair as a result of decreased gap formation at the repair site and improved load sharing. In addition, improved success rates are possible in patients who receive ECM augmentation, as shown by the revision rate and results of shoulder questionnaires. Our findings support the principle of rotator cuff repair with ECM.” [Click here for link.](#)

Mirzayan R, Conroy C, Sethi P. Distal Biceps Repair With Acellular Dermal Graft Augmentation. Techniques in Shoulder & Elbow Surgery. Sept 2015;16(3):89-92.

- Authors describe a technique to repair a ruptured distal bicep tendon using ArthroFlex to augment the repair. Senior “author has performed over 40 repairs with the above technique. There have been no retears, no synostosis, no infections, no inflammatory responses, and no reoperations.” [Click here for link.](#)

Lee B, Acevedo D, Mirzayan R. Reconstruction of the Acromioclavicular Joint, its Superior Capsule, and Coracoclavicular Ligaments Using an Interpositional Acellular Dermal Matrix and Tibialis Tendon Allograft. Techniques in Shoulder & Elbow Surgery. 2014;15(3):79-86.

- This technique article describes a biologic and anatomic reconstruction for the coracoclavicular ligaments and AC joint using ArthroFlex and an anterior tibialis tendon. “ The senior author (R.M.) has performed 12 reconstructions with this technique. There was only 1 failure (8%) at 2 months postoperatively when the patient attempted to do a push up.” [Click here for link.](#)

Atzei A & Bertasi G. “Repair of Distal Triceps Tendon Rupture with a Human Acellular Dermal Matrix (ADM).” 2013 White Paper (68-20-097)

- Case study describes the surgical technique and outcome for use of Dermacell in a successful distal triceps tendon repair.
- NOTE: Dermacell is another trade name for ArthroFlex.
- White paper available upon request.

Atzei A & Bertasi G. “Reconstruction of Finger Flexor Tendon and Pulley Repair with Human Acellular Dermal Matrix (ADM).” 2013 White Paper (68-20-098)

- Case study describes a successful outcome by using Dermacell to augment the flexor digitalis profundus tendon and pulley repair in a 16 year-old male.
- NOTE: Dermacell is another trade name for ArthroFlex.
- White paper available upon request.

Atezei A & Bertasi G. “Matracell®-Processed Dermis Augments Finger Extensor Tendon Reconstruction.” 2015 White Paper (68-20-159)

- Case study describes the surgical technique and outcomes using Matracell processed dermis to augment the extensor tendon in a 40 year-old male.
- NOTE: Matracell processed dermis is another trade name for ArthroFlex.

Acevedo DC, Shore B, Mirzayan R. Orthopedic Applications of Acellular Human Dermal Allograft for Shoulder and Elbow Surgery. Orthop Clin N Am. 2015 Jul;46(3):377-388.

- Authors review the basic science, rationale for use, and surgical applications of human dermal allograft, such as ArthroFlex, in various shoulder and elbow injuries. They conclude that “ADM plays a role in a variety of applications for shoulder elbow surgery. There is a reasonable amount of evidence supporting its use along with good short-term outcomes, particularly in the shoulder. ADM appears to be safe for implantation with a low risk of rejection, infection, or inflammatory response.” [Click here for link.](#)

Cooper J and Mirzayan R. Acellular Dermal Matrix in Rotator Cuff Surgery. American Journal of Orthopedics. 2016;45(5):301-5.

- Authors performed a review of current literature regarding rotator cuff repairs to determine if there is support for augmentation using acellular dermal matrices. They conclude that “the biomechanical and clinical studies summarized support the use of ADM in RC surgery.” [Click here for link.](#)

Hirahara, A. SpeedBridge Rotator Cuff Repair Augmented with ArthroFlex Acellular dermal extracellular matrix. YouTube. 2013. [Click here for video.](#)

Hirahara AM. Biologics – Arthroscopic shoulder rotator cuff repair with ArthroFlex graft. [Click here for video.](#)

Hirahara AM. ECM Patches. [Click here for link.](#)

DeBerardino TM. Presentation: [Click here for link.](#)

Animal and Non-Clinical Reports Using ArthroFLEX

Capito, A.E., Tholpady, S.S., Agrawal, H., Drake, D.B. & Katz, A.J. “Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration Within Various Dermal Substrates.” Annals of Plastic Surgery. 2012 Oct; 68(5):495-500. doi: 10.1097/SAP.0b013e31823b6b01.

- The purpose of this study is to determine and compare these properties of 4 different acellular dermal matrices (AlloDerm, Dermacell, DermaMatrix, and Integra) in an *in vivo* rat model. Tissue specimens were obtained at various time points. Histology and immunohistologic assays were used to quantify the extent of cellular infiltration and revascularization within the various matrices. A bimodal cellular response was observed in all products except for Dermacell. Cellular infiltration was highest in Dermacell and lowest in AlloDerm, and angiogenesis was evident by day 7.
- NOTE: Dermacell is another tradename for ArthroFlex.
- Reprint available upon request. [Click here for link.](#)

Rosines E, Qin X, Chen S. “In Vivo Assessment of Bacteria Infection Clearance of an Acellular Dermal Matrix and a Synthetic Mesh.” A Symposium on Advanced Wound Care and Wound Healing Society, 27th Annual Meeting. Apr 23-28, 2014.

- Matracell treated dermis demonstrated resistance to infection in a rat model where a polyester mesh did not. Both types of grafts were seeded with *S. aureus* and implanted into the abdominal wall of a rat. After 28 days, the implants were removed and analyzed. “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.”

Rosines, E. & Lin, Q. “Analysis of the Acellular Matrix, Growth Factors, and Cytokines Present in ArthroFlex®” 2012. Available upon request.

- Human skin is a complex tissue containing various extracellular matrix molecules, growth factors, and cytokines. The purpose of this study was to ensure that ArthroFlex, a minimally manipulated human skin product, 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.” “ArthroFlex provides the collagens that supplement structural integrity and mechanical strength to surgically attached tendons, aiding in the prevention of a re-tear.”

Moore, M.A. “Inactivation of enveloped and non-enveloped viruses on seeded human tissues by gamma irradiation.” 2012. Cell Tissue Bank. 13(3):401-7. doi: 10.1007/s10561-011-9266-0.

- Author studied effect of low dose gamma irradiation on viruses seeded onto human tissue. “...Data presented here indicate that terminal sterilization using a low temperature, low dose gamma irradiation process inactivates both enveloped and non-enveloped viruses containing either DNA or RNA, thus providing additional assurance of safety from viral transmission.” [Click here for link.](#)

LifeNet Health Research and Development “Analysis of DNA Residuals in ArthroFLEX Tissue” 2013 White Paper. Available upon request.

- Paper shows that “MatrACELL processing effectively removes DNA and cellular components from human dermis, potentially improving graft incorporation, healing, and biocompatibility by decreasing or eliminating cellular immune response.”

Moore MA, Samsell B, Wallis G, Triplett, S, Chen S, Linthurst Jones A, Quiz X. “Decellularization of Human Dermis Using Non-Denaturing Anionic Detergent and Endonuclease: A Review.” Journal of Cell and Tissue Banking.

- “MatrACELL process effectively removes cellular material, including DNA and immunogenic components, yielding an acellular dermis, which retains biomechanical strength and is biocompatible. Both preclinical and clinical results support the use of this allograft tissue in a myriad of clinical applications.” [Click here for link.](#)

Agrawal H, Tholpady SS, Capito AE, Drake DB, Katz AJ. “Macrophage phenotypes correspond with remodeling outcomes of various acellular dermal matrices.” Journal of Regenerative Medicine. 2012. Vol 1, No. 3, pp 51-59.

- Results of study demonstrate that ADM’s, particularly Dermacell, with a higher ration of M2 to M1 were associated with a more constructive tissue remodeling outcome. Greater M2 activity promoted cell proliferation and tissue repair. ADM’s with more M1 activity showed more inflammatory tissue remodeling, which inhibits cell proliferation and causes tissue damage.
- NOTE: Dermacell is another trade name for ArthroFlex. [Click here for link.](#)

Biomechanical or Literature Reports Using ArthroFLEX

Ely E, Figueroa, N, Gilot G. “Biomechanical Analysis of Gap Formation and Ultimate Tensile Failure Loads of Rotator Cuff Repairs with Extracellular Matrix Graft Augmentation.” ORTHOPEDICS. 2014;37(9):608-614.

- Authors performed a biomechanical study to evaluate gap formation and ultimate tensile failure loads of a RTC repair augmented with ArthroFlex. “This study showed 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.” [Click here for link.](#)

Conroy C, Sethi P, Macken C, Wei D, Kowalsky M, Mirzayan R, Pauzenberger L, Dyrna F, Obopilwe E, Mazzocca AD. Augmentation of Distal Biceps Repair With an Acellular Dermal Graft Restores Native Biomechanical Properties in a Tendon-Deficient Model. Am J Sports Med. 2017 Jul;45(9):2028-2033.

- Investigators evaluated if dermal augmentation would improve load to failure of distal biceps tendon repair compared to a non-augmented control. They found “in a tendon-deficient, complete distal biceps rupture model, acellular dermal allograft augmentation restored the native tendon’s biomechanical properties at time zero.” The “dermal augmentation of attritional tendon repair increased the load to failure and stiffness as well as decreased displacement compared with the ungrafted tissue-deficient model.” [Click here for link.](#)

Van der Meijden, O.A., Wijdicks, C.A., Gaskill, T.R., Jansson, K.S., & Millett, P.J. “Biomechanical analysis of two tendon posterosuperior rotator cuff tear repairs: extended linked repairs and augmented repairs.” Arthroscopy. 2013 Jan;29(1):37-45. doi: 10.1016/j.arthro.2012.07.012.

- Investigators compared single-row (SR), extended double-row (DR), and augmented, extended double row (aDR) in 20 cadaveric shoulders. ArthroFlex was used for the aDR group. Authors conclude that “augmentation with a collagen patch (aDR) did not influence biomechanical repair qualities in this model, but did result in less variability in failure load and more consistency in the mode of failure.” [Click here for link.](#)

Beitzel K, Chowaniec DM, McCarthy MB, Cote MP, Russell RP, Obopilwe E, Imhoff AB, Arciero RA, Mazzocca AD. Stability of Double-Row Rotator Cuff Repair Is Not Adversely Affected by Scaffold Interposition Between Tendon and Bone. AJSM. 2012 May;40(5): 1148-54.

- Investigators used 25 cadaveric shoulders to evaluate strength of rotator cuff repairs without augmentation and augmentation using Viscogel, Mucograft, and ArthroFlex interpositionally, as well as augmentation on top of repair (5 groups). Authors conclude that “an increased ultimate load to failure was observed for 2 of the augmentation methods compared with the non-augmented repair (collagen patch as interposition and decellularized dermis patch on top of the reconstruction).” [Click here for link.](#)

Ehsan A, Lee DG, Bakker AJ, Huang JI. Scapholunate ligament reconstruction using an acellular dermal matrix: a mechanical study. J Hand Surg AM. 2012 Aug; 37(8):1538-42.

- Investigators compared reconstruction of the scapholunate ligament using 1.0 mm-thick and 1.5 mm- thick ArthroFlex grafts to the intact native ligament in 15 cadaveric specimens. The authors conclude that “scapholunate ligament reconstruction using acellular dermal matrix and suture anchors demonstrated similar biomechanical properties to previously described techniques” and “warrants clinical investigation as a potential treatment option for chronic scapholunate instability.” [Click here for link.](#)

Arthrex Research and Development. Biomechanical Properties of Tendon Augmentation Materials. 2011. White Paper (LA0822A)

- Ultimate load to failure and suture retention strength testing were performed on ArthroFlex as described by Barber et al in 2012. These results were compared to the published results and performance of the ArthroFlex is just as well as or better than OrthADAPT equine pericardium, SportsMesh synthetic matrix, or GraftJacket human dermal matrix.

Surgical Technique Guides Featuring ArthroFLEX

- Arthrex surgical technique guides, videos and presentations featuring ArthroFlex. [Click here for link.](#)
- Arthrex Superior Capsular Reconstruction for Massive Irreparable Rotator Cuff Tears Surgical Technique. Available upon request.
- Arthrex Achilles Tendon Reinforcement with ArthroFlex Decellularized Dermis Surgical Technique. Available upon request.
- Suture Retention Strength of ArthroFlex by Raffy Mirzayan. [Click here for video.](#)

1864 Concert Drive

Virginia Beach, VA 23453

Phone: U.S. 1-888-847-7831 ☐ 1-757-464-4761 x2000 (OUS)

Fax: U.S. 1-888-847-7832 ☐ 1-757-464-6439 (OUS)

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