REPRESENTATIVE REPORTS USING ARTHROFLEX® SCR

LifeNet Health has distributed over 10,000 ArthroFlex SCR grafts since the Superior Capsule Reconstruction Technique was introduced in the United States using an acellular dermal matrix in 2014. The ArthroFlex SCR allograft bio-implant was designed in conjunction with Arthrex, Inc., as an integral part of an alternative solution to reverse shoulder replacements for patients with irreparable rotator cuff tears and minimal osteoarthritis. LifeNet Health provides high-quality bio-implants with the biomechanical specifications you need to perform successful procedures and understands the safety and quality of your allograft bio-implants are critical to you and your patients. The list of articles below demonstrates the efficacy of ArthroFlex SCR and the Superior Capsular Reconstruction surgery.

Published Literature for SCR

Pennington W, Bartz B, Pauli J. Arthroscopic Superior Capsular Reconstruction for the Treatment of Massive Irreparable Rotator Cuff Tears in the Active Patient: 1-2 year Results. Presentation SS-06 at AANA on May 18, 2017.

- Authors present on first 58 shoulders that underwent arthroscopic SCR for the treatment of irreparable rotator cuff tears and rotator cuff pathology. At minimum one year follow-up, all but one is satisfied and one had revision to a reverse total shoulder arthroplasty. "Outcome data analysis demonstrated significantly improved scores in visual analog scores, simple shoulder test, SANE Scores, ASES Function scores, and ASES Index scores." They concluded that "arthroscopic superior capsular reconstruction with acellular dermal allograft has been a successful procedure in decreasing pain and improving function during this early postoperative period."

Burkhart S, Denard P, Tokish T and Brady P. Preliminary Results of Arthroscopic Superior Capsule Reconstruction with Dermal Allograft. Presentation SS-46 at AANA on May 19, 2017.

- Authors report on 31 patients with minimum follow-up of one year. Compared to preoperative values, forward flexion improved, pain decreased, ASES score improved, and SANE score improved. Five patients underwent revision. They concluded that: "arthroscopic SCR using dermal allograft provides functional improvement and patient satisfaction in the majority of cases. The preliminary results of this joint-preserving technique are encouraging in an otherwise difficult to manage patient population."

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."

Adams CR, Denard PJ, Brady PC, Hartzler RU, and Burkhart SS. The Arthroscopic Superior Capsular Reconstruction. AJO. 2016 July/ August: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."

Tokish JT and Beicker C. Superior Capsule Reconstruction Technique Using an Acellular Dermal Allograft. Arthroscopy Techniques. 2015 December 4(6):e833-9.

- 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."

Hirahara AM & Adams CR. Arthroscopic Superior Capsule Reconstruction for Treatment of Massive Irreparable Rotator Cuff Tears. Arthroscopy Techniques. 2015 Dec:4(6):e637-41.

- 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."

Petri M, Greenspoon JA, Millett PJ. Arthroscopic Capsule Reconstruction for Irreparable Rotator Cuff Tears. Arthroscopy Techniques. Dec:4(6):e751-55.

- 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."

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."

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."

Mihata T, Lee TQ, Watanabe C, Fukunishi K, Ohue M, Tsujimura T, Kinoshita M. Clinical Results of Arthroscopic Superior Capsule Reconstruction for Irreparable Rotator Cuff Tears. Arthroscopy 2013;29:459-70.

- Authors discuss original surgical technique using fascia lata autograft and their clinical outcomes at an average 34 months (24-51 months) post-op. "Average clinical outcome scores all improved significantly after ASCR at the final follow-up" (ASES, JOA, UCLA). Radiographic evaluation also revealed "the acromiohumeral distance increased significantly" and MRI revealed 20/24 (83.3%) intact repairs. Authors conclude "ASCR restored glenohumeral stability and function of shoulder joints with irreparable rotator cuff tears."

Other SCR Publications

Arthrex, Inc. Early SCR Outcomes. CC1-00016-EN_D. 2016. Arthrex.com retrieved 9/26/16.

- Arthrex report of clinical outcomes from their Surgical Outcomes System™. On this report dated 8/26/16 of 176 patients: "pain, function and quality of life scores for SCR trend toward favorable outcomes."

Mihata T, Lee TQ, Itami Y, Neo M. Superior Capsule Reconstruction for Irreparable Rotator Cuff Tear: A Prospective Study in 100 Consecutive Patients. Paper 359 presented at AAOS, March 3, 2016.

- Authors report "ASCR restored shoulder function and resulted in high rates of return to recreational sport and work." "These results suggest that arthroscopic superior capsule reconstruction is a viable surgical option for patients with irreparable rotator cuff tears, especially in patients who work and enjoy sport."

Mihata T, McGarry MH, Pirolo JM, Kinoshita M, Lee TQ. Superior Capsule Reconstruction to Restore Superior Stability in Irreparable Rotator Cuff Tears: A Biomechanical Cadaveric Study. AJSM 2012;40:2248-55.

- Authors investigated glenohumeral biomechanics after various graft patch techniques. Their conclusion is to attach the patch medially to the superior glenoid and not into the supraspinatus muscle in order to restore stability of the humeral head. This method fully restored both superior translation and subacromial contact pressure without altering glenohumeral joint force.

Peterson AB and Park MC. Superior Capsule Reconstruction. Current Orthopaedic Practice. 2017 March/April; 28(2): 142-5.

- Authors perform a literature review for SCR and discuss previous techniques to address irreparable rotator cuff tears, the surgical technique and outcomes from Mihata. They concluded that "SCR is a relatively new technique for the treatment of irreparable rotator cuff tears with a limited body of published data. However, the biomechanical and early clinical results for SCR suggest it to be a promising surgery for patients with regard to both subjective and objective postoperative outcomes."

Mihata T, Bui C, Cavagnaro MA, Akeda M, Kuenzler M, Peterson AB, Itami Y, Neo, M, Lee TQ. Superior Capsule Reconstruction Using Human Dermal Allograft: A Biomechanical Study. Paper 358 presented at AAOS, March 2, 2016.

- Investigators compared abilities of fascia lata (SCR FL) and human dermal allograft, ArthroFlex, (SCR HDA) to restore shoulder biomechanics in a cadaveric study. Both graft types were able to fully restore superior glenohumeral joint force and subacromioal contact characteristics. Superior humeral head translation was fully restored by fascia and partially restored by ArthroFlex. "SCR HDA repairs [ArthroFlex] had significantly increased total range of motion relative to the SCR FL."

Thorsness R and Romeo A. Massive Rotator Cuff Tears: Trends in Surgical Management. Orthopedics. 2016 May/June; 39(3): 145-51.

- Authors discuss treatment options for massive rotator cuff tears, including SCR. "Early biomechanical and clinical results have demonstrated the ability to contain the humeral head from superior migration, and in several cases, SCR was able to reverse a pseudoparalytic shoulder. The current authors choose SCR in patients younger than 65 years with massive irreparable rotator cuff tears without evidence of glenohumeral arthristis."

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."

Narvani AA, Consigliere P, Polyzois I, Sarkhel T, Gupta R and Levy O. The "Pull-Over" Technique for Arthroscopic Superior Capsular Reconstruction. Arthrosc Tech. 2016 Dec; 5(6): e1441-7.

- The authors describe a simple and reproducible technique for SCR to address irreparable rotator cuff tears, as well as explore advantages, risks and pearls for the procedure. They state that "With modern extracellular matrix, advances in processing techniques significantly enhance removal of antigenic material. These processes are reported to exhibit more than 94% removal of DNA, therefore minimizing the risks of immune and inflammatory response and adhesions. We did not have any cases of infection or excessive inflammatory response."

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 adding 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."

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