DERMIS ON DEMAND™ ALLOGRAFT

Value Analysis Brief

DePuy Synthes
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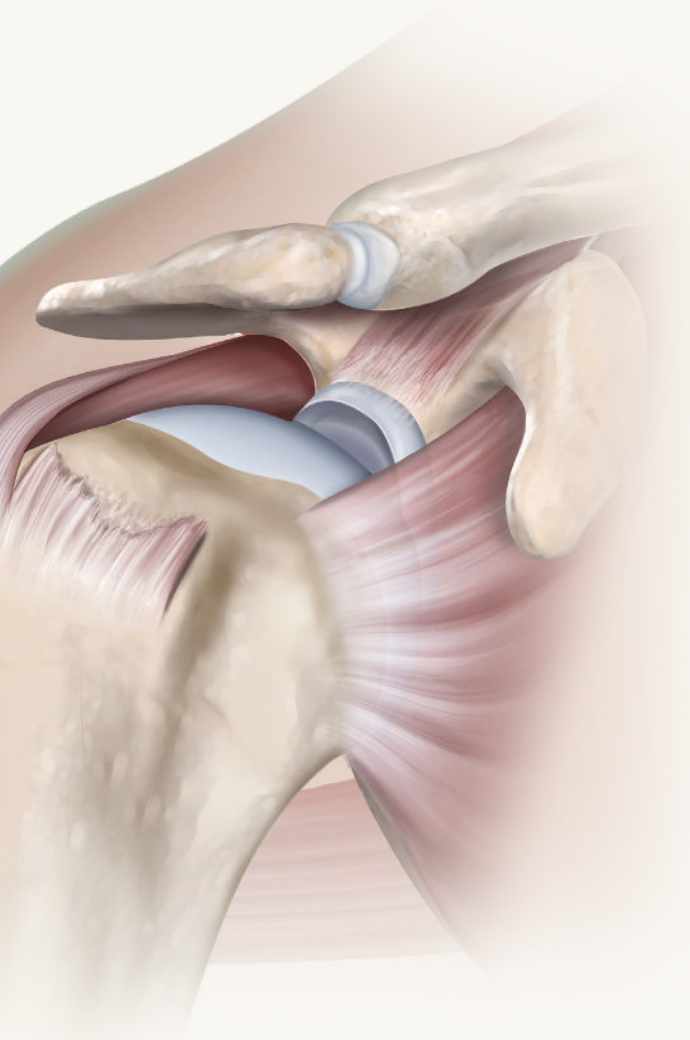
EPIDEMIOLOGY OF ROTATOR CUFF REPAIRS

There has been a growing population of patients receiving Rotator Cuff Repairs (RCR). From 1996 to 2006 there was an estimated 141% increase in RCRs in the United States,[1] with one study in New York State showing an increase as high as 238% between 1995-2011[2] (with similar increases shown in other countries[3]). Currently, over 460,000 RCRs are being done annually, and this is expected to grow at a compound annual growth rate of 4% to surpass 570,000 procedures by 2023.[4]

The growing demand for RCR surgery has highlighted a significant unmet need especially among patients with large or massive tears. In this patient population, repair failures known as re-tears are common and are reported to range from 20-40% of cases.[5] Furthermore, when the tear is massive and the tendon is degenerated and significantly retracted, re-tear rates have been reported as high as 94%.[5] RCR failure may lead to poor clinical outcomes and the need for costly revision surgeries and the potential for transition to shoulder arthroplasty and joint replacement. Thus, innovations that have the potential to reduce repair failures may alter the clinical course in this patient population and reduce the personal and financial burden of follow-up care due to re-tear, as costs and recovery times only increase with subsequent procedures.[5-7]



ROTATOR CUFF RE-TEAR AND REPAIR FAILURE RISK FACTORS

The main risk factors that may influence post-operative re-tears and failure include age, tear size, fatty degeneration, number of tendons involved, acromiohumeral interval, surgical technique, and bone mineral density.[8] Specifically, one study conducted a multivariate regression and found that preoperative fatty degeneration of the infraspinatus was an independent predictor of re-tear in full-thickness rotator cuff tears in patients who underwent arthroscopic repair.[9]

Furthermore, it has also been reported that RCRs fail because sutures may pull through the tendon. This "cheese wiring" effect is one way in which the tendon can move away from the repaired footprint to form a "gap" between the tendon and bone. "Gap formation" may ultimately cause the tendon to fail to heal with the bone.[10-11] In all, it is evident that advancements are needed to help mitigate the risks that may lead to re-tear and RCR failure.

CLINICAL BENEFITS OF TRADITIONAL ROTATOR CUFF REPAIR AUGMENTATION

High failure rates of RCR have led to increasing interest in the addition of biological augmentation for RCR.[12] This has led to the introduction of human acellular dermal allograft. Human acellular dermal allografts may integrate and remodel to tendon-like tissue.[13] This process may lead to an increase in tissue thickness. As most of the rotator cuff re-tears are initiated in the tendon tissue,[14] tendon augmentation with a human dermal allograft may reduce the risk of rotator cuff re-tears.

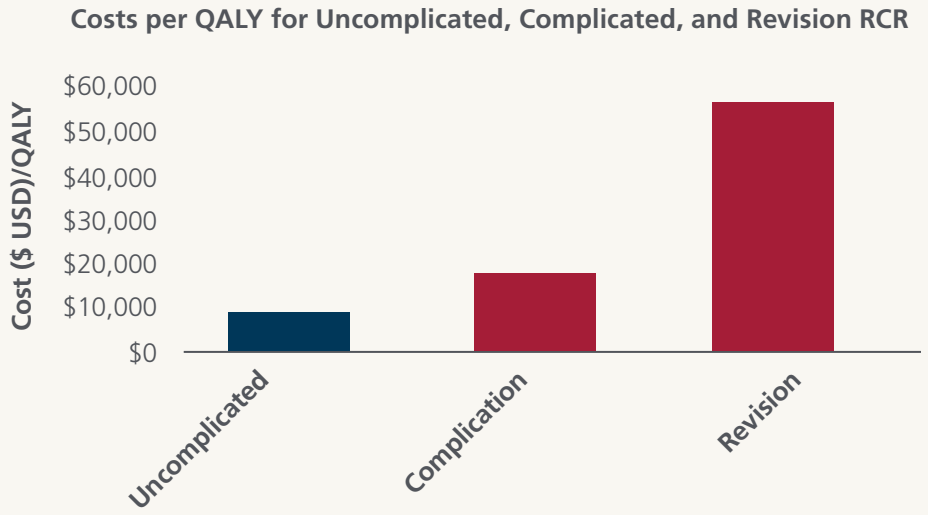
When Compared to Non-Augmented RCR, Augmented RCR Demonstrates:

Lower Re-Tear Rates	There is an understanding that rotator cuff augmentation with traditional dermal allograft reduces rotator cuff re-tear rates[15-18] • A 5-study meta-analysis determined the re-tear rates of augmented repairs and non-augmented repairs at 38% and 43%, respectively.[5]
Improved Patient Reported Outcome Measures	Mean University of California, Los Angeles (UCLA) scores higher in allograft (12.2, 9.1-17.1) compared to non-augmented group (9.3, 4.2-16.4),[5] which achieved a minimal clinical important difference at 24 months.[19] A 5-study meta-analysis determined that augmented repairs had significantly higher American Shoulder and Elbow Surgeons (ASES) scores.[5]
Higher Range of Motion Post-Op	Allograft augmenation (45.4°, 36.0°-55.7°) was shown to have a higher range of motion than non-augmented RCRs (34.6°, 21.4°-51.7°).[5]
Higher Abduction and External Rotation Post-Op	Allograft augmentation has higher abduction (49.3°, 46.7°-52.8°) when compared to non-augmented (37.4°, 1.0°-47.8°).[5] Allograft augmentation also has higher external rotation (18.8°, 4.2°-35.3°) when compared to non-augmented (4.2°).[5]
Graft Repair and Integrity	Grafted repair integrity was 82.2% for allograft repairs (74.0%-90.0%), and 49.3% for non-augmented repairs (26.3-73.3%).[5]
Lower Rates of Complications	Studies have shown that RCR cases that were augmented with human dermal allografts had lower complication rates compared with cases that had no augmentation.[15,20] • No-augmentation group: 70% (14/20) →9 re-tears, 2 cellulitis, 1 shoulder bursitis, 1 fibrosis, 1 biceps tendon rupture[20] • Dermal allograft group: 18% (4/22) →3 re-tears, 1 bursitis[20]

*DERMIS ON DEMAND allograft may not function to load-share in traditional rotator cuff repair configurations.

ECONOMIC BENEFITS OF TRADITIONAL ROTATOR CUFF REPAIR AUGMENTATION

Revision operations and complications associated with RCR are costly, with a cost per Quality Adjusted Life Year (QALY) of $56,099 and $17,403, respectively.[6] Innovations in the space which are designed to reduce re-tear rates, failures, and complications may reduce costs to the hospital and healthcare system.



CURRENT LIMITATIONS OF TRADITIONAL ROTATOR CUFF REPAIR AUGMENTATION

While literature has shown the clinical benefit of human acellular dermal allograft augmentation, it is associated with some limitations:

1. The use of grafts may increase case cost ($2000-$3000 per graft)[12,21]
2. A longer operating room time can be expected[12]
3. Described as technically demanding[12]

DePuy Synthes offers DERMIS ON DEMAND™ Allograft featuring OPEN DERMAL MATRIX™ Technology; designed to address current limitations of human acellular dermal allograft.

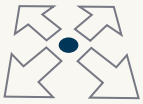
EASE OF USE

In a skills lab time and motion study, 24 DERMIS ON DEMAND (DOD™) Allografts were placed onto rotator cuff tissue by 4 surgeons of varying skill levels, and the time for placement was recorded for each allograft. Time recorded includes the loading of DOD Allograft onto suture, the loading of a knot pusher onto the suture, the pushing of DOD Allograft down the suture into position on the cuff tendon and the removal of the knot pusher. The average placement time was 17.69 seconds, with the fastest time being 9.3 seconds and the slowest time being 27.3 seconds. Statistically, according to this test, 90% of DOD Allografts can be placed within 25.9 seconds – hence the **"30-Second Augmentation"**.[22]

LESS EXPENSIVE

Traditional allografts are sold in larger than necessary sheets and then cut down to size in the operating room. With traditional allografts, much of the donated tissue is discarded. In constrast, **DOD Allograft is offered at a fraction of the cost of traditional allografts** and is "built-up" using smaller pieces so the facility pays for only what is used and little, if any, donated tissue is discarded by a health care facility.[21]

BROADER COMPRESSION



The addition of DOD Allograft to a #2 suture can both substantially and significantly increase the footprint when compared to a #2 suture alone.[23] This may correspond with **more soft tissue to bone contact**,[23] and may distribute the forces of the load of the suture over a greater area.

Suture Type	Example Footprint Map	Normalized Footprint Area
PERMACORD™ Suture		1
FiberTape®		1.51
PERMATAPE™ Suture		1.56
PERMACORD™ Suture with DOD™ Allograft		1.54

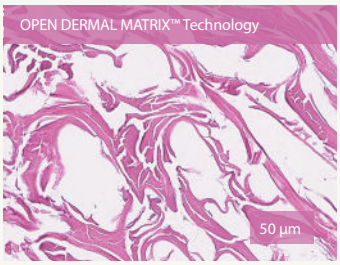
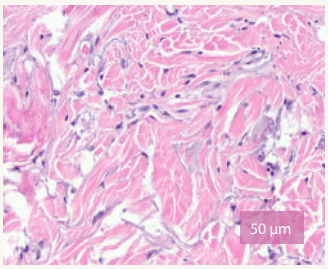
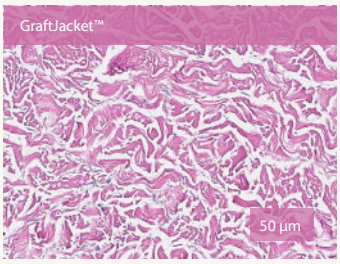
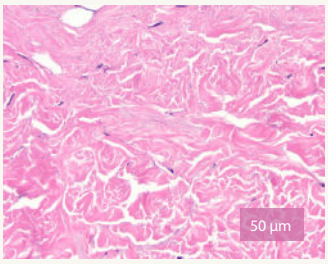
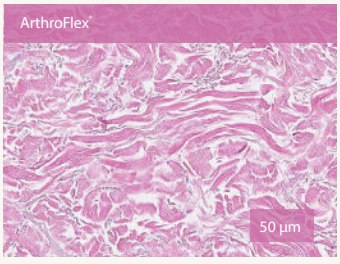
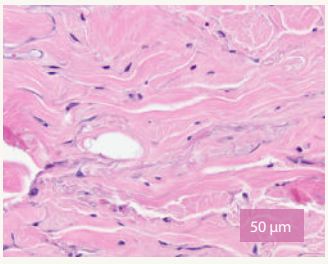
Indicates Contact

Indicates No Contact

Results of the footprints of the suture constructs tested.
Normalized relative to the average footprint area of the #2 PERMACORD™ Suture.

HOST TISSUE INTEGRATION WITH OPEN DERMAL MATRIX™ TECHNOLOGY

OPEN DERMAL MATRIX (ODM) Technology describes the more porous, open structure of the DOD Allograft which is created through a proprietary processing method. Pre-clinical testing has demonstrated that allografts processed with the **ODM Technology may integrate better with host tissue than traditional dermal allograft** due to more openings for blood vessels to penetrate through.[24,25*]

Pre-Implantation[25]	6-Weeks Athymic Rat Model[24]	Histology Report[24]
		• Consistent deep penetration of the article by bands of fibroplasia or fibrous tissue • More blood vessel penetration than compared to traditional dermal allografts • Visible penetration of mesenchymal cells
		• Inconsistent or limited focal penetration of the article by individual cells or by very fine strands of fibroplasia or fibrous tissue • Inconsistent or limited focal penetration (restricted to superficial periphery) of the article by blood vessels • Minimal mesenchymal cell penetration into article
		• Fair, multifocal or diffuse penetration of the article by individual cells or thin bands of fibroplasia or fibrous tissue • Inconsistent or limited focal penetration (restricted to superficial periphery) of the article by blood vessels • Minimal mesenchymal cell penetration into article

*Pre-clinical data may not correlate with clinical results.

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