What is GraftJacket®?

What can it be used for?

What is the current literature on GraftJacket® and Rotator Cuff Tears?
What is GraftJacket®

- Immunologically inert acellular scaffold consisting of collagen and extracellular protein matrices
- Contains elastin, collagen, proteoglycans, and vascular channels, which provide ideal environment for revascularization and cellular repopulation
What is GraftJacket®

Derived from cadaveric human dermal tissue

Human Dermal Tissue

- Remove Cellular Components
- Retain Collagen, Elastin and Proteoglycans
- Preserve Intact Matrix

GRAFTJACKET®
Acellular Matrix

- Reduces Rejection Response
- Allows Revascularization & Cellular Repopulation
- Reduces Inflammatory Response

Regeneration of Normal Tissue
What is GraftJacket®

- **Patented technology** removes cellular components **without** chemical or radiation cross-linking

- Preservation of biochemical and extracellular structural properties of the dermal collagen structure
What is GraftJacket®

- Packaged Dry
- Rehydration process in OR prior to implantation

Figure 6 (A) Graft Jacket is hydrated for at least 10 min in normal saline. (B) The Graft Jacket may also be hydrated in a collection of the patient’s blood, with the possible benefit of autologous growth factors. (Color version of figure is available online.)
What is GraftJacket®

The “Blue Print” for Angiogenesis and Regeneration

**FIGURE 5** | Histological section demonstrating decellularized membrane prior to implantation

**FIGURE 6** | Histological section demonstrating cellular repopulation without signs of inflammatory response

**FIGURE 1** | SEM cross-sectional image illustrates the intact tissue matrix

Preserved vascular channels provide a pipeline for cellular repopulation 400x
What is GraftJacket®

Revascularization after implantation

Preserved vascular channels allows for revascularization and cellular repopulation. 400x

Type IV collagen staining of the preserved vascular channels prior to implantation. 100x

GRAFTJACKET® Matrix 35 days postimplantation with vascular channels stained brown, demonstrating revascularization. Factor VIII 200x
What is GraftJacket®

Benefits
- Revascularization of the extracellular matrix
- Cellular repopulation of the matrix scaffold
- Biocompatible with human tissue
- Exceptional Strength
- Favorable handling properties
What is GraftJacket®

- **Indications:**
  - The GraftJacket® matrix is used for the repair or replacement of damaged or inadequate integumental tissue (Skin, Tendon, Ligaments, Periosteum, etc ...)

- **Contraindications:**
  - Patients with autoimmune connective tissues diseases
  - Infected or nonvascular surgical sites
  - Any pathology that would limit the blood supply and compromise healing
  - Poor nutrition and/or poor general medical condition
  - Sensitivity to specific antibiotics listed on the package
What can it be used for?

Previously described uses in the literature

1. Diabetic Foot Ulcers

2. Tendon Repair Augmentation
   - Rotator Cuff Tendon
   - Achilles Tendon
   - Peroneal Tendon
   - Posterior Tibial Tendon
   - Quadriceps Tendon

3. Ligament Repair and Augmentation
   - Medial Collateral Ligament of the Elbow
   - Ulnar Collateral Ligament of the Hand
   - Anterior Talofibular Ligament
   - Capsular Repair (Hip)

4. Periosteal Patch
What can it be used for?

Images courtesy of Dr. Marie Williams
What can it be used for?

Tendon Reinforcement
Image courtesy of Scott Steinmann, MD Mayo Clinic Rochester

Ulnar Collateral Ligament
Image courtesy of James Chao, UCSD

Pulley Reinforcement
Image courtesy of Scott Steinmann, MD Mayo Clinic Rochester
What can it be used for?

Achilles Tendon, Image courtesy of Dr. Daniel Lee

Peroneal Tendon, Image courtesy of Dr. Brock Liden
What can it be used for?

Quadriceps Tendon Reinforcement

Posterior Hip Capsule

Periosteal Patch

Images courtesy of Mike Neel, MD
What can it be used for?

Figure 1 | Residual gap limitations (10-15mm) for appropriate GRAFTJACKET® Scaffold application.*

Figure 2 | Superior surface application of GRAFTJACKET® Scaffold

Figure 4 | Securing the GRAFTJACKET® composite utilizing sutures and anchors

Figure 6 | *

Figure 7 | Anchoring sutures in place around the circumference of the cuff repair before augmentation. (Color version of figure is available online.)

Figure 9 | Graft Jacket augmentation securely sutured over the previous rotator cuff repair, creating a water tight surface. (Color version of figure is available online.)
What is the current literature on GraftJacket® and Rotator Cuff Tears?

- 3 Relevant Journal Articles

1. Tendon Augmentation Grafts: Biomechanical Failure Loads and Failure Patterns

2. Rotator Cuff Repair Using an Acellular Dermal Matrix Graft: An In Vivo Study in a Canine Model

3. Use of Graft Jacket as an Augmentation for Massive Rotator Cuff Tears
Determine load to failure strengths and modes of failure of various commercially available tendon augmentation xenografts and allografts.

- GraftJacket vs. CuffPatch vs. Restore vs. Permacol vs. TissueMend

- 2 X 5 cm sample with horizontal mattress stitch

- Tensile loads to failure measured using Instron machine
Comparison Testing of Tendon Repair Augmentation Graft Materials Load-to-Failure and Evaluation of Failure Patterns

Single Horizontal Mattress Suture Configuration | #2 FIBERWIRE® Suture

- CUFFATCH® GRAFT (Arthrotek) 32 N
- RESTORE® GRAFT (DePuy/BJJ) 38.2 N
- TISSUEBOND® GRAFT (Stryker Orthopaedics) 76 N
- ZOK® GRAFT (Zimmer) 128 N
- GRAFTJACKET® REGENERATIVE TISSUE MATRIX GRAFT 157 N
- GRAFTJACKET® MAXFORCE GRAFT 182 N
- GRAFTJACKET® MAXFORCE EXTREME GRAFT 229 N

Conclusions

- GraftJacket has the highest load to failure, and the thicker grafts are strongest.

- Weakest point is "suture-graft" interface.

- The suture will pull out before the graft tears.
Rotator Cuff Repair Using an Acellular Dermal Matrix Graft: An In Vivo Study in a Canine Model


- Biomechanical and histological properties of GraftJacket vs. Autologous tissue in primary full thickness infraspinatus tear

- Canine model with full-thickness infraspinatus tendon tear
  - GraftJacket vs. Autologous excised tendon (control) to bridge defect
  - Animals sacrificed ==> Histological + Biomechanical Testing

- Biomechanical
  - Time 0 = strength was equal between groups
  - Time 6 weeks = Autologous was 2X stronger than GraftJacket
  - Time 3 months = GraftJacket equal to Autologous
  - Time 6 months = GraftJacket equal to Autologous = Normal Tendon

- Histological
  - By 6 weeks cells infiltrated both groups equally
  - By 6 months the specimens in both groups mimicked normal tendon
Ultimate Stress = Max Force to Failure / cross-sectional area

Time 0 = GraftJacket stronger than Control

Time 6 months = GraftJacket equal to Control. Both equal to normal/native tendon
Figure 2. (A) Gross images of control autologous tendon repair specimen and (B) experimental acellular dermal matrix repair specimen at 6 months survival.

Regular tendon collagen (top right) adjacent to acellular graft matrix (bottom left) @ 6 months

B = Bone, S = Sharpey’s Fibers, T = Graft matrix tendon, @ 6 months
Conclusion

- At 6 months, the biomechanical and histological characteristics of GraftJacket® are equal to autogenous tendon graft for repair of rotator cuff tear in a canine model.
Use of Graft Jacket as an Augmentation for Massive Rotator Cuff Tears
Semin Arthro 18:11-18 © 2007

- GraftJacket Augmentation for Massive Rotator Cuff Tear in HUMANS

- Case Series
- Prospectively Collected Data
- Clinical Outcome Study
- Not-Blinded
- Single Surgeon (Dr. Burkhead)

- 17 consecutive patients with massive RCT
- Open RCR with GraftJacket Augmentation
- 1.2 years follow up on average
Conclusions

- 64% had no pain or slight pain (IMPROVEMENT)
- 70% had normal function or slight restriction (IMPROVEMENT)
- Overall better ROM
- Overall improved strength
- Improved UCLA scores (9.06 to 26.12, p<0.001)
- No Infections
Summary

- GraftJacket is an acellular scaffolding derived from human skin.
- Contains fundamental characteristics of extracellular matrix (collagen, elastin, proteoglycans and vascular channels).
- Can be used for augmentation and repair of numerous tissues (Skin, Tendons, Ligaments, Periosteum, etc ...).
- Allows for revascularization, repopulation and regeneration with satisfactory clinical outcomes.
The GRAFTJACKET® Matrix is processed and preserves biological components from the human dermal layer which include:

- MULTIPLE COLLAGEN TYPES
- ELASTIN
- PROTEOGLYCANS

Collagen types I, III, IV, and VII

Grannulation Tissue

Rapid Revascularization and Incorporation

Thank You
What is GraftJacket®

- Manufactured by LifeCell
- Distributed by Wright Medical Technology

 Disclaimer

- Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the patient.

- As with any processed donor tissue, the GRAFTJACKET matrix cannot be guaranteed to be free of all pathogens.

- No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of the GRAFTJACKET Regenerative Tissue Matrix.
Time 0 = Equal (no statistical difference)
Time 6 weeks = Control stronger than GraftJacket (statistically significant)
Time 3 and 6 months = Equal (no statistical difference)
Commercial Extracellular Matrix Scaffolds for Rotator Cuff Tendon Repair. Biomechanical, Biochemical and Cellular Properties

**Analysis of Biomechanical, Biochemical and Cellular Properties**

- GraftJacket vs. TissueMend vs. Resotre vs. CuffPatch vs. Canine Infraspinatus Tendon

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**TABLE I Commercially Available Extracellular Matrix Patches for Reinforcement of Soft-Tissue Repair During Rotator Cuff Surgery**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Industrial Source</th>
<th>Tissue Type</th>
<th>Source</th>
<th>Chemically Cross-Linked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restore Orthobiologic Implant</td>
<td>DePuy Orthopaedics</td>
<td>DePuy Orthopaedics</td>
<td>Small intestine submucosa</td>
<td>Porcine</td>
<td>No</td>
</tr>
<tr>
<td>CuffPatch Bioengineered Tissue</td>
<td>Organogenesis</td>
<td>Arthrotek (Warsaw, IN)</td>
<td>Small intestine submucosa</td>
<td>Porcine</td>
<td>Yes (carboxymethyl)</td>
</tr>
<tr>
<td>Tissue Matrix</td>
<td>LifeCell</td>
<td>Wright Medical Technology (Arlington, TN)</td>
<td>Dermis</td>
<td>Human</td>
<td>No</td>
</tr>
<tr>
<td>TissueMend Soft Tissue Repair Mat</td>
<td>TEI Biosciences</td>
<td>Stryker Orthopaedics</td>
<td>Dermis (fetal)</td>
<td>Bovine</td>
<td>No</td>
</tr>
<tr>
<td>Zimmer Collagen Repair Patch</td>
<td>Tissue Science</td>
<td>Zimmer (Warsaw, IN)</td>
<td>Dermis</td>
<td>Porcine</td>
<td>Yes (diphenylmethane)</td>
</tr>
</tbody>
</table>
Elastin stain (Black) of unimplanted GraftJacket

Note: Irregular elastin orientation

Elastin stain (Black) of implanted GraftJacket with maintained **continuity** (@ 6 months)

Note: Regular and continuous elastin orientation relative to native tissue (top right)

Elastin stain (Black) of implanted GraftJacket with **discontinuity** (@ 6 months)

Note: Irregular elastin orientation relative to native tissue (bottom)