



ReGen Presentation

Orthopaedic and Rehabilitation Devices Panel
510(k) K082079 – ReGen Collagen Scaffold (CS)

November 14, 2008

Confidential

Agenda

- ❖ *Introduction*
- ❖ *Surgical Mesh and Pre-Clinical Data*
- ❖ *Histologic Findings*
- ❖ *Clinical Outcomes*
- ❖ *Articular Surfaces*
- ❖ *Safety of the CS*
- ❖ *Shoulder vs. Meniscus*
- ❖ *Conclusion*



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INTRODUCTION

ReGen's Perspective

- Our company developed a surgical mesh designed and engineered for implantation in the meniscus following partial meniscectomy surgery.
- Data demonstrate that the device preserves and reinforces the meniscus and provides a scaffold for tissue growth.
- The CS functions as a surgical mesh by reinforcing soft tissue and it is as safe as any mesh cleared by FDA.

The ReGen Situation

- The CS has the same intended use, materials and technology as FDA cleared surgical mesh devices.
- Use of the CS in the meniscus represents a new indication for use.
- FDA has cleared numerous surgical meshes that were defined by new indications, each representing a first use of a surgical mesh in a specific anatomical location, e.g., anal fistula plugs, meshes for reinforcement of rotator cuff repairs.
- Any new indication raises the same issue of suitability for use. For a resorbable surgical mesh these issues are centered on whether the device provides reinforcement and serves as a scaffold for tissue growth.
- What each new indication had in common with its predicates was not an anatomical location, but mesh function and relative safety.
- ReGen has provided valid scientific evidence which establishes that the CS is as safe as its predicate meshes and functions as a surgical mesh in both acute and chronic populations.

ReGen's Device Description

- The CS is a resorbable collagen-based surgical mesh
 - Bovine type I collagen
 - Semi-lunar shape trimmed by the surgeon to fill voids created by partial meniscectomy

- Intended to reinforce residual meniscal tissue and provide a scaffold for tissue growth
 - Sutured in place for immediate reinforcement and the preservation of native tissue
 - Tissue growth provides long-term reinforcement

Surgical Mesh: Recognized Intended Uses

- Sec. 878.3300 - Surgical mesh, Class II
 - Surgical mesh is intended to be implanted to reinforce soft tissue or bone where weakness exists
- Scope of regulation expanded by FDA 510(k) decisions, e.g., Resorbable surgical mesh provides a scaffold to be replaced by the patient's own tissue:
 - Over 400 surgical meshes cleared;
 - 17 new indications cleared since 2002.

Current Scope of Mesh: Indications for Use

The indications for use of surgical mesh have evolved over the years. When viewed at the same level of abstraction all have the same intended use, despite different indications for use. They are all intended to reinforce soft tissue or bone – only in different tissues or anatomic locations.

- Achilles Tendon
- Anal Fistulas
- Biceps Tendon
- Bladder Support
- Body wall defects
- Colon prolapse
- Enterocutaneous fistulas
- Fascial defects
- Fistula Plug
- Gastroenterological anatomy
- Hernias
- Lung resections
- Muscle Flap Reinforcement
- Patella Tendon
- Pelvic floor reconstruction
- Pubourethral support
- Quadriceps Tendon
- Reconstructive Procedures
- Rectal fistulas
- Rotator cuff
- Sacrocolposuspension
- Solid organ support
- Spine (vertebral body)
- Suture line reinforcement
- Thoracic wall
- Urethral slings for urinary incontinence

CS Indication for Use

- The ReGen Collagen Scaffold (CS) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the meniscus. In repairing and reinforcing meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.
- The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CS is not a prosthetic device and is not intended to replace normal body structure or provide full mechanical strength of the repair.

Clinical Data Supporting Clearance

- Feasibility Study
 - Established safety and long-term viability of tissue
- U.S. Multicenter Clinical Trial
 - 162 CS patients
 - CS was developed as surgical mesh
 - ReGen undertook IDE in 1996, before mesh category broadened
 - With relevant predicates established, 510(k) pathway most appropriate
 - Data confirmed CS acted as surgical mesh
 - Documented tissue growth and shown to be as safe and effective as predicate devices

The Scientific Basis for Expanded Indications

- Preclinical bench and animal testing have formed basis for most FDA surgical mesh clearances, including meshes for new indications.
- Device effectiveness is inherent in each device's ability to reinforce and/or provide a scaffold for tissue growth
- The recognized risks associated with surgery, tissue reactions and infection are mitigated through ensuring biocompatibility and sterility.
- Few surgical mesh submissions, including those with new indications, include clinical evidence of safety and effectiveness.

Clinical Data in Recent Surgical Mesh Clearances

Indications for Use

- Reinforcement of rotator cuff
- Patella, biceps, Achilles, quadriceps, tendon repair
- Repair of anal, rectal and enterocutaneous fistulas
- Urethral sling for incontinence
- Seal air leaks in the lungs
- Maintain position of bone graft in vertebral body of spine

Clinical

- 5 patients – 3 months
- No clinical data
- 25 patients – 3 months
- No clinical data
- 26 patients – thru discharge
- No clinical data

The CS Submission Record

- Like other surgical meshes with new indications, ReGen's CS surgical mesh is intended to reinforce soft tissue where weakness exists.
- ReGen submitted substantial preclinical and clinical data to the FDA demonstrating its device functions as surgical mesh.
- To the extent that data on CS predicates exist, CS data show that it is as safe as those predicates.
- Technological characteristics and indications for the CS do not raise new types of questions regarding its safe and effective performance as a surgical mesh.



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SURGICAL MESH & PRE-CLINICAL DATA

Dr. Stephen Badylak



Biologic Surgical Mesh Devices

- Collagen Based Surgical Meshes
 - Restore, Permacol, Oasis, Collamend, ReGen CS

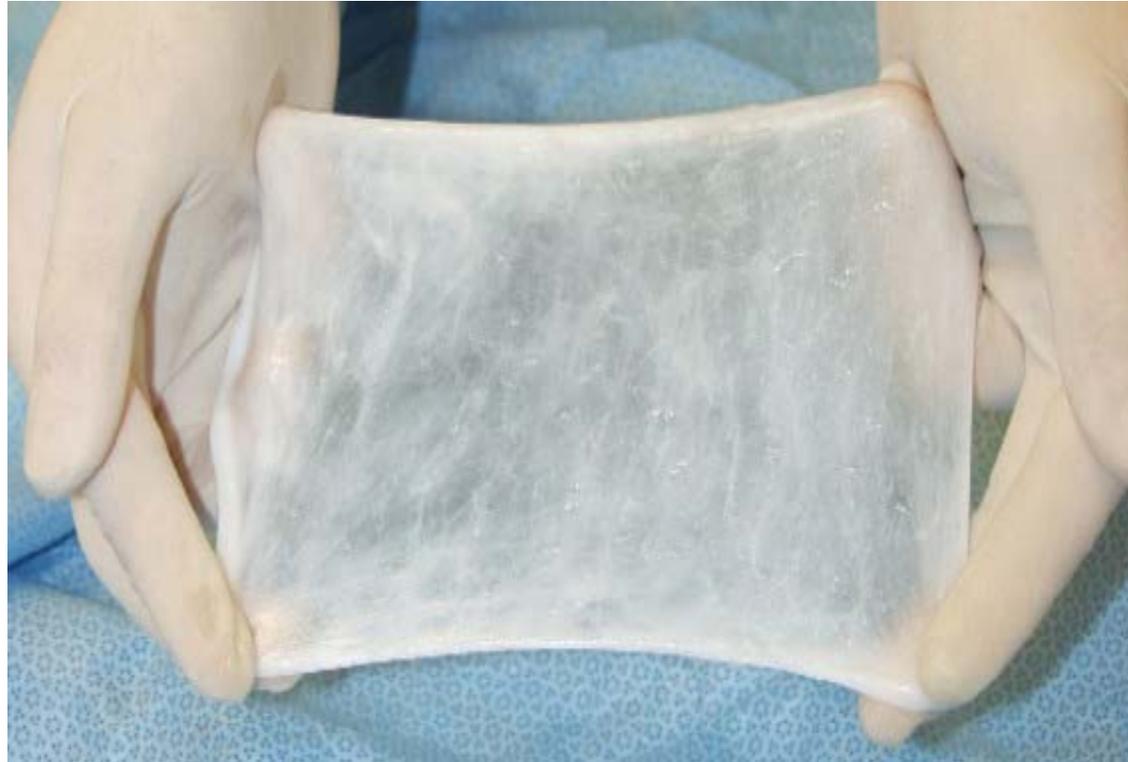
In-Vivo Remodeling

- Biologic surgical mesh devices are intended to degrade, remodel and be replaced by host tissue
- Process of degradation, cellular infiltration, deposition of new matrix, differentiation of cells at site of remodeling, and organization of new matrix is termed “remodeling”
- The microenvironment of the implantation site, including biomechanical loading, largely defines the remodeling process and outcome



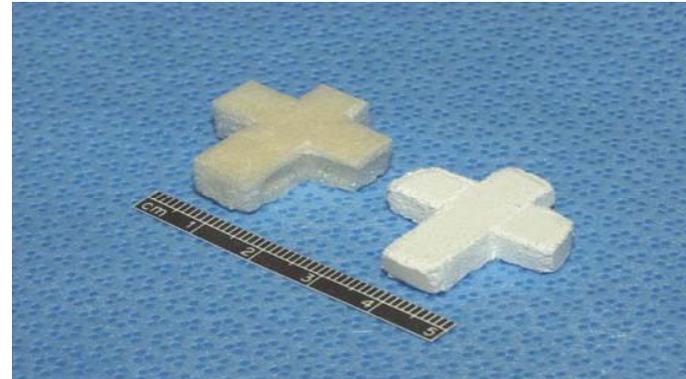
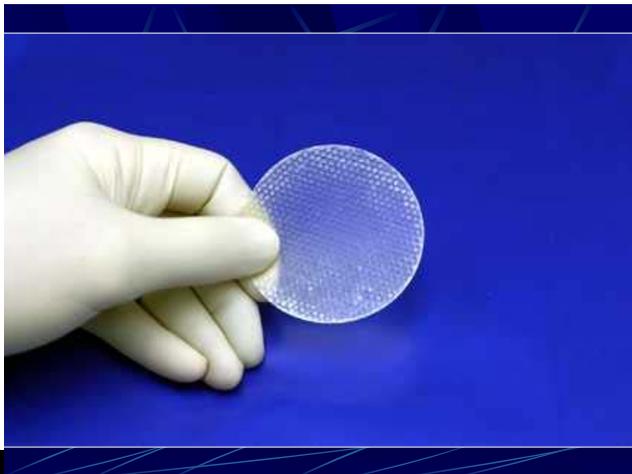
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Biologic Surgical Mesh



Biologic Surgical Mesh

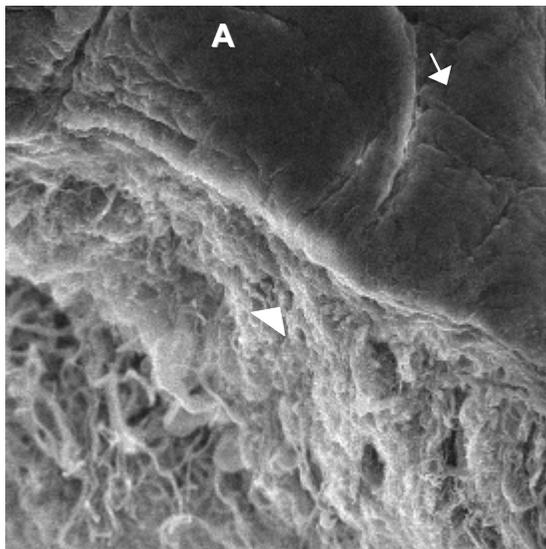
Various Configurations



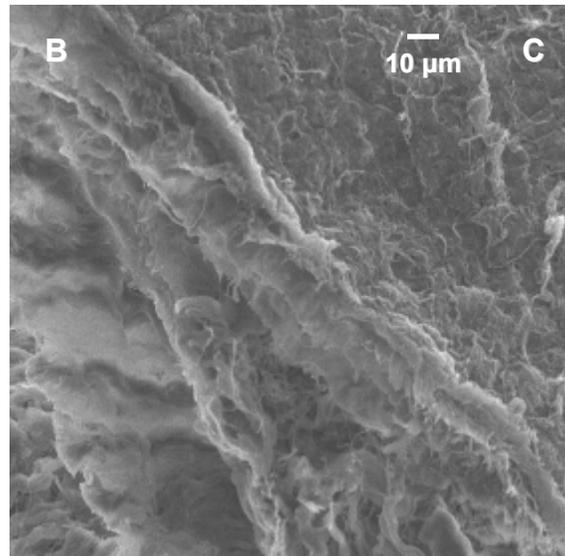


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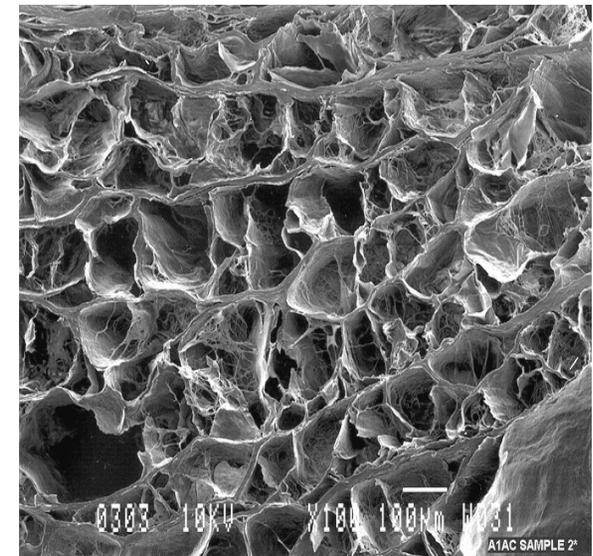
Tissue Scaffolds



Urinary
Bladder
Matrix



Small
Intestinal
Submucosa

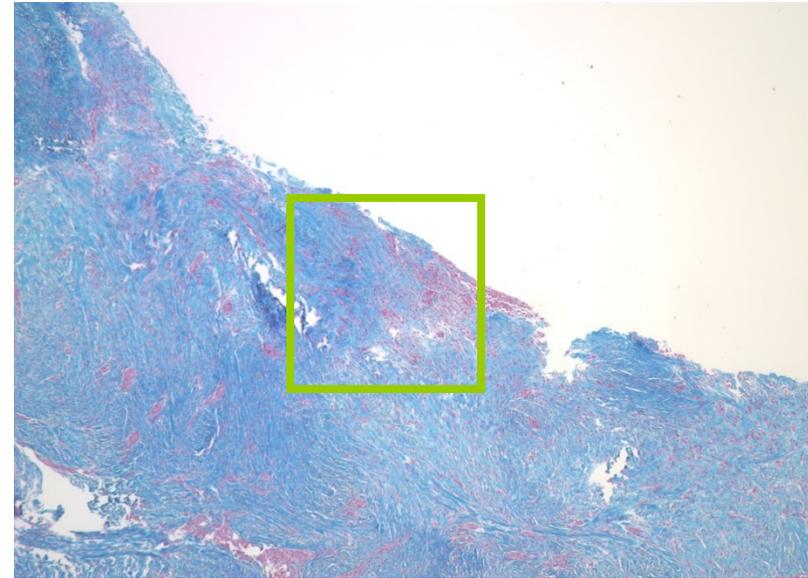
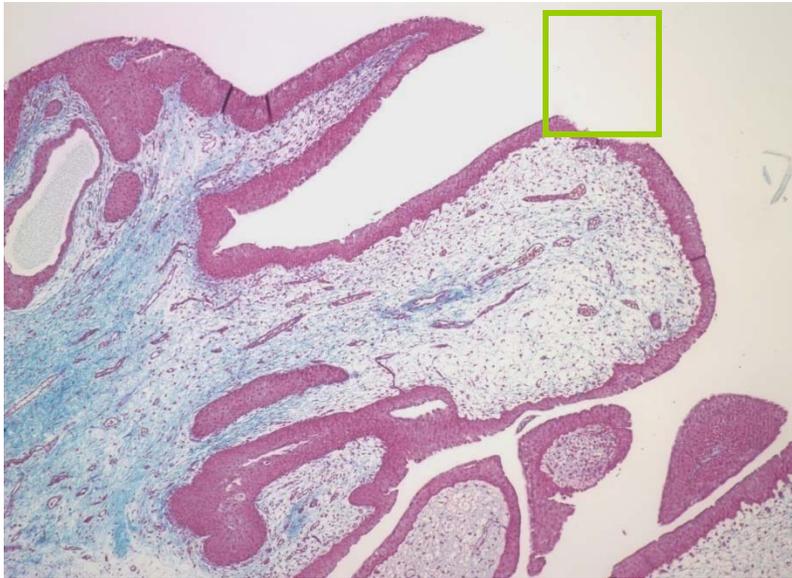


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ROLE OF MECHANICAL LOADING IN CELL DIFFERENTIATION AND TISSUE RECONSTRUCTION

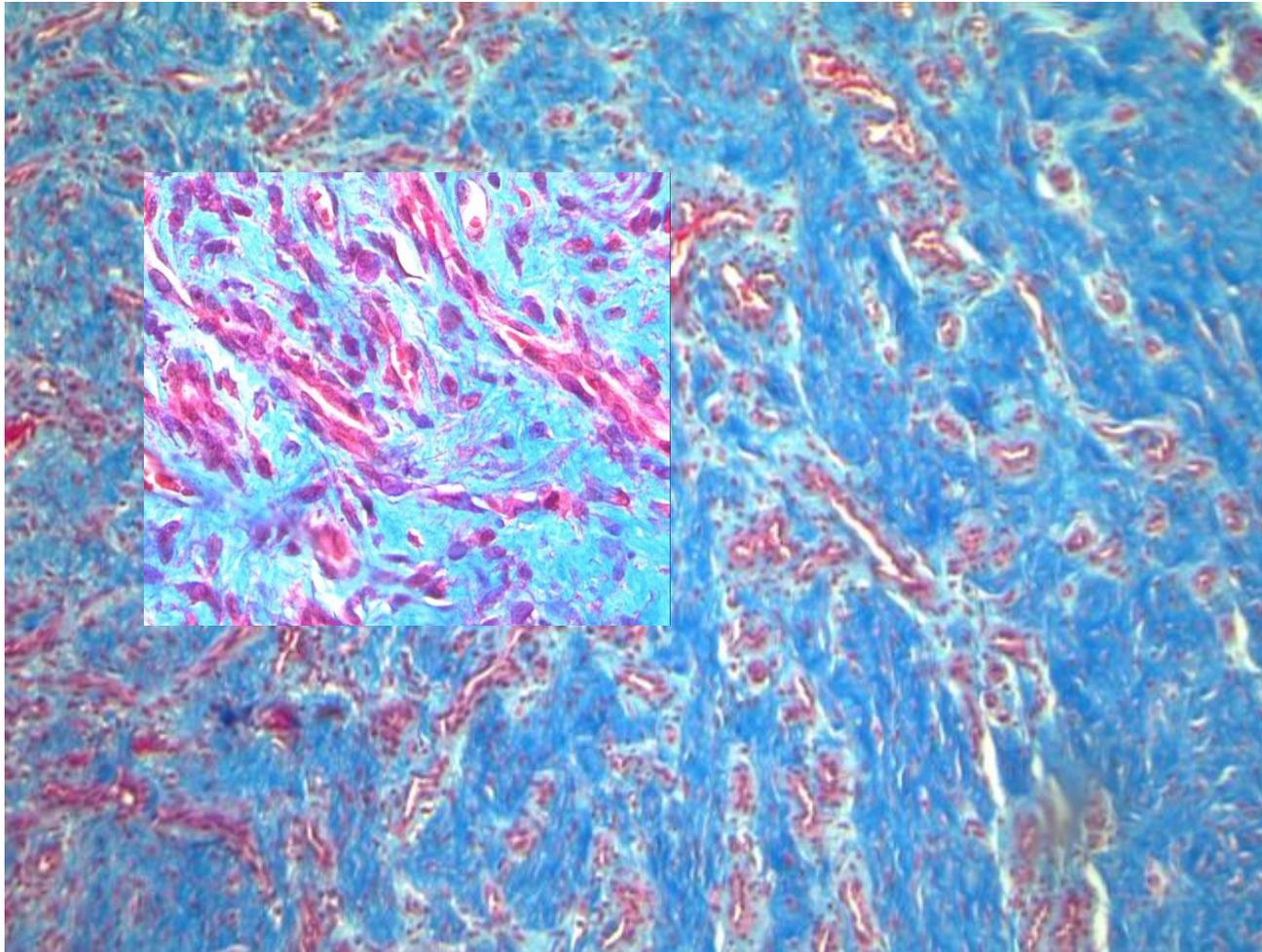


28 days

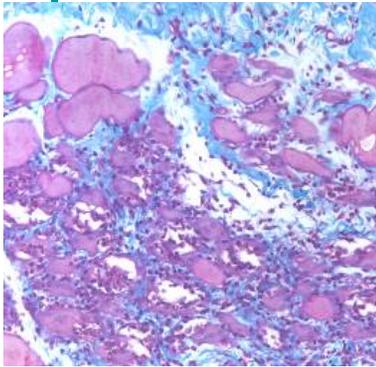


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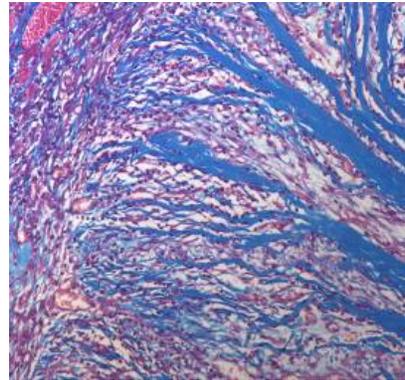
Histology



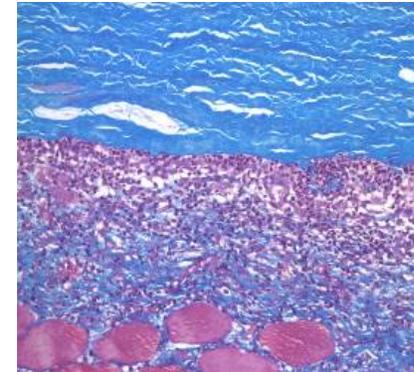
Histology – One Week



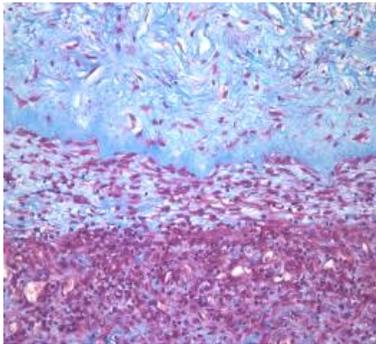
Autologous Tissue



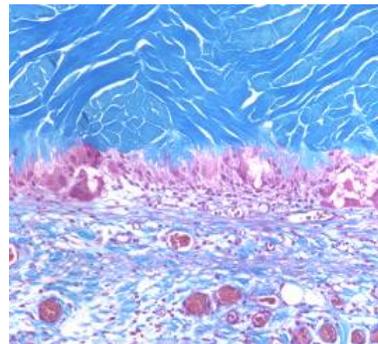
Restore™



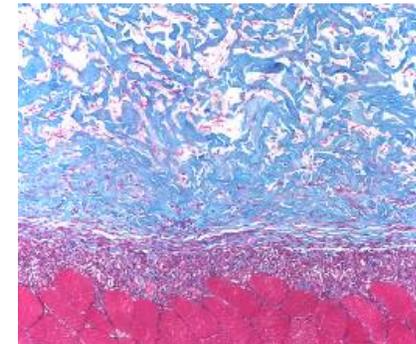
Cuffpatch™



Graftjacket™

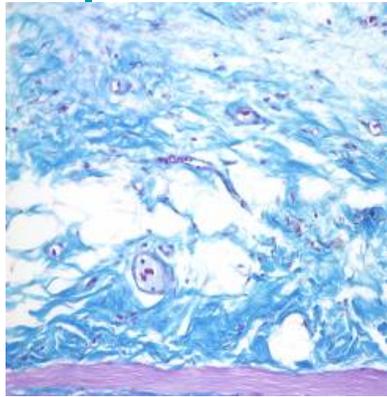


Permacol™

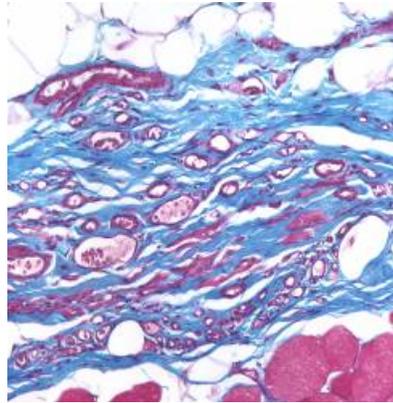


TissueMend™

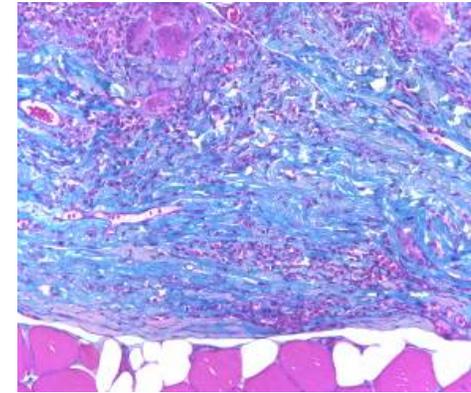
Histology – Sixteen Weeks



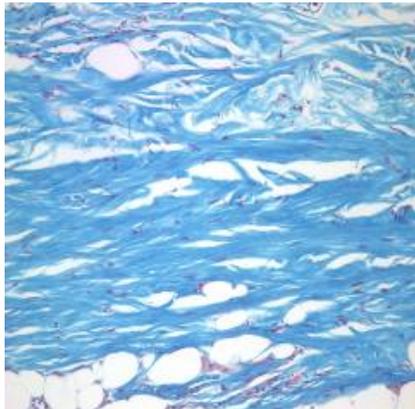
Autologous Tissue



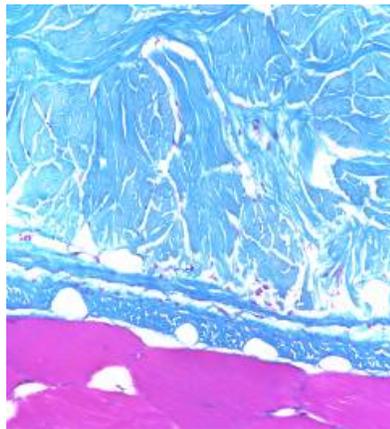
Restore™



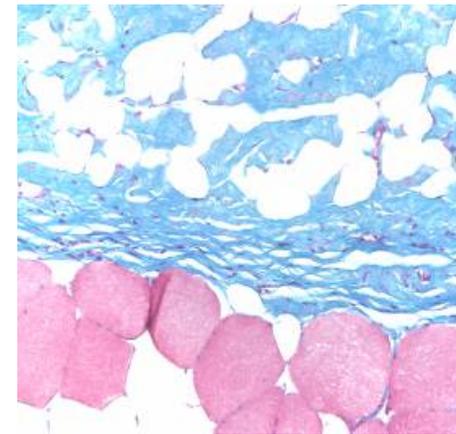
Cuffpatch™



Graftjacket™



Permacol™



TissueMend™

Conclusion

- All surgical meshes elicit a robust host cellular response
- The remodeling process differs for each surgical mesh but it is clear that mesh resorption is associated with constructive remodeling
- Microenvironmental factors, including mechanical forces, are critical determinants of the remodeling process and downstream results

HISTOLOGIC FINDINGS

Dr. Vincent Vigorita

Canine Study Design

- Study Objectives:
 - *Assess the ability of the CS to remain attached to host rim and provide a resorbable scaffold for tissue ingrowth*
 - *Assess the type and progression of tissue ingrowth*

Canine Study

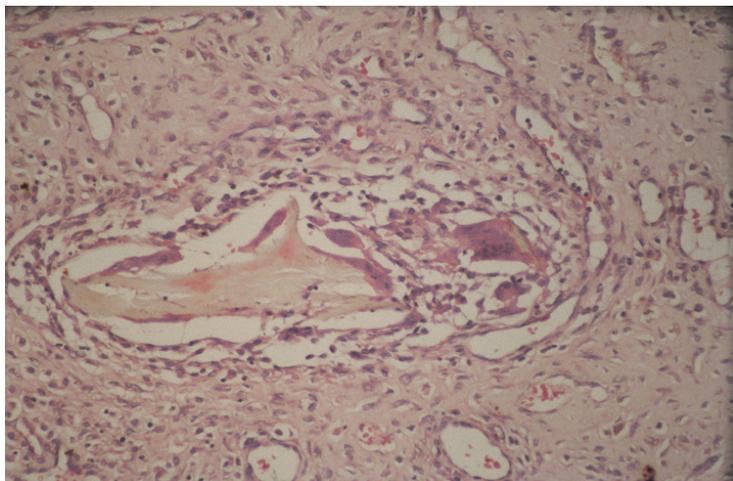
Conclusions

- Mechanical characteristics proved sufficient to maintain attachment to host meniscal rim in a severe animal model
- CS device functions as a tissue scaffold
- Newly formed tissue shows a predictable evolution of early angiogenesis with a reparative type granulation tissue evolving into fibrochondrocytic meniscus-like tissue

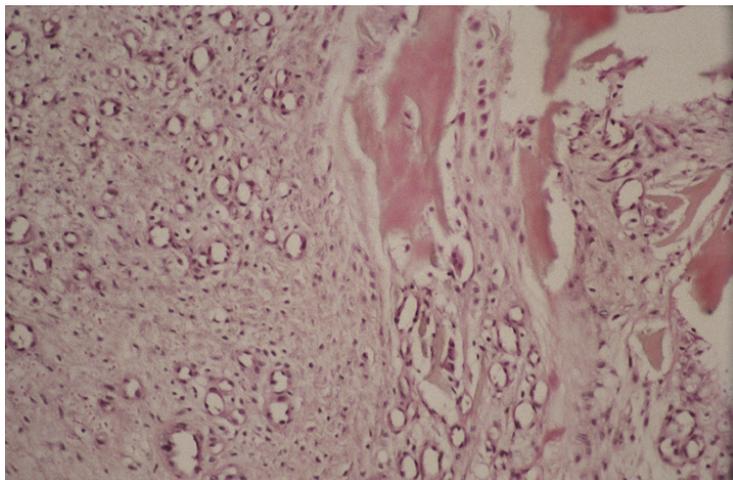


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Canine Study Histology

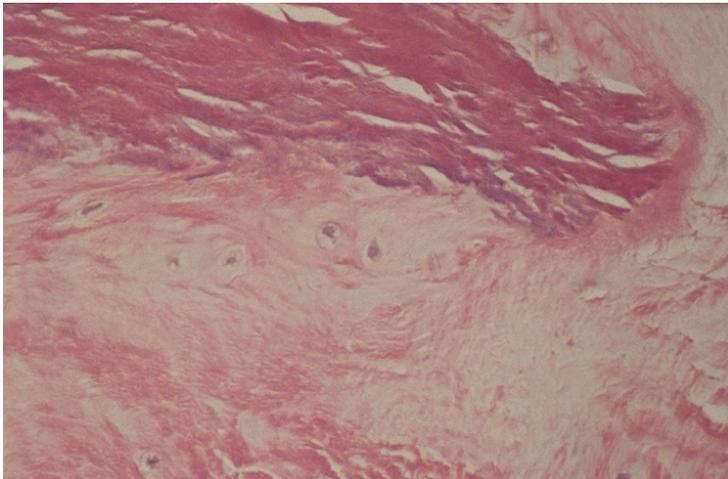


Active giant cell resorption
at 3 weeks

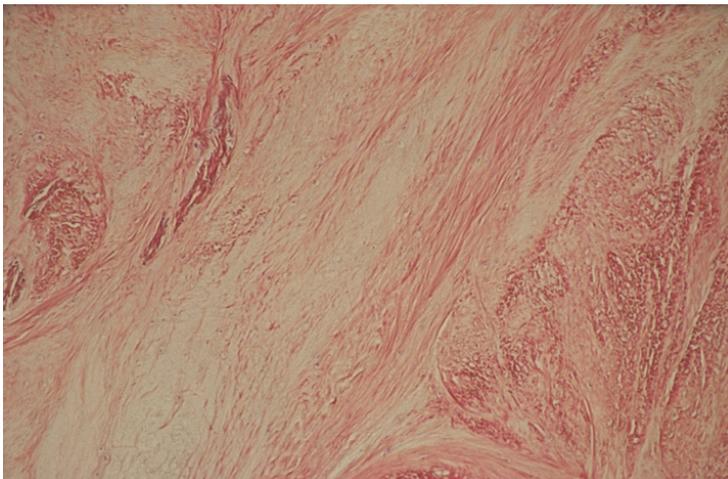


Active angiogenesis
at 6 weeks

Canine Study Histology



Deposition of mature
fibrochondrocytic matrix
at 17 months

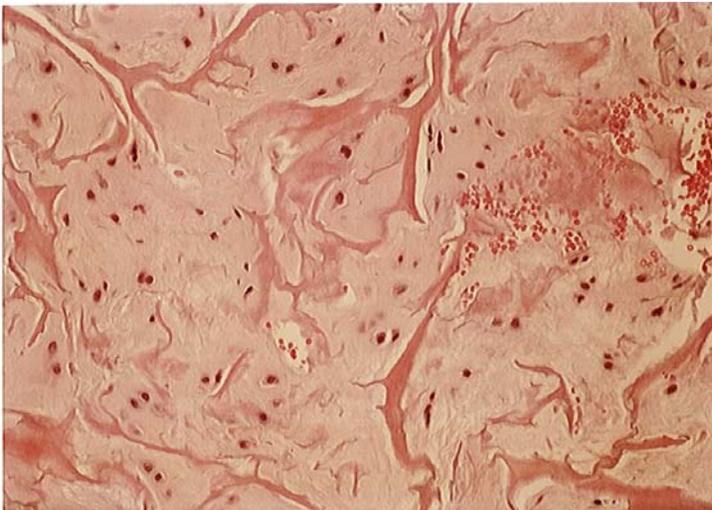


Integration of new tissue
with native meniscal rim
at 17 months

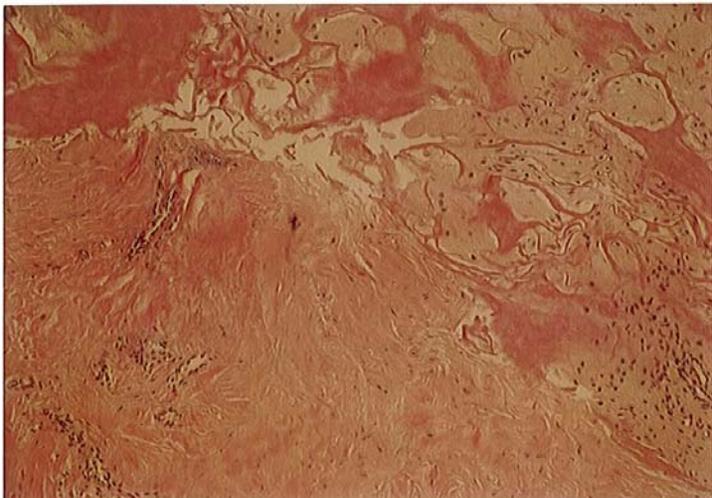
U.S. Multicenter Clinical Study: Histology

- 162 patients received the CS device in a U.S. IDE study
- CS patients had a relook arthroscopy and biopsy at 1 year post implantation
- 136 biopsies examined
- 81 biopsies contained remnants of the CS and were used to evaluate the cellular response to the material

U.S. Multicenter Clinical Study: Histology (cont.)

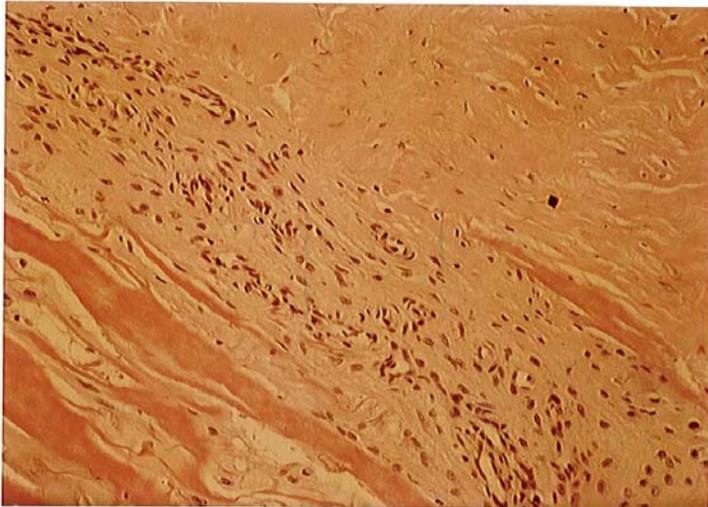


Fibrochondrocyte Ingrowth
Into CS

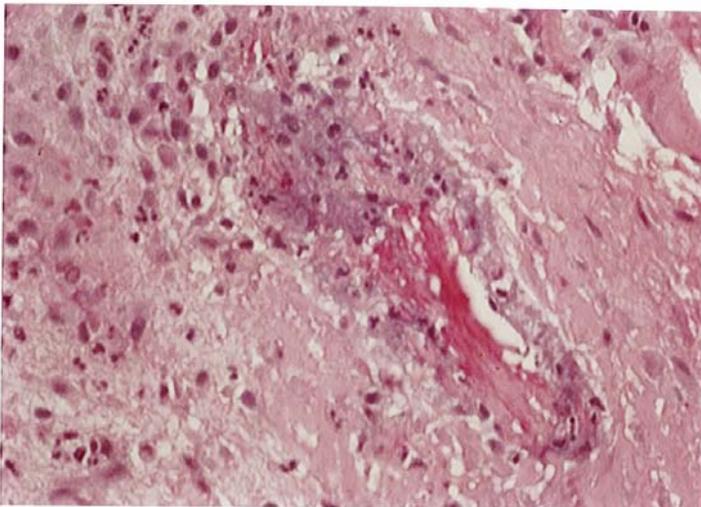


Host / CS Interface

U.S. Multicenter Clinical Study: Histology (cont.)



Host/CS Interface with
Angiogenesis at Interface



Inflammation and resorption
of CS with polymorphonuclear
leukocytes

U.S. Multicenter Clinical Study: Histology (cont.)

Conclusion

- CS provides a scaffold for meniscal-like fibrochondrocytic matrix production
- Newly formed tissue integrated well into the host meniscal rim
- CS material became embedded in newly formed tissue and the scaffold resorbed or was assimilated into matrix
- No significant adverse reaction to the material
- Rarely observed inflammatory response similar to that seen with materials like suture
- Results consistent with those seen in canine study



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Meniscal Surgery and Clinical Outcomes

Dr. Kenneth DeHaven

A Goal of Mesh Use in the Meniscus

- Conserve as much meniscus as possible
 - Loss of meniscus tissue tied to increased stress on articular cartilage and long term degenerative changes
 - The number of meniscus repair and allograft surgeries have increased to preserve as much meniscus tissue as possible

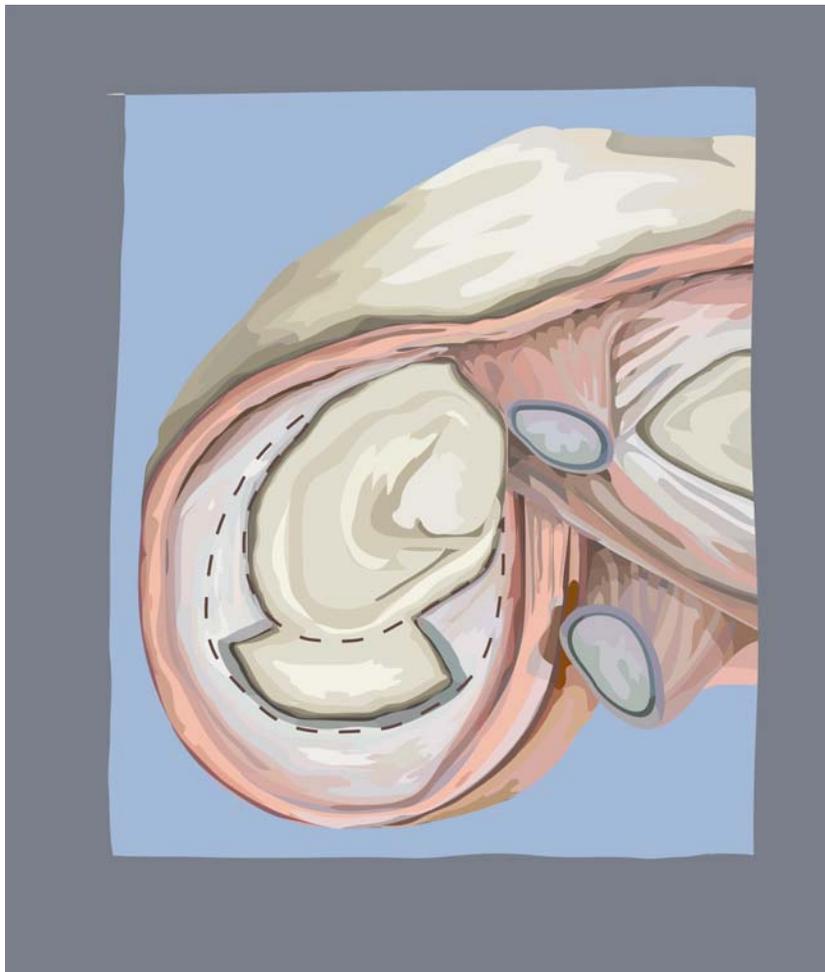
Partial Meniscectomy

- One of the most successful orthopaedic procedures for short term results
- However, it leaves patient with a permanent tissue loss and potential for long-term degenerative changes

Use of CS Device

- Patients must have intact meniscal rim and horns
- Defect must extend at least into red/white zone of the meniscus
- Patients undergo meniscectomy procedure even if CS is not used – CS provides reinforcement and scaffold for tissue ingrowth
- CS provides patients with an irreparable meniscus injury the option of regaining lost tissue after a partial meniscectomy

CS Preserves and Reinforces Meniscus



The dotted line outlines additional tissue that would be removed in a partial meniscectomy procedure without the reinforcement of the CS device

Tissue Growth is Impressive

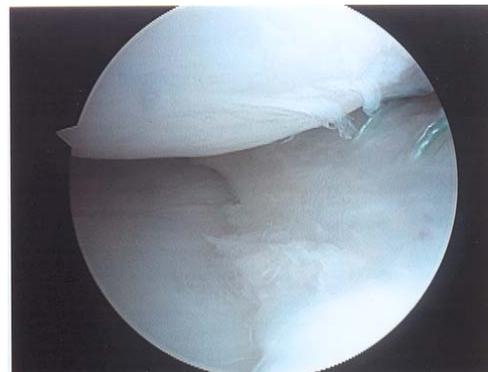
BEFORE SURGERY



POST SURGERY



1-YEAR POST SURGERY

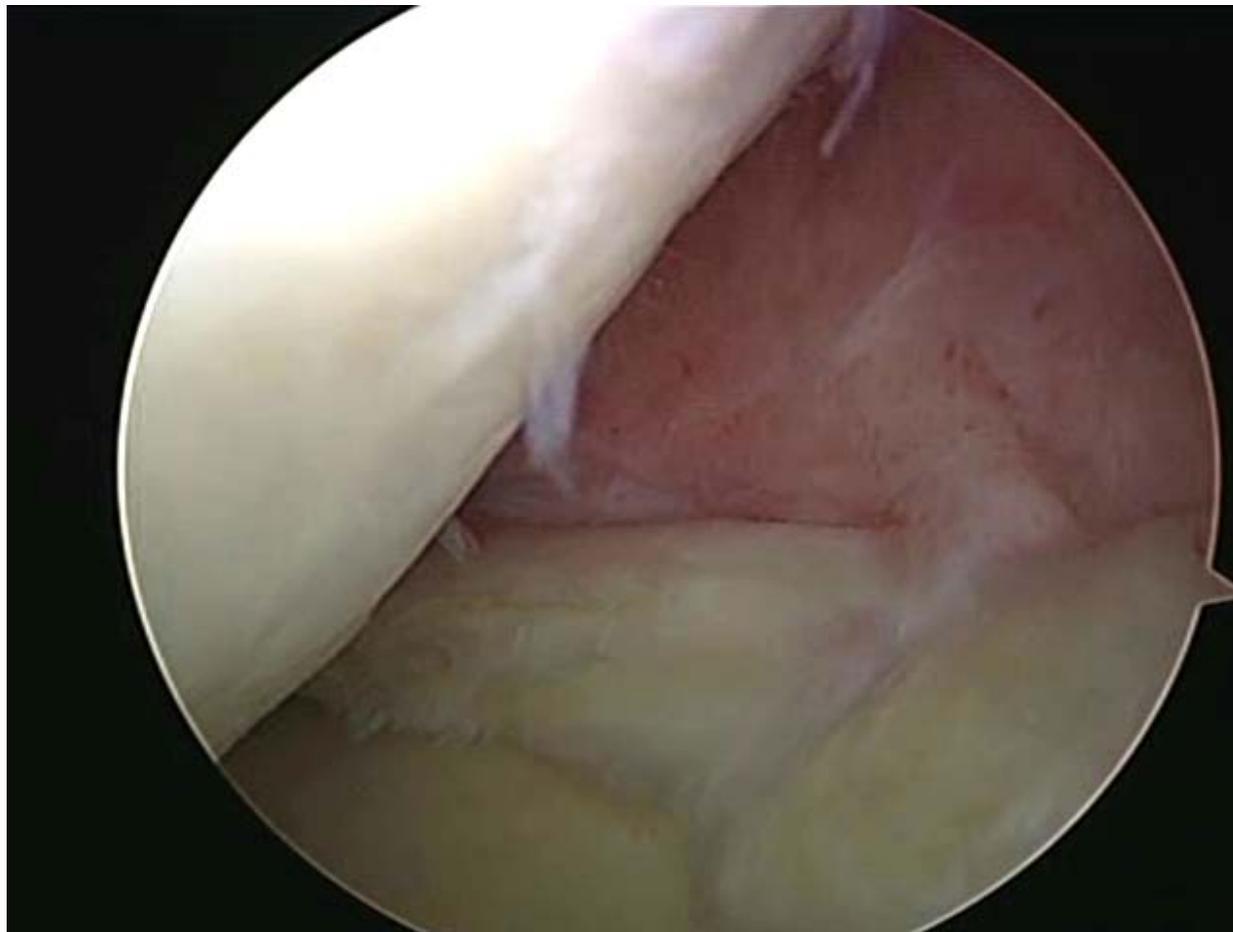




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Outcomes

Durability is More Impressive



11 Year Relook Surgery

Confidential

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Use of the CS Device

- Native meniscus rim and horns bear the major portions of the load, just as they would in a partial meniscectomy without the CS.
- Restricted weight bearing after surgery allows an opportunity for healing and tissue integration.
 - This is similar to labeling of predicate meshes which recommend limits on activities over a specified period to facilitate tissue incorporation into the mesh.
- Rehabilitation following CS placement similar to that used after meniscal repair procedure.

Clinical Outcomes: US Multi-center Study

- 26 surgeons at 16 investigational sites
- 162 cases received CS device (75 acute cases, 87 chronic cases)
- Assessed new tissue growth at 1 year via relook surgery and biopsy
- Assessed VAS pain, function via Lysholm, activity via Tegner, self-assessment
- Followed through 7 years (mean 4.9 years)

Clinical Outcomes: US Multicenter Study

Significant Increase in Tissue at 1 year For All Patient Populations

	Initial Surgery		Relook Surgery			P Value
Population	N	Meniscus Remaining	N	Total Tissue	Tissue Gain	Change
Chronic + Acute	160	43 %	140	73 %	70 %	<0.0001
Chronic CS	85	37 %	76	73 %	97 %	<0.0001
Acute CS	75	51 %	65	73 %	43 %	<0.0001

Clinical Outcomes: US Multicenter Study

Results show statistically significant improvements in clinical outcomes from pre-operative status at 4.9 years post-operative

(Chronic + Acute Patients)

Parameter	Mean Score Pre-Injury	Mean Score Pre-operative	Mean Score at Longest Follow-up	Change in Mean Score	p-Value
VAS Pain	---	35.0 N=160	14.5 N=150	19.97 N=148	<0.0001
Lysholm (Function)	---	63.3 N=162	83.6 N=150	20.39 N=150	<0.0001
Self-Assessment	---	43.8% (normal or Nearly normal) N=162	84.6% (normal or Nearly normal) N=150	40.8% N=142	<0.0001
Tegner Activity Level	6.7 N=162	3.0 N=162	4.5 N=150	1.5 N=150	<0.0001

Conclusions from MCT

- CS patients had significantly more tissue filling the defect left by partial meniscectomy
 - Tissue preservation is goal of meniscus treatment
 - Added tissue may serve to protect the joint
- CS patients had statistically significant improvements from pre-op in Pain, Lysholm, self-assessment and Tegner Activity Level
 - These clinical outcomes complement the data establishing performance as a surgical mesh
 - Comparable outcomes to PM which is one of the most highly successful orthopaedic surgeries for short term outcomes but long-term tissue loss can result in degenerative changes

Published Studies

- Feasibility study – established tissue durability and safety of device to 5.8 years
- JBJS article – confirmed CS serves as surgical mesh in acute and chronic patients—superiority demonstrated in the chronic CS group as compared to PM in certain outcome measures
- European publications confirmed that CS is biocompatible, resorbable and provides a scaffold for tissue growth

Clinical Feasibility Study

- Single surgeon; 8 patients with mean follow-up of 5.8 years
- Relook surgery performed at 6 months or 1 year, and again at mean of 5.8 years on all 8 patients
 - Approximately 70 % of the meniscal defect was filled with new tissue
 - The amount of new tissue growth remained constant from 6 months or 1 year through 5.8 years demonstrating tissue durability
- Histology showed meniscus-like fibrochondrocytic tissue formation and maturation from 1 year to 5.8 years
- Patients improved in outcomes of Pain, Lysholm, self-assessment and Tegner Activity measures from pre-op
- Complete resorption of scaffold in tissue samples at 5.8 years
- No complications related to the use of the device

JBJS Article

- Authors compared the results obtained with the CS to the partial meniscectomy control.
- For both the chronic and acute patient groups the article showed:
 - CS acted as a scaffold and facilitated a significant increase in tissue
 - Improved clinical results from baseline
- Comparison of the CS to a surgical procedure is not what we are here to consider today

Results - JBJS Article

- Results from the authors' analyses demonstrate superiority of the chronic CS patients to partial meniscectomy in chronic patients:
 - Regained more of their lost activity level as measured by the Tegner Index than chronic controls
 - Had a lower reoperation rate related to meniscus symptoms when compared to chronic controls

Tegner Index - JBJS Article

- Tegner Index showed that chronic CS patients regained 42% of their lost activity level and chronic controls regained 29% of their lost activity level; statistically significant ($p=0.02$)
- Questions about Tegner and Tegner Index
 - Tegner has been separately validated for use in assessing meniscal injuries (K. Briggs, M. Kocher, et. al.)
 - Tegner Index is a mathematical calculation using a validated scale – no need to validate calculation
 - Tegner Index (unlike difference pre-op to post-op) takes into account individuals pre-injury activity level
- Potential for recall bias addressed – all patients asked to recall pre-injury level at same point in the trial

Reoperation Rate – JBJS Article

- Reoperation rate for meniscal symptoms in chronic CS patients significantly lower than in chronic controls
 - Chronic CS reoperation rate was 9.5% and chronic control reoperation rate was 22.7% (p=0.04)
- Same definition used for both:
 - CS and partial meniscectomy
 - Acute and chronic groups

Conclusions from Clinical Data

- More clinical data were collected on CS than on any other cleared surgical mesh – 170 patients (Multicenter and Feasibility studies) with 5.8 years of follow-up
- Device provides a stable interface with the host rim resulting in a 70% increase in tissue to reinforce the remaining meniscus rim and horns
- Data show that tissue remains viable through at least 5.8 years
- CS patients improved significantly from pre-operative in pain, function, self-assessment and activity level
- Outcomes results comparable to PM which is a procedure with a very successful short-term outcome - in addition, the CS patients have the added benefit of more tissue
- Both acute and chronic patients benefitted from an increase in tissue and improved clinical outcomes



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SAFETY

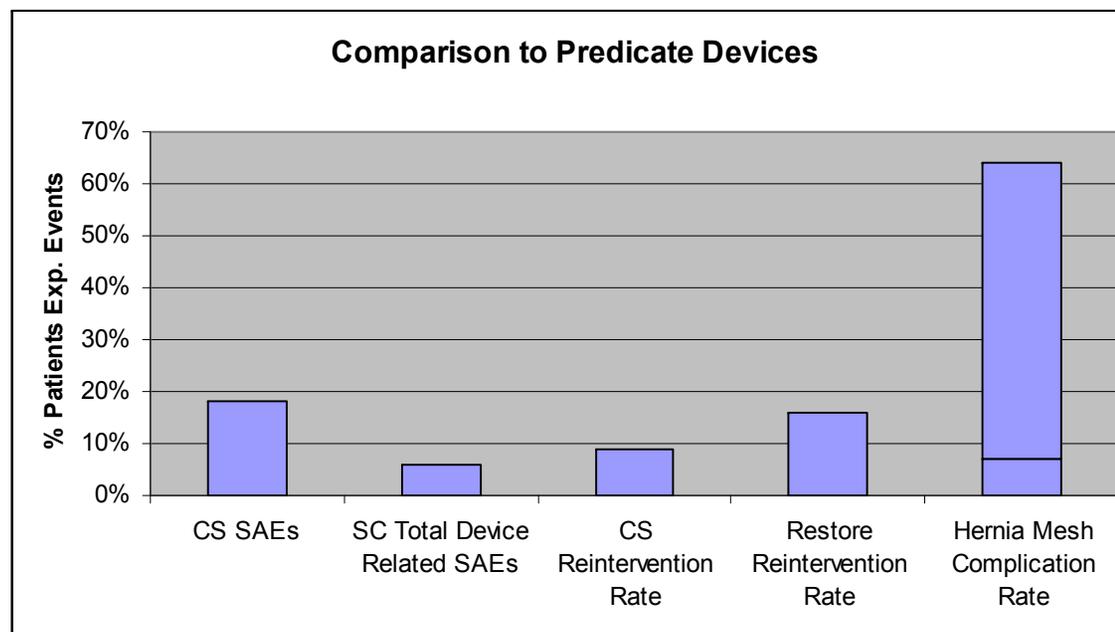
Dr. William Montgomery

Evaluation of SAEs

- Extensive safety information was collected in the IDE study for 162 CS patients followed for a mean of 4.9 years
- **Adverse Event (AE)** is broadly defined in protocol as any event that is not of benefit to the patient
 - *Includes every report of pain, swelling, etc., regardless of whether anticipated*
 - *Too broad to be compared to Complications in literature or databases*
- **Serious AE (SAE)** is defined as an AE which is fatal, life-threatening, permanently disabling, unexpected, or results in hospitalization
 - *Includes pain, swelling, parasthesia at a time point where it would not be expected or of a degree that is greater than would be expected*
 - *Comparable comparison to complications*
- SAEs were evaluated as a basis of comparison to predicate meshes
 - *Sources: literature, predicate product labeling, and FDA MDR/MAUDE databases*
- Safety data collected under the IDE included all SAEs, not only those related to the operative knee

Comparison to Predicates

- The types and incidence of SAEs and SDAEs occurring in the CS group are comparable to those occurring with predicate meshes
 - 18% of the CS patients had SAEs and 6% of the CS patients had Serious Device related AEs (SDAEs)
 - Heniford reported in 2003 complication rates for hernia repair ranging from 7% to 57%
 - Reintervention rate (which is a subset of SAEs) for the Restore device in the shoulder has been reported in the literature as 16%; compared to 8.8% for the CS device



Comparison with Partial Meniscectomy

- Results from the CS study showed no statistically significant difference in the rate of SAEs between the CS and PM groups, even though the CS patients experienced an additional relook surgery and biopsy at 12 months post-placement
 - No statistical difference was shown on either a per-patient basis or per-event basis, either cumulatively or at any time point through mean 4.9 years (max, 7 years)
 - This is an excellent indication of safety – no other mesh has been compared in such a manner to surgery without mesh
- JBJS publication of CS study reported 7.5% of CS patients and 7.3% of the PM control patients had an operative knee related SAE that required some form of treatment

Safety of CS Device Relook: Tissue Attachment

- At relook procedure, it was noted that 16% of patients (22) reported the was CS not firmly attached to meniscus
- This did not mean that the implant was loose, rather that it may not have been firmly attached along the entire interface
- Of these 22 patients:
 - 17 patients showed an average of 20% tissue gain with a mean total tissue of 64%
 - 3 patients showed no meniscal growth
 - 2 were explant cases
- The lack of firm attachment to the entire rim does not translate into failure of the device, or failure of the device to provide increased tissue within the defect.
- Literature on other mesh devices point out that areas of the mesh that are not in direct apposition to the host tissue will resorb without providing an adequate interface for integration and tissue growth (e.g., shoulder, hernia)

Additional Results from CS Study

- During relooks, there were no observations of damage to the articular surfaces that appeared to be the result of the device.
- Probing of tissue at relooks showed the tissue to be pliable and similar to native meniscus.
- Histological examination showed no evidence of a negative tissue reaction to the implant material, with tissue developing into fibrochondrocytic (meniscal-like) tissue.
- Results of immunology study showed no evidence of clinically significant humoral immune-mediated response to the CS.

Results of CS Feasibility Study

- Safety of CS assessed in a feasibility study: 8 patients with 5.8 year follow-up
 - No unanticipated adverse events
 - No significant complications
 - Relooks showed no damage to articular surfaces related to the use of CS
 - Radiologic assessments at pre-op, 1 and 2 years showed no significant progression of Fairbanks changes, and no noteworthy changes in joint space or axial alignment

Experience with OUS Marketing

- Marketing experience outside the US indicates no CS safety issues:
 - More than 2000 CS devices implanted;
 - Complaint rate is 0.31%; no complaints indicate a significant safety issue.
- Publications of European experience indicate no complications associated with the use of the device.

Conclusions

- Clinical data with up to 7 years follow-up demonstrate long-term safety of the CS for its proposed intended use
 - AEs were not unexpected and were consistent with those associated with predicate surgical meshes
 - Data from 141 relook procedures and 136 biopsies show the CS device provided a scaffold for meniscus-like matrix production by the host, with no damage to the joint or adjacent articular surfaces caused by the CS
 - Even compared to PM (which does not involve a mesh, does not treat the meniscus loss and did not require a relook surgery and biopsy) there was no significant difference in SAEs at any time point
- Safety data provide reasonable assurance that the CS device is as safe as legally marketed surgical mesh predicates,
 - No new types of safety or effectiveness questions raised when compared to predicates with the same intended use of soft tissue reinforcement and providing a scaffold for replacement by the patient's own tissue.



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SHOULDER VS. MENISCUS

Dr. William Montgomery

Use of Mesh in the Shoulder

- Restore Surgical Mesh shares the same intended use as all meshes – to reinforce soft tissue or bone.
- Specific Indication:
For use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a resorbable scaffold that initially has sufficient strength to assist with soft tissue repair, but then is replaced by the patient's own tissue. In addition, the implant is intended for use in the specific application of reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

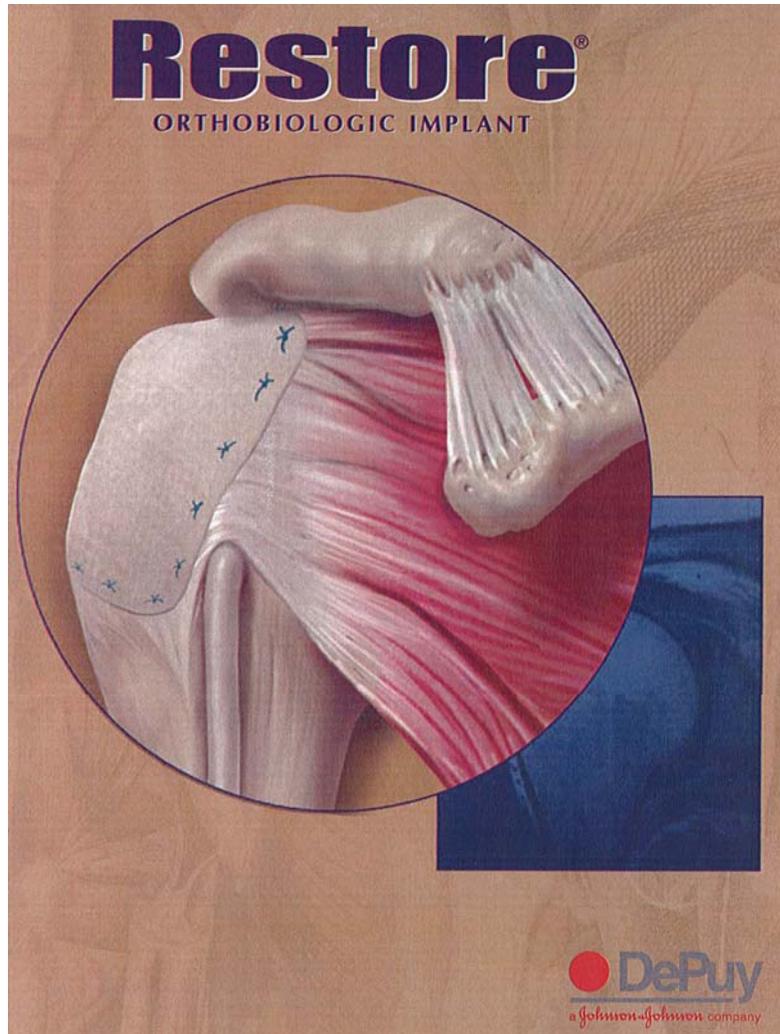
Similarities: Use of Mesh in the Shoulder and Meniscus

- For purposes of substantial equivalence, there are a number of similarities between the shoulder and the knee.
- Shoulder joint is not weight-bearing; however, the primary force on the rotator cuff is tensile.
- Primary force on the meniscus is also tensile.
- Tensile force in the shoulder is higher (as much as an order of magnitude higher than meniscus).
- Shoulder also sees compressive forces – impingement of rotator cuff against the acromion.

Similarities: Use of Mesh in the Shoulder and Meniscus

- Restore device *in the shoulder*:
 - Does not replace the rotator cuff
 - Does not provide the full mechanical strength of the repair – sutures or anchors do this
- CS device *in meniscus*:
 - Does not replace the meniscus
 - Does not provide the full mechanical strength of the repair - sutures, meniscus rim and horns do this

Use of Mesh in the Shoulder (cont.)



Restore is placed over a large area of the rotator cuff – not only the suture line

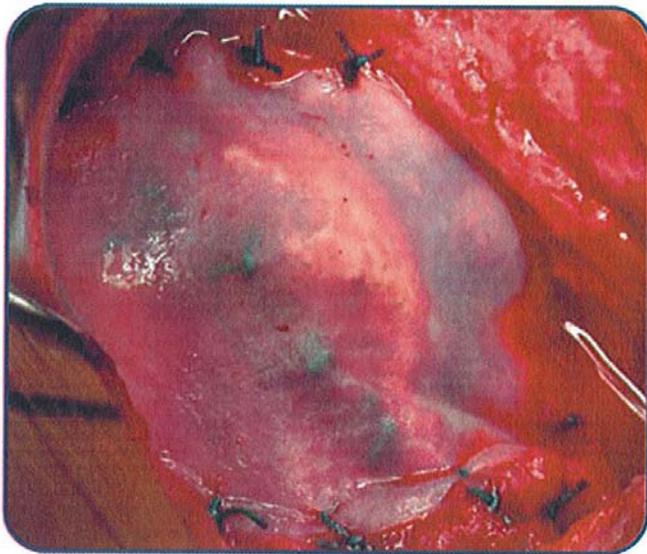
Unlike Restore, meshes like the Bioblanket are specifically labeled for “...suture line reinforcement...”

Use of Mesh in the Shoulder (cont.)

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Inspection and Classification

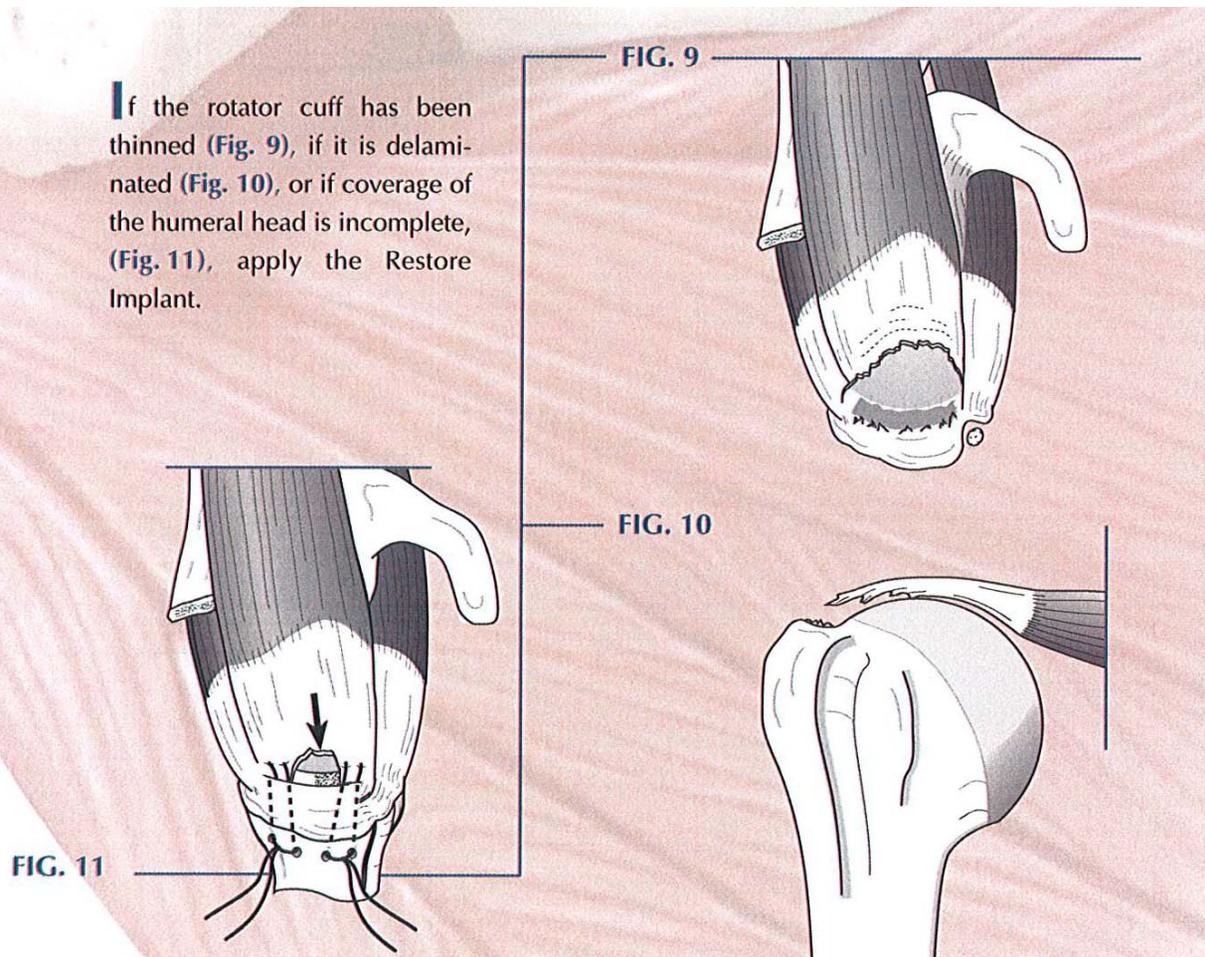
After the completion of a preferred exposure technique, perform a thorough, systematic inspection of the rotator cuff. If the tendon appears healthy and robust (Fig. 1), the Restore® Implant is not necessary. If the tendon is thin, delaminated or frayed (Fig. 2), or if it is a revision case, use of the Restore Implant should be considered. If there is a massive, chronic, retracted tear that cannot be mobilized back to bone or where the muscle tissue has undergone substantial fatty degeneration, the Restore Implant should not be used (Fig. 3).



Surgical technique indicates Restore should be used if tendon is thin, delaminated or frayed. Intent is to allow tissue growth into the deficient areas - not only to reinforce the suture line. Therefore, adding mechanical strength is inherent in its use as a surgical mesh in this procedure.

Use of Mesh in the Shoulder (cont.)

If the rotator cuff has been thinned (Fig. 9), if it is delaminated (Fig. 10), or if coverage of the humeral head is incomplete, (Fig. 11), apply the Restore Implant.



Restore implant is also labeled to fill gaps where the coverage of the humeral head is incomplete.

Surgical Mesh Reinforces Soft Tissue

- FDA has indicated that the Restore mesh is not used to repair the rotator cuff:
 - Yet, the labeling and use of the device show the intention to provide a scaffold for tissue growth to reinforce the deficient tissue and aid in repair.
- FDA has indicated that the Restore mesh does not add mechanical strength:
 - Purpose of the resorbable mesh in shoulder and knee is to add tissue volume that reinforces the deficient tissue and adds mechanical strength.



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SUMMARY

Conclusion

- Bench testing and animal studies show the CS:
 - Functions to reinforce the meniscus following partial meniscectomy; and
 - Provides a resorbable scaffold that is replaced by meniscus-like fibrochondrocytic tissue.
- Clinical data from single center feasibility study and multi-center trial show the CS is safe and effective when used as a mesh in the meniscus.
- Clinical data show the CS device is as safe and effective as other legally marketed devices.