

COLLAGEN MENISCUS IMPLANTS (CMI)



**MULTICENTER CLINICAL TRIALS:
MARCH 2002 UPDATE**

OUR GOALS

- Regenerate/Regrow New Meniscus-Like Tissue
- Prevent DJD
- Enhance Joint Stability
- Provide Pain Relief

CRITERIA FOR IMPLANT DESIGN

- Resorbable
- Non-Immunogenic
- Surgically Implantable
- Fits All Joints

COLLAGEN MENISCUS IMPLANT

BOVINE ACHILLES TENDON

- **Trimmed, Minced, Washed**
- **Purified: Salt, Acid, Enzymes**
- **Filtered, Washed, Freeze-Dried**
- **Molded and Crosslinked**
- **Lyophilized**



UNITED STATES

CMI

MULTICENTER

CLINICAL

TRIALS

U.S. MULTICENTER CLINICAL TRIAL

- **Prospective and Randomized**
- **Two Study Arms**
 - **No prior involved meniscus surgery**
 - **1, 2 or 3 prior involved meniscus surgeries**
- **50% Receive CMI/50% Controls**

INCLUSION CRITERIA

- **Partial meniscus loss with intact rim**
- **Medial side only**
- **Age 18 to 60 years**
- **No inflammatory or systemic disease**
- **OK in conjunction with ACL stabilizing procedure**
- **Intact chondral surface**

EXCLUSION CRITERIA

- Total meniscus loss or unstable segmental rim defect
- Grade IV DJD
- More than 3 previous surgeries on involved meniscus
- PCL insufficiency or unstabilized ACL deficiency

UNITED STATES MULTICENTER TRIALS

- **Frequent Clinical Followups**
- **Blood Samples to Check for Immune Response**
- **Radiographs at 1 and 2 Years**
- **Re-Look and Biopsy of All CMI Patients (Not Controls)**

CLINICAL OUTCOME MEASUREMENTS

- Pain
- Lysholm
- Self-Assessment (Per IKDC)

CURRENT ENROLLMENT

Protocol 9601

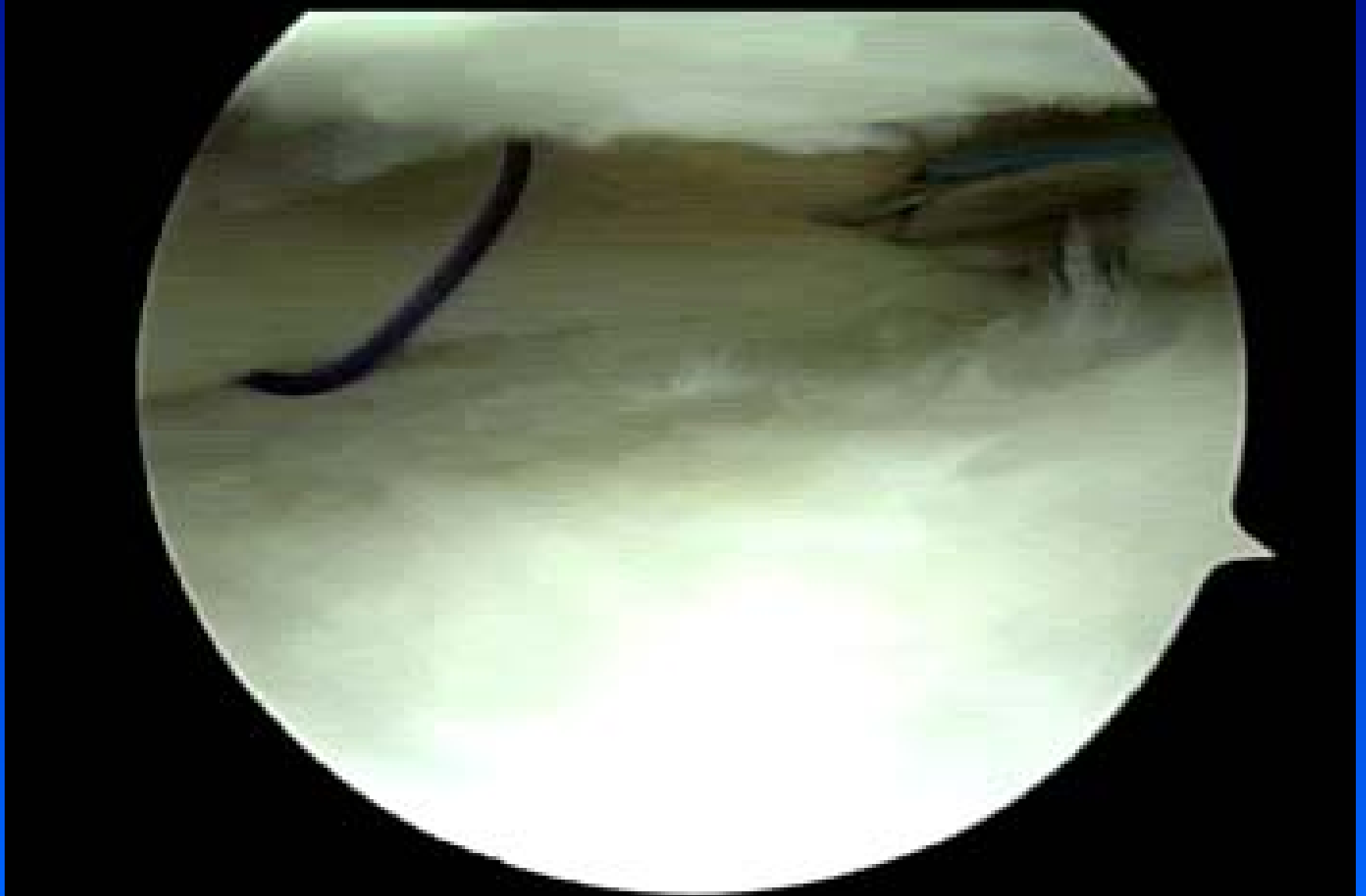
	Total	CMI	Control
Theoretical	144	72	72
Enrolled	144	72	72

Protocol 9602

Theoretical	144	72	72
Enrolled	130	67	63

CMI UPDATE

SUTURE TECHNIQUE



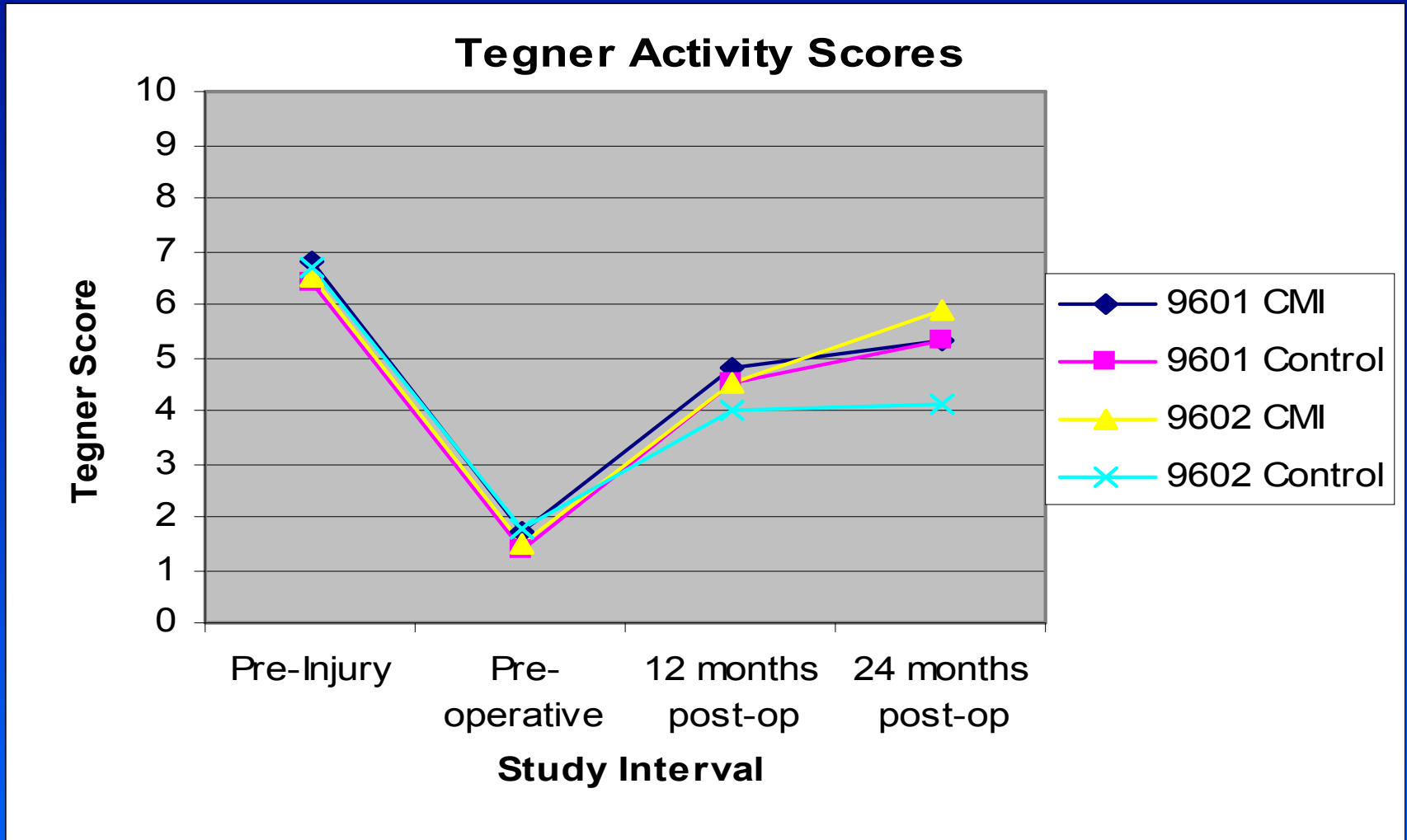
1-YEAR S/P CMI RELOOK



CLINICAL OUTCOMES

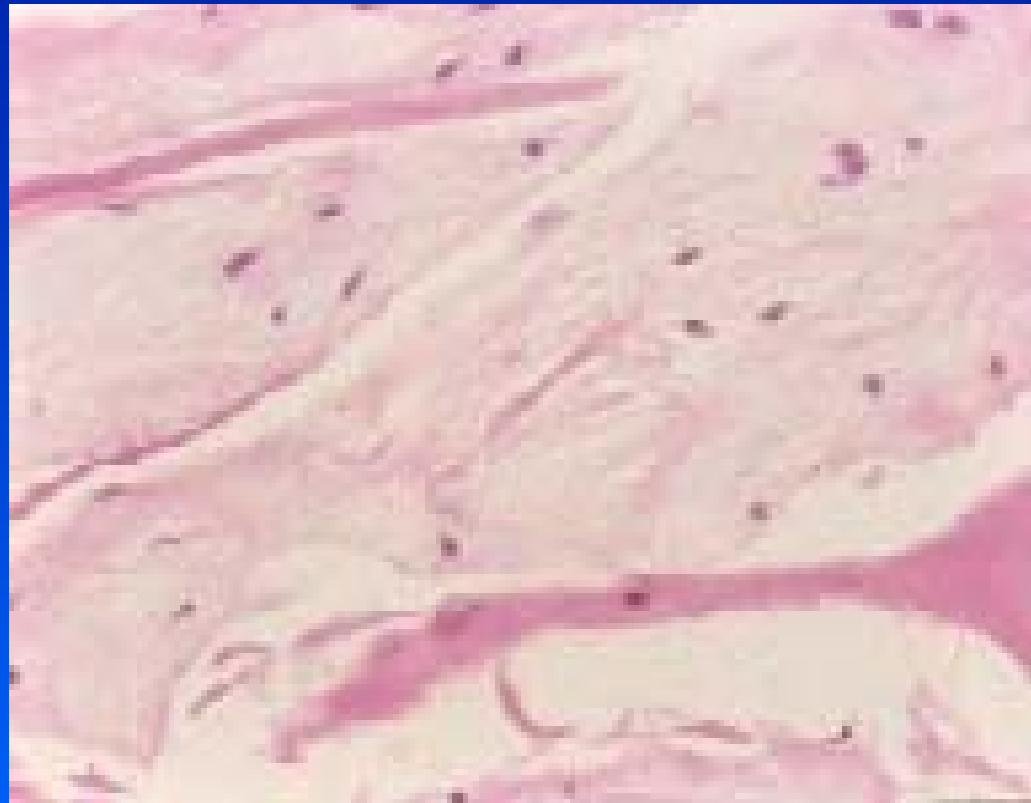
- **Chronic Patients Have More New Tissue Than Acute Patients**
 - Closer to the blood supply?
 - More compliant with rehab?
- **CMI Patients Better Than Controls at 1 and 2 Years for Pain and Self-Assessment**
- **No Difference for Lysholm Scores**

CLINICAL IMPROVEMENT



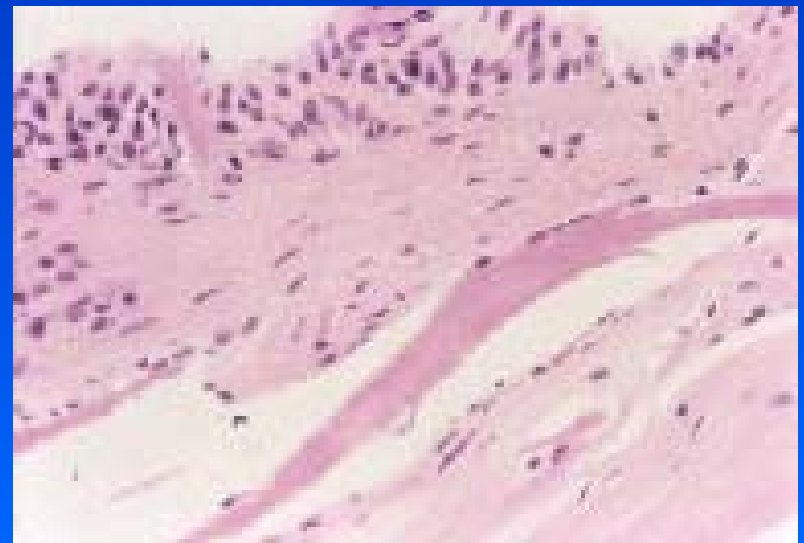
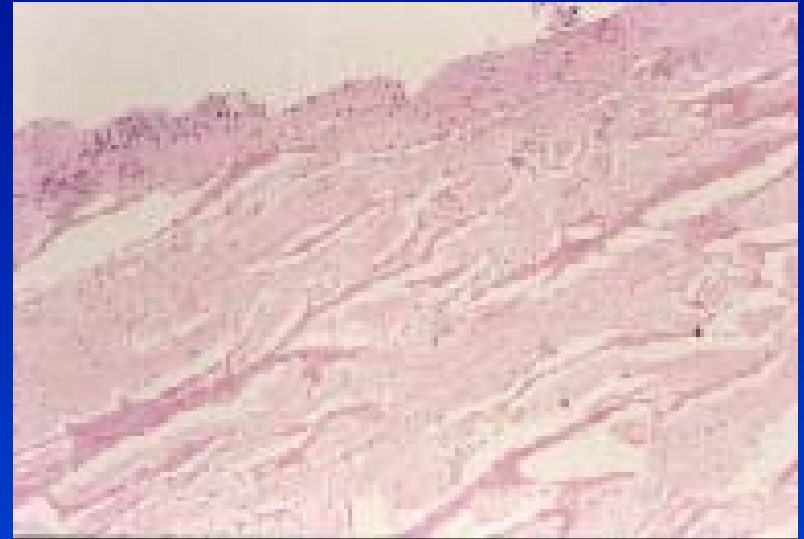
25 RECENT CMI BIOPSIES

- 23 (92%) = Moderate to Extensive Filling
- 13 (52%) Had Dense FCT
- 20 (80%) Had Fibrochondral Tissue
- Some Dense, Meniscus-Like Tissue
- Maturation Process Ongoing



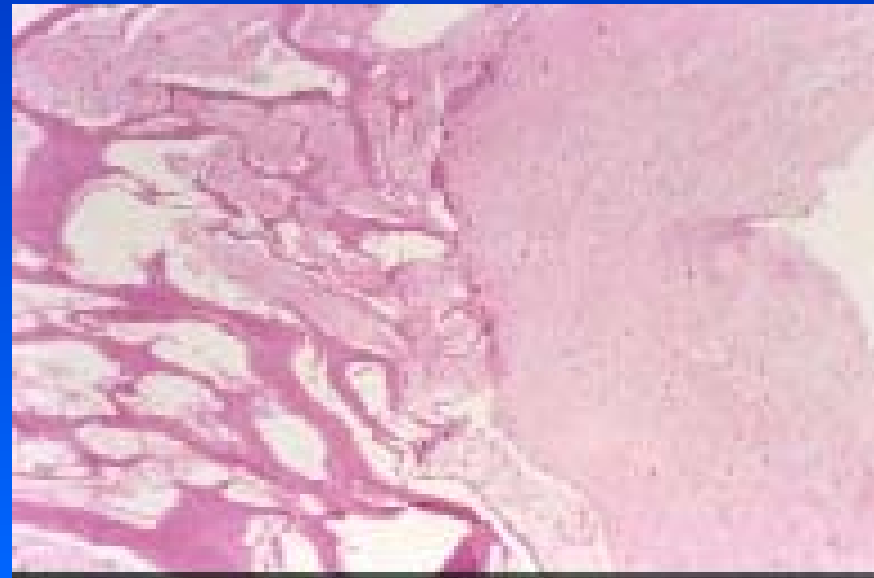
SYNOVIAL TISSUE

- 16 (64%) Contained Synovium
- Synoviocytes May Be Cell Source to Populate CMI
- Synoviocytes Become Fibroblastic (Spindle)
- Produce FCT Initially ⇒ Matures to Fibrochondral Tissue



HOST-CMI INTERFACE

- **Extremely Difficult w/ Needle Bx**
- **One In This Group**
- **Excellent Tissue Integration**



CORRECT TECHNIQUE

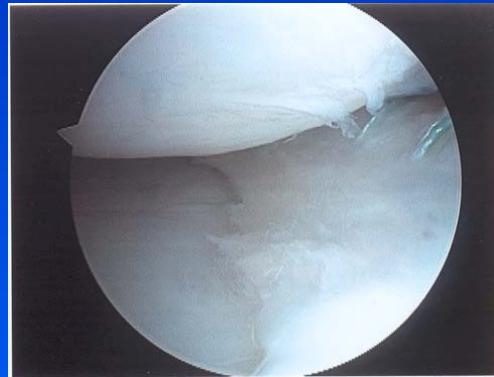
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Re-look



Well sized, well sutured, excellent regrowth

CONCLUSIONS - CMI

- **Implantable**
- **Biocompatible**
- **Bioresorbable**
- **Supports New Tissue
Ingrowth/Regeneration**

CONCLUSIONS - CMI

- **New Tissue Appears Functional**
- **No Serious Adverse Effects**
- **Safe Over At Least 8 Years**
- **International Multicenter Trials Continue**
- **CE Mark in Europe – FEB 2000**

THANK YOU!



CMI UPDATE