What Is a Research Study?

A research study or clinical trial is a scientific study that evaluates the safety and effectiveness of investigational drugs or devices. The Food and Drug Administration (FDA) often requires the satisfactory completion of research studies before it will consider an investigational product for approval and public use.

Research Study Tips

- Read all of the information that's provided to you carefully
- Ask questions about the procedures and associated risks
- Understand your responsibilities as a study participant
- Communicate openly with the study staff and the physician

CAIS™

Cartilage Autograft Implantation System

08-CAIS-05-CPB-10.10.V1

CAIS™

Cartilage Autograft Implantation System

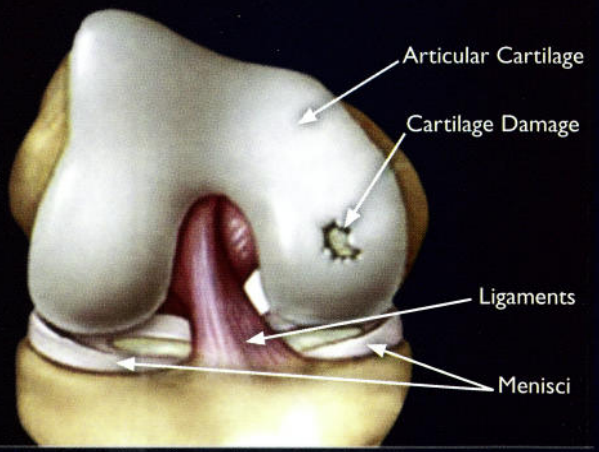
Do you have ***knee pain*** that's causing you ***difficulty*** or ***limiting your activities?***

Understanding Knee Cartilage and Pain

Cartilage is a tough, flexible tissue found in many areas of the body, including your knees. Its main function is to serve as a cushion for your bones and joints. Excessive stress on knee cartilage may cause it to become thin and worn down. Knee injuries can also result in cartilage damage.

When cartilage in the knee is damaged, symptoms may include: knee pain, swelling, tenderness, clicking, popping or grinding in the knee, and limited motion of the knee joint.

Knee Joint Anatomy



Knee Pain Research Study Opportunity

Physicians in your area are conducting a research study evaluating an investigational surgical treatment intended to repair damaged knee cartilage and alleviate knee pain.

Eligible participants must be between the ages of 18 and 55, and have knee pain caused by knee cartilage damage.

Qualified participants will receive medical care, including an MRI, and knee surgery. You may also receive compensation for time and travel.

To learn more, call:

(732) 545-0400
University Orthopaedics Group, LLC
215 Easton Ave.
New Brunswick, NJ 08901

Or visit http://www.KneePainStudy.com

Study Purpose and Treatments

This study will evaluate the safety and effectiveness of the Cartilage Autograft Implantation System or CAIS™, which is a surgical treatment for cartilage damage in the knee. CAIS will be compared to a standard surgical treatment called microfracture.

During the CAIS procedure, surgeons remove a sample of healthy cartilage from a non-weight or low-weight bearing area of the patient's knee. The tissue is broken up and combined with a unique absorbable material on which cells grow, called a scaffold, which is then implanted at the site of cartilage damage. CAIS can be applied in one surgical procedure.

Microfracture is a standard surgical procedure used to treat damaged cartilage in the knee. Using arthroscopic instruments, surgeons clean up the damaged area and make small holes in the underlying bone with the intention of stimulating new cartilage growth.

The study staff will address any questions you have related to this study.

CAIS is an investigational device limited by federal and local regulations to investigational use only.

CAIS™
Cartilage Autograft Implantation System

08-CAIS-05 Knee Study Fact Sheet

Welcome to this research study. You have been invited to participate in this study because your doctor has determined that your knee pain may be the result of damage to the cartilage in your knee, and that you are a candidate for arthroscopic surgery.

Study Purpose

This study will evaluate the safety and effectiveness of the CAIS™ Cartilage Autograft Implantation System as a surgical treatment of cartilage lesion(s) in the knee compared to a standard surgical treatment called microfracture. CAIS is a kit of devices that allows the surgeon to prepare healthy cartilage tissue taken from a non-weight bearing or low-weight bearing area of your knee and deliver it to the damaged site with the intention of regenerating (repairing) the cartilage in a single operation.

Study Groups

- Approximately 300 subjects will be assigned by chance to one of two groups to receive either CAIS (the study treatment) or microfracture (the control treatment).
- Subjects with larger cartilage defects may be entered into a group that will automatically receive CAIS.
- Since the size of the defect will not be confirmed until the surgery, you will not know which treatment you will receive before your surgery.
- The microfracture procedure is a standard method for treatment of cartilage damage in which the surgeon cleans the site of your cartilage damage and then makes several small holes in the underlying bone with the intention of stimulating new cartilage growth.
- During the CAIS study procedure, surgeons remove a sample of healthy cartilage from a non-weight or low-weight bearing area of the knee. The tissue is broken up and combined with a unique absorbable material on which cells grow, called a "scaffold", which is then implanted at the site of cartilage damage during the same surgical procedure.
- Participants will receive medical care related to their knee surgery, including an MRI. You may also receive compensation for time and travel.

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CAIS™

Cartilage Autograft Implantation System

Length of Study

- The doctor's office will monitor your progress for up to 4 years and your overall well-being will be assessed throughout your participation
- Study visits include 1 visit for prior to surgery, 1 visit for surgery, and a least 11 visits to the clinic to follow-up on progress

Potential Risks of Study Treatment

- Possible risks associated with your participation in this study will be explained to you by your study doctor and/or staff, and are outlined in the Consent Form
- Clinical staff is available to answer your questions, discuss any health changes, or address any other concerns that you may have during the study

Participation details

- You must meet all appropriate eligibility criteria and sign an Informed Consent Form
- During the study you must follow the standardized rehabilitation program for your group
- In addition, while in the study you must:
  - give correct and accurate information about your medical history and current medical condition
  - tell the study doctor about any health problems you have during the study
  - tell the study doctor about any new medicine or drug you take during the study
  - complete the pain rating scale as instructed
  - come to all doctor appointments
  - not be pregnant nor become pregnant until six months after your surgery
  - not be breastfeeding
- Participation is voluntary; you may remove yourself from the study at any time
- Again, the clinical staff is available to answer your questions, discuss any health changes, or address any other concerns that you may have during the study

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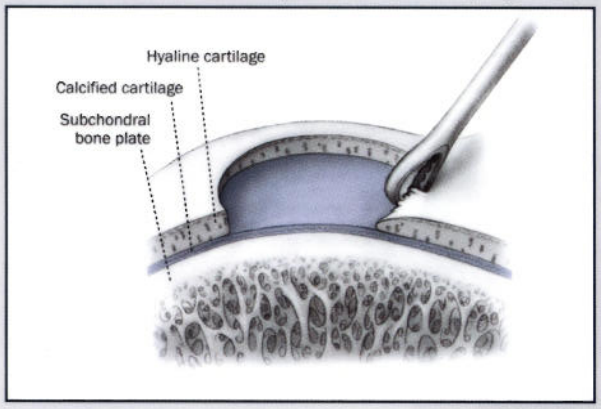
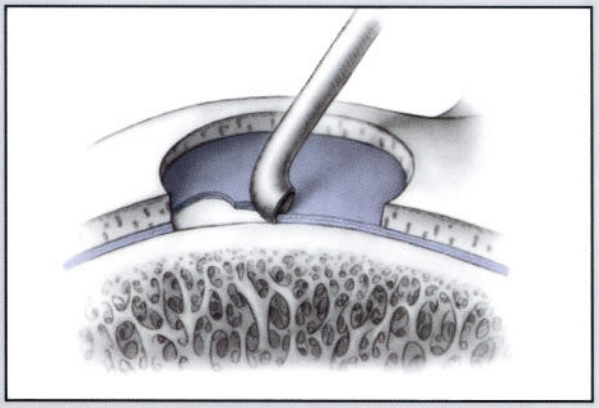
CAIS™
Cartilage Autograft Implantation System

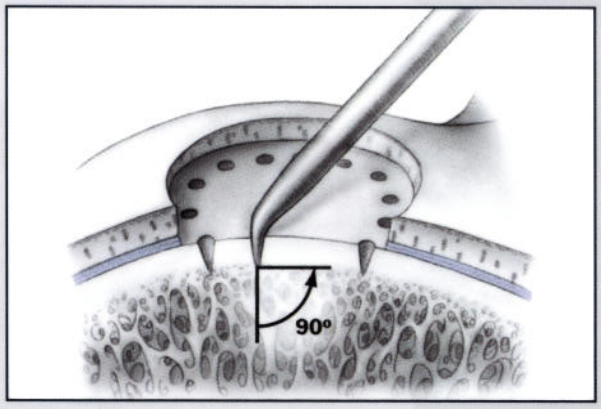
Microfracture Technique*

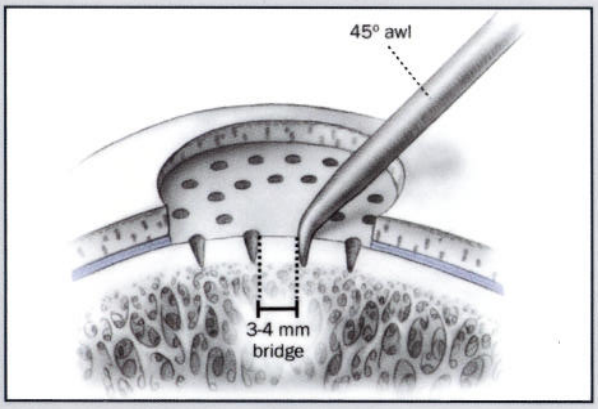
The cartilage defect is cleaned, removing unhealthy cartilage and creating stable edges; additional tissue is removed to expose the underlying bone



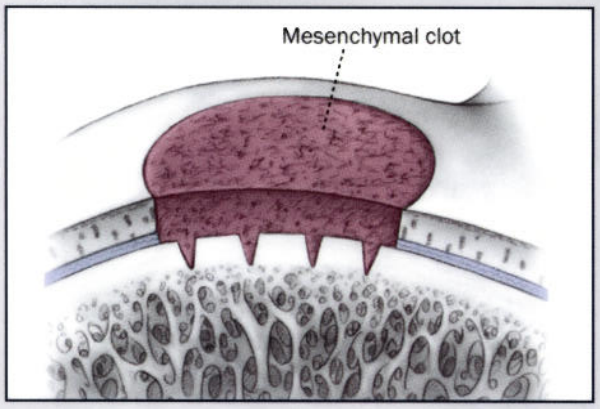


A small pick is used to create evenly-spaced holes in the bone, which allow blood and cells from the underlying bone to go into the cartilage defect





A blood clot is formed, which contains cells to help grow new tissue



*Mithoefer et al. *JBJS Am*. 2006. Microfracture technique images used with permission.

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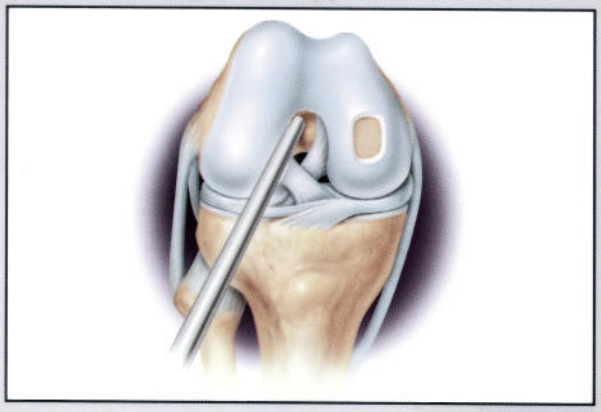
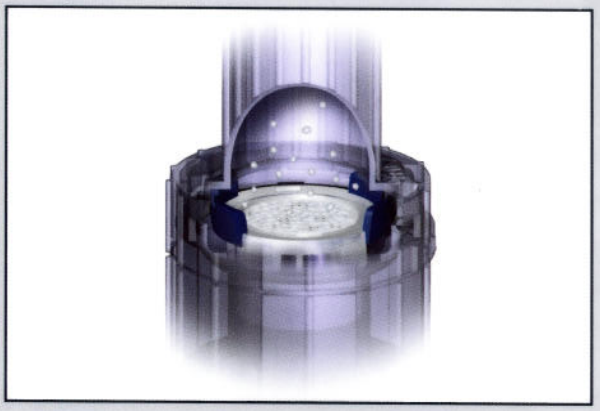
Cartilage Autograft Implantation System

CAIS Technique

A small sample of cartilage is harvested from a low or non-weight bearing part of the knee

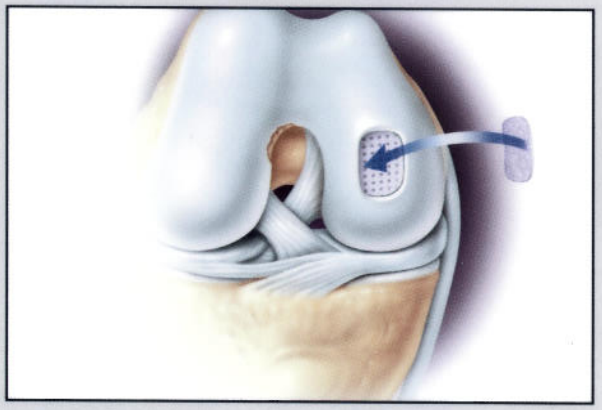


The tissue is minced or broken up into small pieces and spread evenly over a bioresorbable scaffold

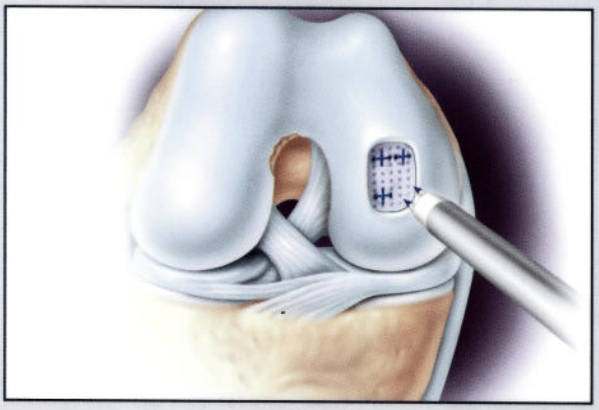


Fibrin sealant is applied to secure the cartilage pieces on the scaffold

The implant is trimmed to match the size of the cartilage defect



Absorbable staples are used to secure the implant in the defect



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