Synthetic Cartilage Implant for 1st MTP Osteoarthritis: The Difference is DATA™

This educational activity is supported by an educational grant from Cartiva, Inc.
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Dr. Chang has disclosed no relevant financial relationships with any commercial interests

Dr. Blume has disclosed no relevant financial relationships with any commercial interests
Learning Objectives

1) Describe the science and clinical evidence behind motion-preserving treatments and their relevance in the armamentarium of options for great toe arthritis

2) Review recently published clinical study results on the use of a synthetic cartilage implant for the treatment of moderate to severe hallux rigidus

3) Explore clinical case studies of a synthetic cartilage hemiarthroplasty implant highlighting surgical pearls and pitfalls of this procedure
Hallux Rigidus

Symptoms

- Pain
- Stiffness
- Decreased motion
- Altered lateral loading
- Activity modification
- Shoe fit limitations

Hallux Rigidus

Most common arthritic condition of the foot

- Affects 1:40 over the age of 50
- 2.2 million in US
- 50%-80% bilateral
- 60%-70% women

Moderate to Severe Hallux Rigidus
Coughlin Scale for Hallux Rigidus

GRADE 2
- Moderate to severe pain & stiffness that may be constant
- Pain occurs just before maximum motion
- Dorsiflexion: 10°-30° and/or 50%-75% loss

GRADE 3
- Nearly constant pain & substantial stiffness at extreme ROM, but not at midrange
- Dorsiflexion: ≤10° and/or 75%-100% loss of plantarflexion (≤10°)

GRADE 4
- Same as Grade 3 w/ definite pain at midrange passive ROM
- Dorsiflexion: Same as Grade 3

Surgical Treatment Options

- **Joint Sparing**
  - Cheilectomy
  - Osteotomy

- **Joint Destructive**
  - Arthroplasty
    - Resection
    - Interpositional
    - Distraction
    - Resurfacing
  - Arthrodesis
Surgical Treatment Options

What Does the PATIENT Want?

Which Treatment Is BEST?

EVIDENCE!

• Joint Sparing
  – Cheilectomy
  – Osteotomy

• Joint Destructive
  – Arthroplasty
    • Resection
    • Interpositional
    • Distraction
    • Resurfacing
  – Arthrodesis
Evidence Based Medicine (EBM)

- The conscientious use of current best evidence from clinical care research in making health care decisions
- Provides patients with best available treatment options
- Avoid bias (systematic deviation from truth)
- Avoid decision making by
  - Industry marketing
  - Insurance companies
  - Other interested 3rd parties

How to Analyze the Evidence?

“Introducing Levels of Evidence to the Journal”
Wright JG, Swiontkowski MF, Heckman JD

“Grades of Recommendation”
Wright JG, Einhorn TA, Heckman JD

Step 1: Assess the Quality of Each Paper

“Introducing Levels of Evidence to the Journal”

Wright JG, Swiontkowski MF, Heckman JD

Step 2: Provide Grade of Recommendation for Treatment

“Grades of Recommendation”
Wright JG, Einhorn TA, Heckman JD

## Evidence-based Analysis of the Efficacy for Operative Treatment of Hallux Rigidus

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Mostly Level IV & V Studies
Evidence-based Analysis of the Efficacy for Operative Treatment of Hallux Rigidus

No Grade A Recommendation

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Grade B for Arthrodesis
Fusion

- Reliable pain relief

- Limitations
  - Sacrifices motion
  - Alters foot function
  - Shoe fit problems
  - Patients want to avoid fusion procedures
  - Potential for nonunion/malunion/prominent hardware
  - Women less satisfied due to shoe wear limitations

Unmet Clinical Need for Motion
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Grade C for Arthroplasty Procedure
Arthroplasty and Hemiarthroplasty Procedures

- Intended to preserve motion
- Limitations
  - Excessive bone resection
  - Transfer metatarsalgia
  - Wear debris/bone loss
  - Difficult to revise

Need Higher Quality Evidence-Based Research

Need for Randomized Controlled Trials

“Introducing Levels of Evidence to the Journal”
Wright JG, Swiontkowski MF, Heckman JD

Level I Evidence

- Randomized, controlled trial
- Multicenter across two continents and 49 surgeons
- Best study to date on a surgical treatment for hallux rigidus
- Demonstrated safety and efficacy of Cartiva hemiarthroplasty as compared to fusion
Device Description

- Single-construct implant
- Composed of polyvinyl alcohol (40%) and saline (60%)
- Designed to mimic cartilage
  - Elastic and compressible
  - Low friction
- Passed extensive preclinical testing
- Supported by Level 1 clinical evidence
- Avoids failure modes of silicone

# Material Extensively Tested

## BIOCOMPATIBILITY OF CARTIVA SCI DEVICE

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<td>IC Injection</td>
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<td>Acute Systemic Toxicity</td>
<td>Systemic Injection</td>
<td>Negative</td>
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<tr>
<td>Subchronic Toxicity</td>
<td>Femoral Condyle Implantation</td>
<td>Nontoxic</td>
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<tr>
<td>Genotoxicity</td>
<td>Ames Reverse Mutation</td>
<td>Nonmutagenic</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Chromosomal Aberration Assay</td>
<td>Nonclastogenic</td>
</tr>
<tr>
<td>Implantation</td>
<td>Bone Implantation Femoral Condyle</td>
<td>Negative/no reaction</td>
</tr>
<tr>
<td>Pyrogenicity</td>
<td>Rabbit Pyrogen Test</td>
<td>Nonpyrogenic</td>
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## BIOCOMPATIBILITY OF CARTIVA SCI INSTRUMENTATION

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## ANIMAL SAFETY STUDIES

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<tr>
<td>Animal Study 1 Year Goat</td>
<td>Cartiva device implanted in load-bearing region of medial femoral condyle in stifles of 8 mature goats; control defects in 4 goats At one year, knees evaluated via: - High field strength MR imaging system for morphology and quantitative T2 and T1-rho parameters - Histological processing - Biomechanical testing</td>
<td>- No evidence of local or systemic toxicity - No inflammatory reaction around implant or osteolytic bone loss - Nonsignificant change to opposing tibial surface - No difference in presence of subarticular cysts with control - No device fragmentation or dislodgement - No particulate migration</td>
</tr>
<tr>
<td>Particulate Implant Study 6 month rabbit</td>
<td>- 5 million cycle wear debris quantified and characterized - Particulate replicated and injected via bolus in a quantity 9x - Test injections and control (saline) administered to 16 animals. At 3 and 6 months, histology and pathology per ISO standards</td>
<td>- No complications on injection - No test article-related adverse changes - No significant findings on clinical observation, gross pathology, histomorphometry, or histopathology of localized tissue - Systemic issues showed no microscopic changes related to the treatment - No wear debris or foreign body giant cells with injected material</td>
</tr>
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Data on file at Cartiva, Inc.
### FUNCTIONAL TESTING

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<tr>
<td>Fatigue Testing</td>
<td>Cycles: 5 million</td>
<td>- Mechanical durability demonstrated after 5 million continuous cycles at peak load of 4 MPa</td>
</tr>
<tr>
<td></td>
<td>Test Surface: Stainless Steel</td>
<td>- Significant mass and height recovery upon unloading</td>
</tr>
<tr>
<td></td>
<td>Axial Load: 4 MPa</td>
<td>- The Cartiva device demonstrated adequate strength to survive the repetitive, compressive loads that occur clinically in the 1st MTP.</td>
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### MATERIALS PROPERTIES

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| Unconfined Compression | Loading of unconfined devices to achieve 10%, 20%, 30% and 40% strain to measure deformation resistance of the matrix and determine compatibility of the device with surrounding native tissue. | Compressive Modulus: 3.05 ± 0.12 MPa, Articular Cartilage: 0.31 - 0.80 MPa  
                     |                                                                              | Equilibrium Elastic Compressive Modulus: 2.68 – 3.34 MPa, Articular Cartilage: 0.54 MPa |
| Confined Compression | Devices confined in compression fixture with 5%, 10%, 15%, 20%, and 25% strain applied to assess matrix stiffness at equilibrium (ie when load-induced fluid flow has ceased). | Higher polymer content and presence of physical cross links in Cartiva results in a mean aggregate modulus of 6.7±1.0 MPa where cartilage values range between 0.6 and 1.2 MPa. |
| Shear               | Devices seated between test blocks that are moved apart perpendicularly until failure or 5 mm displacement; thereby, providing a baseline understanding of the simple shear properties of the material. | Shear Moduli: CARTIVA 0.16 – 0.36 MPa, Articular Cartilage: 0.45 MPa (0.22 – 0.68 MPa)  
                     |                                                                              | Fatigued devices exhibited no change in shear properties and resistance to mechanically induced degradation properties. All devices exhibited full 100% lateral shear strain without tearing or showing shear fracture. |
| Creep               | 4 MPa loading in confined compression fixture to elucidate structural changes since equilibrium swelling properties are sensitive to the nature and stability of the hydrogel crosslinks | - Biphasic creep  
                     |                                                                              | - 4%-5% mass loss |
| S-N Analysis        | Devices loaded in a confined fixture to 8, 12, 18, and 24 MPa out to 5 million cycles | - No catastrophic failure  
                     |                                                                              | - Continuous 5 million compression cycles  
                     |                                                                              | - Extreme loads of 24 MPa (6x peak load)  
                     |                                                                              | - Even under significant stresses, no failures |

Data on file at Cartiva, Inc.
Cartiva Wear Testing Fixture

Cartilage specimen held in fixture (rotates 18 degrees) over Cartiva implant

Saline

Where fluid is drained and particulate collected

Holder for Cartiva implant; 2 MPa load applied
Empirical Test Laboratories

Negligible wear at 5 million cycles

- Average mass loss per device – 1.2%
- Average height loss per device – 2.1%
Indications

The Cartiva Synthetic Cartilage Implant is intended for use in the treatment of patients with degenerative or post-traumatic arthritis in the first metatarsophalangeal (MTP) joint (hallux rigidus/limitus)

- In the presence of good bone stock
- With or without mild hallux valgus (<20°)
Contraindications

- Cartiva should **not** be implanted in patients with the following conditions:
  - Active infection of the foot; active gout
  - Known allergy to polyvinyl alcohol
  - Inadequate bone stock due to significant bone loss, avascular necrosis, and/or large osteochondral cyst (> 1 cm) of the metatarsophalangeal joint
  - Diagnosis of active gout with tophi
  - Physical conditions that would tend to eliminate adequate implant support (eg, **insufficient quality or quantity of bone** resulting from cancer, congenital dislocation, or osteoporosis), systemic and metabolic disorders leading to progressive deterioration of bone (eg, cortisone therapies or immunosuppressive therapies), and/or tumors of the supporting bone structures
Before and after Cartiva Implant

Damaged cartilage is replaced with a new Cartiva bearing surface

Burns No Bridges

- 50% less bone removed, no bone shortening
- 14 patients in clinical trial easily converted to fusion
  - Results comparable to overall fusion arm at 24 months
  - Mean VAS Pain score of 9 (86.4% reduction)
  - Mean FAAM score of 88 (39 point improvement)

VAS = Visual Analogue Scale; FAAM = Foot and Ankle Ability Measure.
Cartiva surgery is 40% faster than the standard of care (fusion)

Clinical Study Design

- Prospective, randomized, non-inferiority study
- Fusion control
  - 2:1 randomization
- 202 patients treated
  - Grades 2, 3 and 4
- 12 sites; 29 surgeons
- Outcomes of pain, function and safety
- 24 month follow-up
- Level 1 clinical evidence

2-Year Median VAS Pain

Substantial reduction in pain with demonstrated durability at 2 years

MCID $\geq 30\%$

-93%

2-Year Median FAAM Sports Score

Substantial improvement in foot function

MCID ≥ 9

+168%

2-Year Median Range of Motion

Fusion has no motion

N = 130

+50%

Subsequent Surgical Interventions

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<th>Cartiva Safety (N=152)</th>
<th>Fusion mITT (N=50)</th>
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<tr>
<td>Removal</td>
<td>9.2% (14)</td>
<td>8% (4)</td>
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<tr>
<td>Reoperation</td>
<td>0.7% (1)</td>
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<tr>
<td>Revision</td>
<td>0.7% (1)</td>
<td>6% (3)</td>
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<td>Supplemental Fixation</td>
<td>0.7% (1)</td>
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<tr>
<td><strong>Overall</strong></td>
<td><strong>11.2% (17)</strong></td>
<td><strong>12% (6)</strong>*</td>
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- Low and comparable rate of subsequent surgeries
- No implant infection or inflammatory reactions, or mechanical failures
- No implant wear upon inspection of removed implants

*One fusion subject had 2 secondary surgeries for initial removal of screw at 6 weeks and the remaining hardware at 1 year*
Results

- 29 patients identified, with 27 available for follow-up
- Average follow-up 5.3 years
- 96.2% of implants were retained at follow-up
- 96% would undergo the procedure again
- Radiographs of 23 of 27 patients were reviewed
  - No changes in implant position
  - 2 patients with proximal phalanx cyst
  - 8 patients with osteophyte development
  - No correlation of X-ray findings with clinical outcomes

5-Year Median VAS Pain

Substantial reduction in pain with demonstrated durability at 5 years

5-Year Median FAAM Sports Score

Substantial improvement in foot function

+112%

5-Year Median Range of Motion

Conclusions

• Cartiva continues to function well at 5 years
• Patients are satisfied and report a high level of function
  – 96% of patients would have the procedure again
• Low revision rate comparable to standard of care
  – Straight forward revision if required; burns no bridges
• Implanted during short (35 min) simple surgical procedure
• Viable treatment option for 1st MTP osteoarthritis
Cartiva is implanted using dedicated instrumentation designed to provide the surgeon with an implant that is well-seated through a press-fit implantation

- Reusable instruments provided non-sterile; require sterilization prior to use
- Instrumentation validated for their intended function and use with a cannulated drill, and are specific to the size of the device (8 mm or 10 mm) being implanted

10 mm Metatarsal Drill Bit
10 mm Introducer
10 mm Placer
2 mm Guide Pin

Sterilization Tray with Instruments
Drill Geometry

The drill is designed with a stop to ensure the press-fit Cartiva SCI is ~1.5 mm proud relative to the surrounding cartilage.
Exposing the MTP Joint

- Expose the entire joint, using a small dorsal or straight medial incision
- Gain access to the central metatarsal head
- Ensure enough exposure to allow implantation perpendicular to the metatarsal head
Osteophyte Resection

- Perform initial resection of osteophytes from the proximal phalanx and/or metatarsal head
- Take care to ensure adequate dorsal bone stock is preserved for insertion and stability of implant
- Cartiva implant requires a minimum of 2 mm of surrounding good bone stock
- Final osteophyte resection may be done following implantation
Identifying the Target Implant Position and Location

- Using the concave end of the placer, ensuring it is centered in the medial/lateral plane, create a perpendicular angle to the metatarsal head to identify the target implantation site.
- Place can be relatively central but can be slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head.
- Cartiva requires a minimum of 2 mm of surrounding good bone stock.
Preparing the Guide Pin

- Insert the guide pin into drill and slide the placer over the guide pin.
- As noted above, the placer should be positioned relatively central but can be slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head.
Creating the Metatarsal Head Cavity

- Slide the cannulated drill bit over the guide pin

- Advance the drill until the post/stop is just flush with the surrounding metatarsal head surface

- Care should be taken to advance only to the drill stop using light pressure
Creating the Metatarsal Head Cavity

- Carefully, remove the drill bit and guide pin from the implant site.

- Flush out and remove all debris from metatarsal head defect, to allow the implant to be appropriately seated within the bone.
Preparing the Implant for Insertion

- Insert the implant into the introducer with the flat end of the implant facing down, and the “round” or “convex” portion of the implant facing up.
- Use the small, flat end of the placer to press the implant to the distal end of the introducer tube.
Implant Insertion

• Place the distal end of the introducer tube at the implant site, but not into the defect, perpendicular to the metatarsal head.
**Implant Insertion**

- Press down on the placer to press fit the implant into the metatarsal head defect.

- The implant will be clearly visible following implantation.

- Implant will sit slightly proud (~1.5 mm) in the metatarsal head following implantation.

- Perform joint capsule repair and closure.


