

Subject: CartiMax - Breakdown of Studies
Date: Monday, February 24, 2025 at 4:10:16 PM Central Standard Time
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Attachments: image001.png

Pre-Clinical Data | Viability Study

- The cartilage fibers were thawed, rinsed of the of the cryopreservation media and then assessed for cartilage viability through live/dead staining. Also assessed cell function and production of hyaline components.
- Demonstrated **an 86.6% cell viability**
- **Production of Hyaline Components:** Showed proof of collagen type II and proteoglycans, which are classic hyaline components found in articular cartilage.

Pre-Clinical Data | Cell Marker Characterization

- Focused on the cryopreserved viable cartilage fibers; the fibers were thawed and stained with antibodies for specific cell surface markers present on the chondrocytes.
- **Chondrocytes typically express CD44 and CD49e and not CD45**
- **Results: you can clearly see the presence of CD44 and CD49e, but no CD45.**

Pre-Clinical Data | Retention Model

- This study focuses on the **retention** and **implant integrity** of CartiMax in a defect under cyclical testing without the use of fibrin glue
- In a cadaver knee, a defect in the medical **femoral condyle** was filled with CartiMax and cycled **500 times** (flexion-extension)
- Then a **patella defect** was filled with CartiMax and cycled **100 times** before opening back up to evaluate.
- Both experiments show that **CartiMax is fully retained in chondral defects after extensive cyclic testing without fibrin glue.**

In Vivo | Animal Study

- Cartimax was implanted in chondral defects in goat knees. Defects were created in the trochlea sulcus and the medial femoral condyle
- Microfracture Vs. CartiMax: microfractures were created in the trochlea sulcus and CartiMax was implanted into the medial femoral condyle
- The goats were observed during the recovery at 12-, 24- and 52-weeks post-implantation;

osteocondral biopsies were then harvested and tested for proteoglycans, collagen type II, collagen type I and H&E.

- **Cell viability was measured at 94+3%**
- **There was evidence of proteoglycans and collagen type-II staining (critical components of hyaline cartilage)** observed by 12 weeks and sustained over time to 52 weeks
- The results of this study show that the addition of **CartiMax to cartilage defects, in comparison to microfracture procedures, induces chondrogenic activity** demonstrated through the positive staining for proteoglycans and collagen type II
- Supports that there is remodeling of the viable cartilage graft into hyaline cartilage that is also well-integrated with surrounding host tissue.

Talar Chondral Lesion Repair with CartiMax Dr. Reeves

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- Case study of a 53-year-old patient with a 2cm medial talar dome lesion and associated subchondral cyst
- AlloAid SubChon implant with CartiMax was used to treat both the subchondral and cartilage defect
- Achieved a stable and reliable repair without microfracture – 3 months post op patient had improved pain and function

Treatment of Chondral Lesions Using CartiMax in eight patients Dr. Neufeld MD

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- 8 patients with median age of 31 (17-48) underwent successful chondral lesion repair with CartiMax: 7 with lateral and 1 with medial **talar defects**. Average size of lesion was 1.62cm²
- With average follow up of 3.8 months, patients reported decreased pain scores, improved range of motion, and overall improved function.

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