

## Subchondroplasty for the Treatment of Post-Traumatic Bone Marrow Lesions of the Medial Femoral Condyle in a Pre-Clinical Canine Model

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### Summary:

The objective of this study was to assess the safety and efficacy of subchondroplasty for the treatment of bone marrow lesions of the femoral condyle in a canine model of post-traumatic osteoarthritis.

### Abstract:

**Objective:** Impaction injury to the femoral condyles is often a pre-cursor to post-traumatic osteoarthritis (PTOA). Appropriate treatment of the pain and dysfunction associated with bone marrow lesions (BML) in this setting is unknown. Subchondroplasty (SCP) involves the percutaneous injection of calcium phosphate into the region of the BML. The objective of this study was to assess the safety and efficacy of SCP for the treatment of BMLs of the femoral condyle in a canine PTOA model.

**Methods:** With ACUC approval, purpose-bred research hounds (n=12) underwent an arthroscopic-assisted impact injury (40N) to both medial femoral condyles (MFC) to result in focal articular cartilage damage with associated BML. Twelve weeks after impact injury, dogs were treated by injection (3 ml) of calcium phosphate SCP (AccuFill BSM, Zimmer) into one MFC and sham injection in the contralateral MFC using fluoroscopic and arthroscopic guidance. Dogs were evaluated over the following year for clinical function and kinetics, radiographic and MRI scoring and at 3, 6 and 12-month endpoints (n=4/time) by arthroscopic, gross, microCT, and histologic assessments. Data were compared for statistically significant ( $p < 0.05$ ) differences to pre-operative measures and between groups.

**Results:** Twelve weeks after impact and prior to treatment, all dogs had MFC BMLs and significantly ( $p < 0.01$ ) more lameness/less limb loading, greater pain and joint effusion, and decreased knee range of motion compared to pre-operative values, with no significant difference between limbs. Transient pain and lameness requiring extended oral analgesic treatment were noted for up to 3 months after SCP injection. At all time points after treatment, all dogs had radiographic evidence of mild osteoarthritis and MRI-evident BMLs of the MFC with associated clinical symptoms, with no significant differences between groups until 1 year after treatment. At the 1-year endpoint, SCP was associated with significantly ( $p < 0.05$ ) less pain, better knee range of motion, and better arthroscopic scores. BMLs were present in both groups based on one-year MRI, microCT, and histology with SCP-treated MFCs showing subjectively better trabecular bone architecture. SCP injectate was retained in all MFCs at one year and was well integrated with trabecular bone with no evidence of associated pathology. Both groups showed MRI, gross, and histologic evidence for medial compartment gonarthrosis at all time points with no significant differences noted between groups for these assessments.

**Conclusions:** In this pre-clinical canine model of PTOA, the treatment of BMLs of the medial femoral condyle with SCP was associated with superior clinical results and better trabecular bone architecture at the one year time point when compared with sham controls. Despite improvements in clinical outcomes and bony histology, there were no difference detected in the progression of medial compartment post-traumatic gonarthrosis between groups. Clinical

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trials are warranted to further validate these results and to determine the efficacy of SCP in human subjects.