Safety and Effectiveness of Coblation (Radio Frequency Plasma) for Knee Chondroplasty
A Multi-Center Prospective Randomized Controlled Clinical Study

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All disclosures for all faculty are documented in the Program

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Articular cartilage defects are commonly detected during arthroscopy when treating knee pathology such as a torn meniscus or damaged anterior cruciate ligament. 60% to 70% subjects having arthroscopic knee surgery who have concomitant chondral lesions\textsuperscript{1,2,3}

Traditional treatment: Mechanical debridement Control (MC)  
Other possible treatment: Latest Radiofrequency (RF)-based technology based on Plasma generation (Coblation\textsuperscript{TM})

The impact of RF-based chondroplasty compared to mechanical debridement over time has not been evaluated with magnetic resonance (MR) imaging

Hypothesis: Radiofrequency (RF) chondroplasty would be as safe as MC with no adverse events on MR imaging or patient reported outcomes

\textsuperscript{1}Figueroa D, Calvo R, Vaisman A, Carrasco MA, Moraga C, Delgado I. Knee chondral lesions: incidence and correlation between arthroscopic and magnetic resonance findings. Arthroscopy 2007; 23(3):312-315.  
STUDY DESIGN: Prospective, randomized clinical trial
9 enrolling sites in the US

SAMPLE SIZE:

57 subjects requiring arthroscopic treatment (*)

(*) Note: target sample size was higher but was not met due to slow study enrolment

INCLUSION/EXCLUSION CRITERIA:

- Included: single medial femoral chondral lesion (ICRS Grade 3A) + partial medial meniscectomy
- Excluded: multiple chondral lesions, ACL replacement patients, revision surgeries, higher grade (full-thickness) cartilage lesions

All subjects received an ICF and a verbal explanation from the Investigator (or designee) about the nature of the study, its purpose, procedures, expected duration and benefits, and risks of participation.
Available MRI imaging: Axial/Coronal/Sagittal PD FS, Coronal T1, Sagittal T2 FS, 3D sagittal T1 SPGR, and Sagittal T2 Mapping. Required 3 Tesla for MRI equipment

MR Time Points: PreOp, PostOp (10 days), 52 Weeks (1 year), 104 Weeks (2 years)

Imaging endpoints analyzed:
- % Lesion fill (PLF)
- Change in Percentage Lesion Fill (PLF)
- Quantitative and semi-quantitative scoring of knee morphology: MOAKS\(^1\), WORMS\(^2\), ICRS\(^3\)
- T2 mapping analysis of Cartilage tissue quality
- Adverse events (bone marrow abnormality, MOAKS abnormal cartilage, cysts, bone changes)

Patient Reported Outcomes: KOOS, IKDC, SF-12, EQ-5D-5L, VAS, Subject Satisfaction

SAFETY RESULTS:
• No device-related adverse events in either group at any time point
• No adverse MRI findings in either group at any time point

PERFORMANCE RESULTS:
• Post-operatively, imaging analysis showed no significant differences in the Percent Lesion Fill (PLF) between the two study groups.
• The overall differences in change of PLF at any visit (week 52 and 104) were not significant (P>0.05) between the treatment groups.
Main Results: Patient Outcome scores

- Mean KOOS scores improved in both treatment groups from the pre-operative status to each study visit.

- This improvement in KOOS scores was greater in subjects randomized to RF-based debridement for pain only at Weeks 12 and 24.

- No evidence of significant difference in overall KOOS scores between the groups at any visit.
Trend of improvement (not significant (p=0.07)) in the KOOS Sports/Recreation subscale with an increase in PLF between the postoperative baseline and Week 52 visits.
Chondroplasty with Coblation

Intra-op visualization of ICRS grade 3A lesion and fibrillation

Intra-op visualization of lesion after debridement with Coblation
Chondroplasty with Coblation
Example of MR Changes Over Time

Post Op: PLF = 45.2%  @52Week: PLF change - 2.9%  @104Week: PLF change +12.2%
Mechanical debridement
Example of MR Changes Over Time

Post Op: PLF = 49.0%  @52Week: PLF change - 4.6%  @104Week: PLF change - 20.7%
In this RCT with over 2 yr. follow up (MR and PROs):

- MR and PROs similar between 2 groups
- **No device-related adverse events** from RF (Coblation)
- No adverse MRI findings in either Coblation or Mechanical
- May be correlation between structural properties and functional outcomes (trend of improvement with RF)

- **More clinical evidence is needed to understand long-term effects of knee chondroplasty**

**LIMITATIONS:**

- Target sample size was not met due to slow patient enrolment
- Results generated for Coblation (RF-based plasma technology) cannot be translated to other bipolar radiofrequency technologies