COBLATION° Chondroplasty Found to Be Safe and Effective in a Large Retrospective Patient Series

The use of COBLATION technology for treating chondral lesions in arthroscopic knee surgery is supported by encouraging clinical results. Second-look arthroscopic evaluation indicates that COBLATION-treated lesions exhibit limited progression (12% of lesions), with the majority having signs of partial or complete filling of the originally treated defect. Results from a randomized controlled trial with up to 10 years follow up indicate that COBLATION chondroplasty produces better clinical outcomes (as measured by Tegner score and Knee and Osteoarthritis Outcome Score [KOOS]) and a lower proportion of revisions due to persistent knee problems than mechanical debridement. Despite these promising data, a larger population study was needed to evaluate the safety of this treatment. Such research was recently published in the form of a longitudinal analysis in more than 800 patients undergoing COBLATION chondroplasty for chondral lesions encountered during knee arthroscopy. The results of this study are discussed in detail in this Bone&Joint Appraisal.

Conclusion
This large series of more than 800 patients had a low rate of complications and reoperations, none of which were associated with the use of COBLATION technology. Patients had significant improvements in the key clinical outcomes of KOOS and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score. Based on their results, the authors concluded that COBLATION chondroplasty is a safe modality in treatment of chondral lesions.
A Retrospective Study Assessing Safety and Efficacy of Bipolar Radiofrequency Ablation for Knee Chondral Lesions.

Gharaibeh M, Szomor A, Chen DB, MacDessi SJ. Cartilage. 2017 Apr 1. [Epub ahead of print]

Goal of Study
To evaluate the safety and efficacy of bipolar radiofrequency ablation (COBLATION® technology; AMBIENT® SUPER MULTIVAC 50®, ArthroCare Corporation, Austin, TX, USA) in the treatment of chondral lesions encountered during knee arthroscopy.

Interventions
840 cases (824 patients) of knee arthroscopic chondroplasty with COBLATION technology, with or without treatment of other lesions within the knee including treatment of meniscal tears and removal of loose bodies.

Mean age, 47 years; 61% male

Chondral lesions per knee, %
- 1 lesion (62%)
- 2 lesions (29%)
- 3 lesions (9%)

492 of original patients (59.7%) had pre- and postoperative clinical scores available

Clinical Scores
- KOOS
  - Pre-operative: 45.9
  - Post-operative: 65.5
  - p<0.0001

- WOMAC
  - Pre-operative: 37.7
  - Post-operative: 19.4
  - p<0.0001

Main study outcomes
Complications and Associated Surgeries
- 19 complications (2.2%) in 840 cases
- 23 patients (2.7%) underwent additional surgery within 6 months

No complications or additional surgeries were associated with the use of COBLATION technology

Was study sufficiently designed to assess intervention?
- Yes

Are study outcomes relevant and adequately measured?
- Yes

Is sufficient information available to objectively assess results?
- Yes

Conclusion
The authors behind this large case series of patients with chondral knee lesions treated with COBLATION technology reported that it was safe, with a low rate of complications and revisions, none of which were directly associated with the use of COBLATION. Secondary outcome measures indicated that COBLATION chondroplasty significantly improved the key clinical outcomes of KOOS and WOMAC scores.
Explaining Study Outcomes

Patient-reported outcome measurements

**Knee and Osteoarthritis Outcome Score (KOOS)**
Evaluates the short- and long-term consequences of knee injury and primary osteoarthritis. The KOOS scores use 42 items in five separately scored subscales: pain, symptoms, function in daily living, function in sport and recreation, and knee-related quality of life. The normalized KOOS score is graded from 0 (extreme symptoms) to 100 (no symptoms).6

**Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)**
A patient-reported outcome for measuring the three scales of pain (0-20), stiffness (0-8), and physical function (0-86). In the Likert version of the WOMAC used in this study, higher scores indicate worse outcomes.7

Study Terms

**Clinical study**
Any study in living human participants.

**Case series**
A study reporting on a consecutive collection of patients treated in a similar manner, without a control group.

**P values**
The result of a test to determine if a conclusion or difference is significant. P values are expressed in thresholds of ‘extremely significant’ (< 0.001), ‘very significant’ (0.001 to 0.01), ‘significant’ (0.01 to 0.05), and ‘not significant’ (≥ 0.05).

**Statistical significance**
The likelihood that an outcome is attributable to a specific cause, rather than a random occurrence.

Study Appraisal Criteria

<table>
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<tr>
<th>Study appraisal questions</th>
<th>Level I-IV studies’ appraisal criteria</th>
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| Was study sufficiently designed to assess intervention? | – Research question or objective clearly stated  
– Intervention(s) described in sufficient detail to recreate study design if necessary  
– Comparison groups well balanced  
– On-label usage is studied, or if not, this fact is explicitly acknowledged and controlled for in the study  
– If clinical, patients are representative of those who commonly receive device or treatment |
| Are study outcomes relevant and adequately measured? | – Includes commonly accepted outcomes for measuring safety and/or efficacy of chosen device or treatment  
– Data collection methods clearly established  
– Outcomes were measured using commonly accepted standards |
| Is sufficient information available to objectively assess results? | – Includes a statistical analysis  
– Study is adequately sized and powered to measure chosen endpoints  
– Follow-up time is sufficient to measure association between an exposure and outcomes, if present  
– Any design flaws identified are adequately controlled for  
– All relevant study limitations are noted by the authors |

Each of the three main study questions is categorized as one of the following:

- **Yes** If all their sub-criteria are met
- **mostly** If a majority of sub-criteria are met (and the minority that are not met are considered relatively minor [e.g., research question is poorly defined])
- **No** If none or a majority of sub-criteria are not met (or when any sub-criteria not met are considered major [e.g., study is not well-balanced, lack of a statistical analysis])
The Bone&Joint literature series helps to support healthcare professionals in achieving better outcomes for patients, by enhancing understanding of techniques and our products.

References


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