The evidence is in...
Controlled ablation | Proven outcomes\textsuperscript{2,3}

\textbf{Faster*}
patient recovery\textsuperscript{1}

\textbf{Better*}
patient outcomes\textsuperscript{2,3}

\textbf{Safe}
for use on all joint soft tissue\textsuperscript{4–10}

\textbf{Lower*}
total costs\textsuperscript{11–14}

*Compared with mechanical debridement.
Chondral defects in the knee are common\textsuperscript{15} and can cause significant morbidity\textsuperscript{16}

In a review of over 31,000 knee arthroscopy cases,\textsuperscript{15} chondral lesions were observed in 63\% of cases.

Untreated lesions can lead to a variety of complications:

- Pain, swelling, reduced function, increased disability\textsuperscript{7}
- Worse outcomes following repair of anterior cruciate ligament tears\textsuperscript{9}
- Osteoarthritis,\textsuperscript{16} which may require a total knee replacement

Treating chondral lesions with mechanical debridement has been associated with:

- A ‘tearing’ effect on the cartilage, that can lead to further lesion propagation\textsuperscript{19}
- Inadvertent removal of adjacent healthy cartilage\textsuperscript{9}
- Failure to improve clinical outcomes compared with observation alone\textsuperscript{20}

\textbf{COBLATION\textsuperscript{®} Technology provides a clinically proven alternative to mechanical debridement}

Using COBLATION Technology for knee procedures delivers:

- Faster patient recovery*\textsuperscript{1}
- Better patient outcomes*\textsuperscript{2,3}
- Safe for use on all joint soft tissue\textsuperscript{4–10}
- Lower total costs\textsuperscript{11–14}

*Compared with mechanical debridement
Faster patient recovery*1

- Significantly less post-operative knee pain at all follow-up points (6 hours to 1 year)
- 91% reduction in relative risk of taking NSAIDs for knee pain at 1 year
- 24% faster return to work

A randomised controlled trial of 60 patients undergoing medial meniscectomy with idiopathic grade III medial-femoral cartilage defects. Patients were randomised into two groups; COBLATION chondroplasty (n=30) or chondroplasty using mechanical debridement (n=30). At 1 year follow-up patients in the COBLATION group experienced:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>COBLATION</th>
<th>Mechanical debridement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significantly less knee pain</td>
<td>p&lt;0.001</td>
<td>p=0.329</td>
</tr>
<tr>
<td>91% reduction in relative risk of taking NSAIDs for knee pain at 1 year</td>
<td>p&lt;0.001</td>
<td>p=0.014</td>
</tr>
<tr>
<td>24% faster return to work</td>
<td></td>
<td>p=0.014</td>
</tr>
</tbody>
</table>

*Compared with mechanical debridement. NSAIDs = non-steroidal anti-inflammatory drug; VAS = visual analogue scale
Patients from this randomised controlled trial were then followed at 4 years and 10 years. At these medium- and long-term follow-up points, COBLATION™ was superior to mechanical debridement in several outcomes.

### Improved clinical outcomes

Among patients not requiring revision or replacement surgery (n=40), those treated with COBLATION had statistically significant improvements in clinical outcomes compared with mechanical debridement at 4 years²

- **Significantly better KOOS and Tegner scores at 4 years²**
- **88% reduction in the relative risk of joint replacement surgery at 4 years²**
- **Significantly extends average time to revision surgery by 2.6 years³**

Varus angle increases were smaller with COBLATION vs the mechanical debridement group (2.3° vs 4.0°; p<0.001) at 4 years²

- **Slower varus angle progression**

KOOS and Tegner scores at 4 years:

- COBLATION: 71.8 (p<0.001)
- Mechanical debridement: 53.2

Tegner Score at 4 years:

- COBLATION: 4.5 (p=0.005)
- Mechanical debridement: 3.3

KOOS = Knee Osteoarthritis Outcome Score

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*p* Compared with mechanical debridement. KOOS = Knee Osteoarthritis Outcome Score
Reduced revision

At 4 years, a significantly lower proportion of revision procedures for persistent knee problems occurred in the COBLATION™ group than the mechanical debridement group (p<0.01)²

<table>
<thead>
<tr>
<th>COBLATION (n=30)</th>
<th>Mechanical debridement (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Replacement</td>
<td>8 Replacements</td>
</tr>
<tr>
<td>2 Osteotomies</td>
<td>4 Osteotomies</td>
</tr>
<tr>
<td>1 Revision</td>
<td>2 Revision arthroscopies</td>
</tr>
</tbody>
</table>

71% reduction in relative risk of revision²
(13% vs 47%; p=0.006)

88% reduction in relative risk of joint replacement surgery
(3% vs 27%; p=0.014²²¹)

At 10 years, revision rates remained significantly lower in the COBLATION group compared with the mechanical debridement group (p=0.061)³

<table>
<thead>
<tr>
<th>COBLATION</th>
<th>Mechanical debridement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean time to revision (years)</td>
<td>7.8</td>
</tr>
</tbody>
</table>

61% reduction in relative risk of revision surgery³
(23% vs 60%; p=0.061)

A significantly longer mean time to revision

*Chi-square analysis based on data from Spahn et al.²
Safe for use on all joint soft tissue

- Demonstrated safety for chondroplasty in a study with 824 patients
- No cases of osteonecrosis or chondrolysis reported
- COBLATION is indicated for use in the knee on all soft tissue types

Established clinical safety
in a retrospective study of 840 chondroplasty procedures using COBLATION technology

Low rates of complications and re-operations...

0 cases of osteonecrosis or chondrolysis reported

2.2% Post-op complications within 6 months
2.7% Re-operations within 6 months

...with zero complications or additional surgeries linked to the use of COBLATION

...with the potential to stabilise and fill partial cartilage lesions

In a second-look arthroscopy study of 25 lesions in 15 patients treated with COBLATION (mean follow-up 10.4 months)

88% of lesions showed no signs of progression
56% of cartilage defects demonstrated to have partial or complete filling of lesion

COBLATION has been used in over 1.5 million knee procedures*

*Figure calculated by capturing the number of COBLATION wands sold from July 2008 to May 2016
Lower total costs*\(^{11-14}\)

- Substantial cost savings at 4 years compared with mechanical debridement\(^{2,11-14}\)
- Proven value shown in analyses of multiple national payer systems\(^{11-14}\)

COBLATION\(^*\) compared with mechanical debridement demonstrates meaningful reductions in physical therapy service use at 6 weeks\(^1\) and overall revision rates at 4 years\(^2\)

Using these data, economic analyses for multiple national payer systems was performed comparing COBLATION and mechanical debridement.

In patients with chronic pain due to medial meniscus tear and an International Cartilage Research Society (ICRS) grade III focal chondral lesion, projected 4-year post-surgery total cost savings per patient were:

- **€2,073** Spain\(^{11}\)
  - Based on the 2016 Spanish Health Costs database

- **€2,310** Germany\(^{12}\)
  - Based on the 2016 German Health Costs database

- **£1,780** UK\(^{13}\)
  - Based on 2017/2018 UK NHS National Tariff Payment System

- **$3,237** USA\(^{14}\)
  - Based on 2017 National Medicare Fee-for-Service Payment data

*Compared with mechanical debridement.
WEREWOLF™ COBLATION™ System with FLOW~IQ™ Technology

**FLOW~IQ™ Technology**
- Automatically regulates saline outflow with COBLATION™ energy to optimise performance across all tissue types.
- The only platform to control energy output and outflow suction.
- Enables VAC mode to rinse the joint and clear debris with a simple push of a button.

**FLOW 50° Wand**
- Removes tissue approximately 4 times faster than our market leading 50 degree wand*23.
- Removes tissue at lower temperatures than our market leading 50 degree wand*23.
- Curved shaft and small tip allow good access.
- 5 modes addresses multiple tissue types and minimises instrument exchanges.

**COBLATION™ Technology**
- The controlled plasma field produced by COBLATION™ allows for precise removal of soft tissue with minimal thermal damage (100–200 μm) evident in untargeted cartilage tissue.24

**SCOPE-SENSING™ Technology**
- Proprietary circuits detect when a wand is in close proximity to metal and will automatically suspend energy delivery.
- When a safe distance is achieved, COBLATION™ energy will automatically resume.

**AMBIENT™ Technology**
- First and only system offering two-zone real-time temperature monitoring of intra-articular fluid.
- New two-zone monitoring measures both the intra-articular fluid temperature and outflow temperatures within the hand piece.

*Compares AMBIENT™ SUPERMULTIVAC™ 50 (set point 9) to WEREWOLF FLOW 50 Wand (Vac Mode). The results of the in vitro simulation testing have not been proven to predict clinical performance.
References
