



Coblation in the knee

Ben Price

Disclaimer

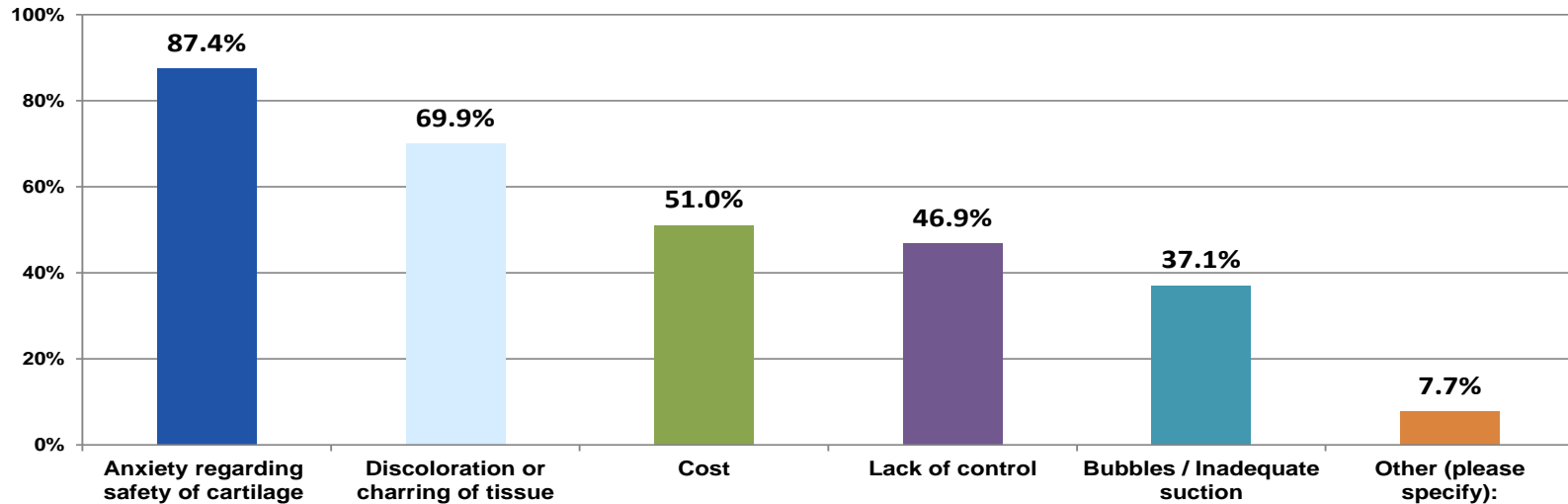
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Total Arthroscopies performed in Europe in 2011

Ratio of Knee to Shoulder
procedures = 3 : 1

Ratio of Knee to Shoulder wands
sales = 1 : 3

What are the biggest problems you experience when using existing RF systems to debride articular cartilage lesions? (Please select the top 3 that are most problematic) [% Selected] - N=143



Coblation Market research. Actionable Research. August 2011

What is the WHY?

WHY should a surgeon use Coblation in the Knee?

WHY should a surgeon use Coblation in the Knee

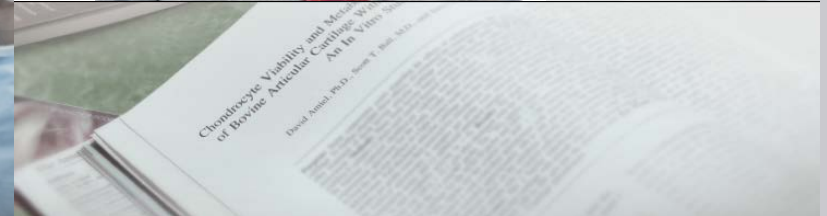
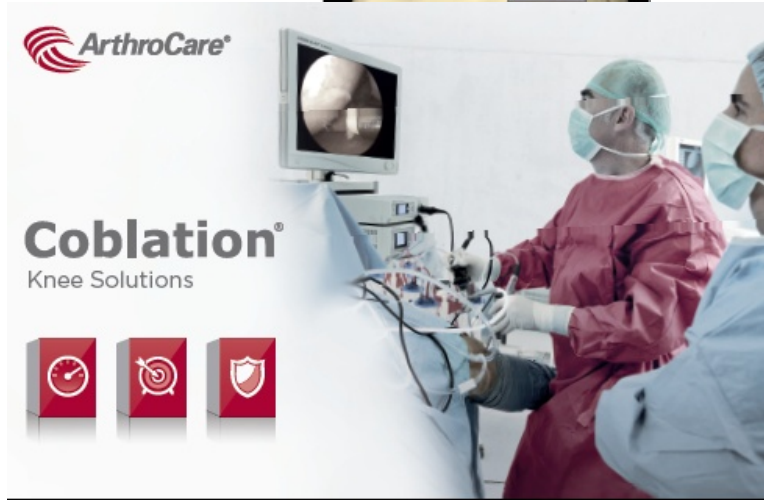
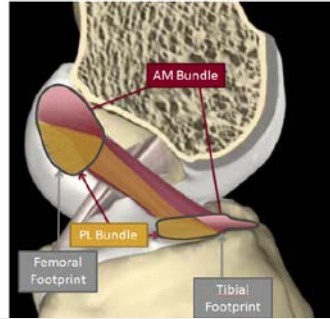
Knowledge &
Understanding

Confidence

Achieve improved clinical
outcomes

Belief

HOW?



In-Sight. The use of Coblation in the Knee

1. ACL Notch clearance and identification of the femoral footprint
2. Chondroplasty
 1. Isolated Femoral defect
 2. Degenerative femoral defects
 3. Rim stabilisation in an isolated Grade 4 femoral defect
 4. Patella defect
 5. Trochlear defects
3. Meniscal debridement

Primary Bony Anatomy

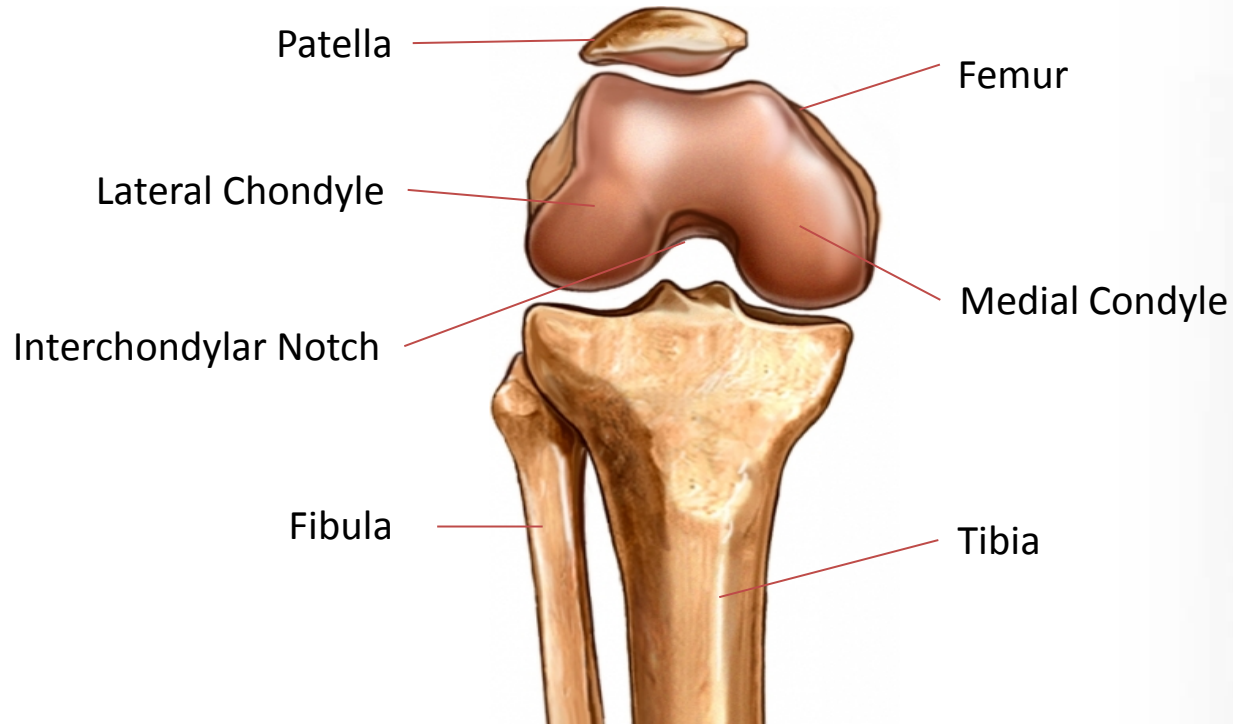


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Primary Ligament and Meniscus Anatomy

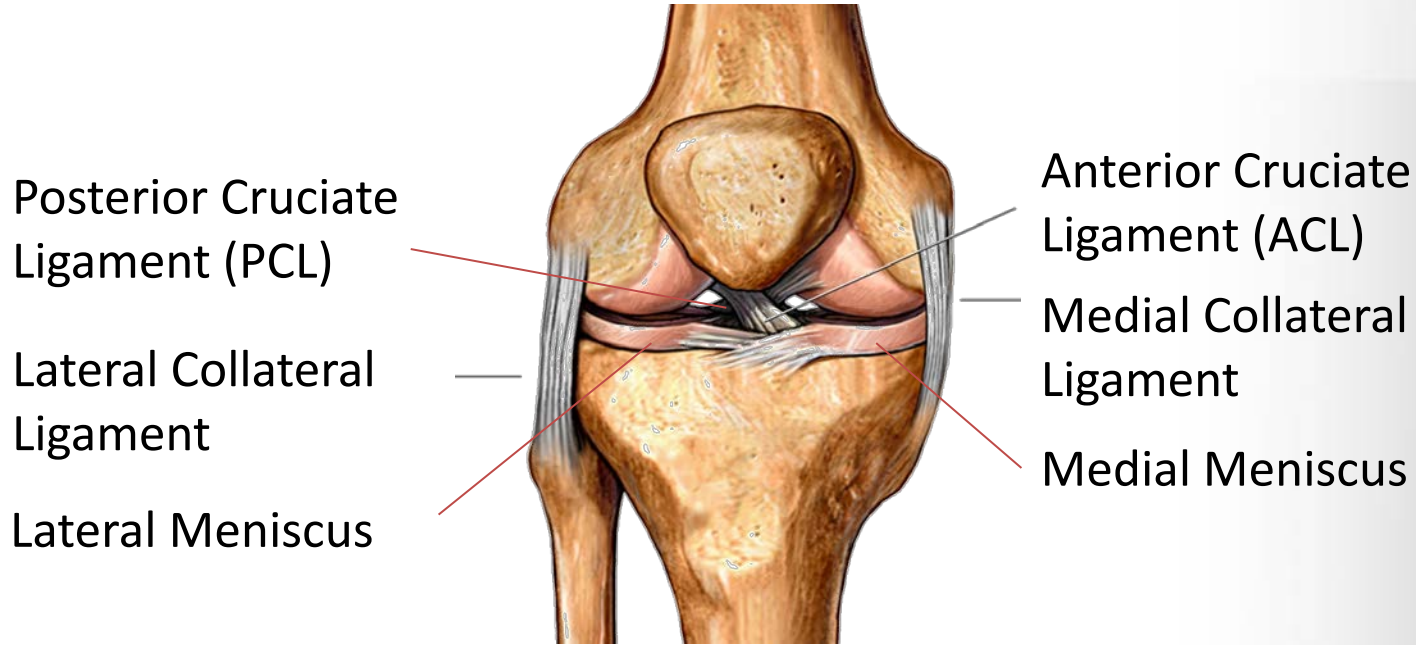


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ACL Kinematics

[ACL Kinematics Animation. PN 52115A](#)

Mr James Robinson MS FRCS (Ortho)

Consultant Orthopaedic Surgeon
Avon Orthopaedic Centre, Bristol UK

In-Sight: Knee Coblation



In-Sight. Knee Coblation



Knee Coblation Workshop 2 – Clinical review of Coblation in the knee

Ben Price

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Clinical Review of Coblation the Knee

“What Clinical Proof do you have?”

“Why should I change from My Shaver”

“What you need is an RCT Vs Shaver”



Arthroscopic Knee Chondroplasty Using a Bipolar RF Based Device Compared to Mechanical Shaver:

Results of a Prospective, Randomized Controlled Study

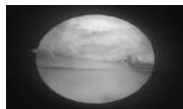
Spahn G et al. *Knee Surg Sports Traumatol Arthroscopy*. 2008 Jun; 16(6):565-73.

Purpose:

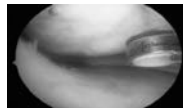
Compare clinical results after bipolar radiofrequency based chondroplasty (RFC, Arthrocare Paragon)) to mechanical shaver debridement (MSD, Arthrex).

Methods:

60 patients with a medial meniscus tear and grade III defect of the medial femoral condyle were randomly assigned to receive one of the two treatments (30 per group). Clinical outcomes were assessed using the Tegner score, visual analogue scale (VAS) score, and Knee and Osteoarthritis Outcome Score (KOOS) assessment.



Arthroscopy photo immediately following MSD



Arthroscopy photo immediately following RFC (at setting 6)

Results: See figures at right.

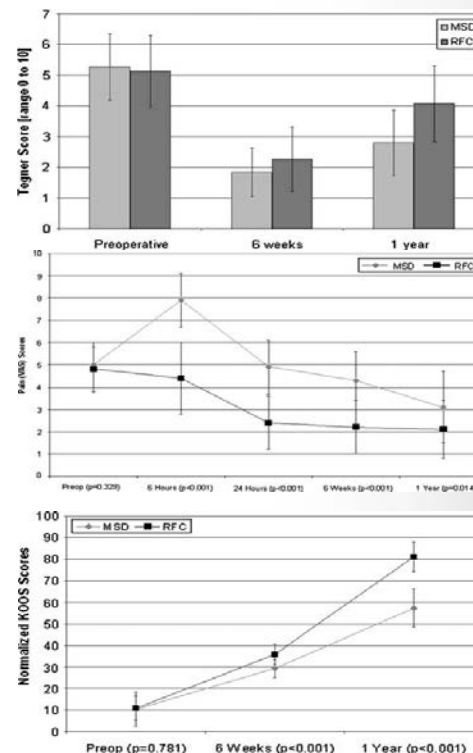
Conclusion:

This study provides evidence that treating Grade III medial femoral condyle lesions concomitantly with meniscectomy using RFC rather than MSD may provide better overall clinical results. The RFC patients demonstrated earlier recovery from the arthroscopy than MSD patients and had significantly superior outcomes, which were assessed using several different measures, at both 6 weeks and 1 year postoperatively. The RFC approach appears to be an effective treatment for debriding chondral fibrillations and may have the potential to stabilize the defect.

Study Limitations:

- Meniscectomy may have confounded the results although random assignment was employed to minimize any bias.
- The study lacks a control group in which no treatment was performed for the femoral condyle defect.

*Human In-Vivo
Prospective, Randomized
ArthroCare Device*



RFC patients had significantly better Tegner score than the MSD patients at the 1 year follow up ($P<0.0001$), although patients in both groups had significantly worse scores than before the injury ($p<0.001$).

RFC patients had significantly less pain as measured using a visual analog scale (range 0-10), than the MSD patients at all postoperative time points.

RFC patients had significantly better normalized KOOS scores than the MSD patients at 6 weeks ($P<0.001$) and 1 year postoperatively ($P<0.0001$).

Four-Year Results From a Randomized Controlled Study of Knee Chondroplasty With Concomitant Medial Meniscectomy: Mechanical Debridement Versus RF Chondroplasty

Spahn G et al. Arthroscopy 2010 Sept; 26(9):S73-S80.

Purpose:

Compare the effectiveness of simple mechanical debridement and $\leq 50^{\circ}\text{C}$ controlled bipolar chondroplasty.

Methods:

60 patients with a medial meniscus tear and grade III defect of the medial femoral condyle were randomized assigned to receive one of the two treatments (30 per group). All patients underwent partial or subtotal meniscectomy. Clinical outcomes were assessed using the Tegner score and Knee and Osteoarthritis Outcome Score (KOOS) assessment

Total N=60	Randomized	At Four Year Follow Up
	30 MSD Mechanical Shaving	1 - Deceased 14-Required 2 nd Surgery 15 → Remaining Group
	30 – RFC RF Chondroplasty	1 – Lost to Follow up 4-Required 2 nd Surgery 25 → Remaining Group

Results:

See figures at right.

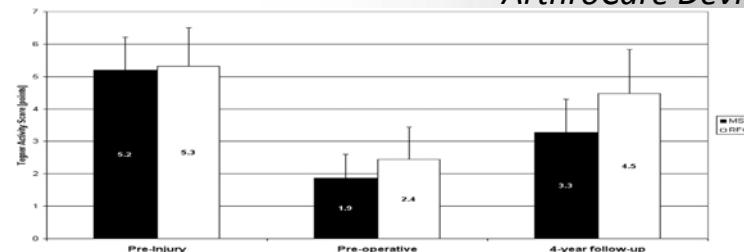
Conclusion:

Compared with classical mechanical debridement, bipolar RF currently appears to be the superior method for achieving a good midterm result. Further evaluations with long term follow-up are required

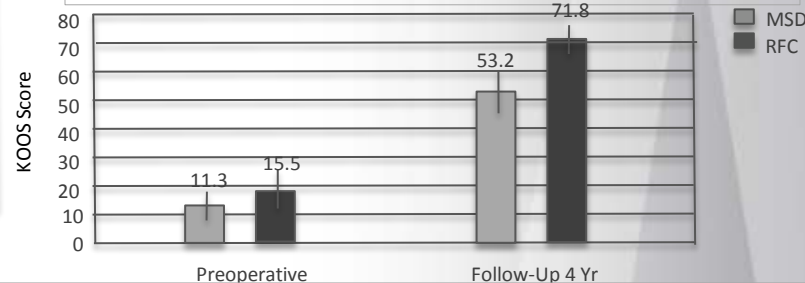
Study Limitations:

- Only patients with Grade III articular cartilage lesions and concomitant medial meniscus tears were studied.
- Only the differences between MSD and RF treatment were studied with no real control group.
- 30% of the patients were lost to follow-up or required a second attempt at surgery.

Human In-Vivo
Prospective, Randomized
ArthroCare Device



Physical Activity level (Tegner Score). Before their illness, the patients had no difference in Tegner scores ($P=.745$). The disease related score decreased at the time of operation in both groups ($P=.63$). At follow-up patients in the RFC Group had a significantly higher level of physical activity ($P=.005$)



Both groups benefited from the operation. The pre-operative KOOS was 11.3 points in the MSD group, and 15.5 points in the RFC group ($P=.279$). Patients from the MSD group had a KOOS of 53.2 points at follow up. In the RFC Group the KOOS(71.8) was significantly better ($P<.0001$)

Arthroscopic Evaluation of Radiofrequency Chondroplasty of the Knee

Voloshin I, et al. *Am J Sports Med.* 2007 Oct; 35(10):1702-7

Hypothesis:

Partial-thickness articular cartilage lesions treated with bipolar radiofrequency-based chondroplasty will show no progressive deterioration

Methods:

193 consecutive patients underwent bipolar RF based chondroplasty over 38 months; 15 patients with 25 defects underwent repeat arthroscopy for recurrent or new injuries. Time from the initial to repeat arthroscopy ranged from 0.7 to 32.7 months. At both procedures, the location, size, grade, and stability of lesions were evaluated, recorded, and photographed arthroscopically.

Results:

At the initial procedure, 25 lesions treated ranged from 9 to 625mm² (mean , 170.2±131.2mm²; median, 120mm²); at second look, lesion size was 9 to 300mm² (mean , 107.7±106.7mm²; median, 100mm²). At second look, 3(12%) demonstrated unstable borders with damage in the surrounding cartilage that appeared progressive. Eight (32%) lesions were unchanged in size. Eight (32%) demonstrated partial filling with stable repair tissue, and 6 (24%) demonstrated complete filling with stable repair tissue. Lesions in the tibiofemoral compartments showed better response to radiofrequency chondroplasty than did those within the patellofemoral joint (P<0.05).

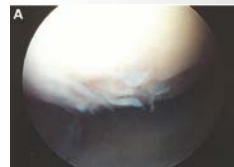
Conclusion:

Only 3 of 25 lesions demonstrated progression. More than 50% showed partial or complete filling of the defect. Bipolar radiofrequency chondroplasty is an effective way to treat partial-thickness cartilage lesions; however, long-term effects of this treatment on cartilage remain unknown.

Study Limitations:

- The only patients included in this study had symptoms sufficient to warrant repeat arthroscopy. Thus this study group cannot truly represent the incidence of cartilage lesion progression in the original group of 193 patients because of obvious selection bias.
- The authors of the article performed the grading and size measurements of the lesions at the time of surgery.
- No biopsies of the repair tissue that filled the defects were performed, and the author can only speculate about its histologic nature.
- Data did not include functional outcomes of the patients in the study group.

Human In-Vivo Prospective ArthroCare Device



A. Partial-thickness condral defect of the medial femoral condyle before bipolar radiofrequency-based chondroplasty.



B. After radiofrequency chondroplasty, the borders of the lesion are smooth and stable.



C. Fibrocartilage-like tissue filling the previously treated lesion is observed on second look arthroscopy.

Other Resources

- Acute effect of RF energy on Articular Cartilage
- Competitor RF Vs Shaver
- Cell death Vs Shaver
- Charing
- Risk of Osteonecrosis

The Acute Effects of Radiofrequency Energy in Articular Cartilage: An in Vitro Study.

Kaplan L, Uribe JW. *Arthroscopy* 2000 Jan-Feb;16(1):2-5. (P/N 44330)

*Human In-Vitro
Prospective
ArthroCare Device*

Purpose:

To determine the acute effect of radiofrequency (RF) energy on articular cartilage.

Methods:

Six fresh human articular cartilage specimens were obtained from patients undergoing total knee arthroplasty for unicompartmental osteoarthritis. A jig was used as the RF energy was delivered to 2 designated treatment areas. These areas included a normal and a diseased area of articular cartilage tested at 3 voltage settings (kilohertz per voltage root mean square), 133 to 147 (setting 2), 161-179 (setting 4) and 190-210 (setting 6) for 3 seconds. The designated testing areas were marked with tissue dye and processed using standard histological techniques.

Results:

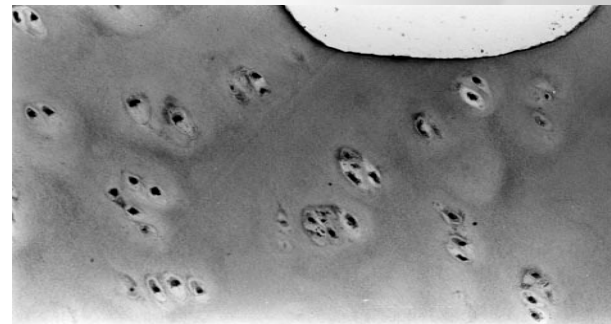
A scalloped concave excavation with a smooth surface remains at each treatment site. The chondrocytes are viable at the RF treated sites without alterations in nuclear cytoplasmic nor lacunae structure when compared with collateral untreated areas.

Conclusion:

The chondrocytes remain viable, no collagen abnormalities are detected, and diseased areas are smoothed without further evidence of fibrillation. RF Energy appears to be safe for use on articular cartilage.

Study Limitations:

- Settings used are not consistent with those recommended by the manufacturer.



A scalloped concave excavation with a smooth surface remains at each treatment site.

Ex vivo Comparison of Mechanical Versus Thermal Chondroplasty: Assessment of Tissue Effect at the Surgical Endpoint

Lotto ML, et al. *Arthroscopy*. 2008 Apr;24(4):410-5. (P/N 44325)

Purpose:

Evaluate tissue effect (tissue removal plus underlying cell death) of two chondroplasty techniques: mechanical debridement (MD) using a rotary shaver blade (4.5mm full-radius shaver, Dyonics Power) and thermal chondroplasty using radiofrequency energy (RFE) (Dyonics Glider)

Methods:

Forty-eight human chondromalacic cartilage samples were treated with either MD or RFE. Pre- and post-treatment arthroscopic images of the cartilage surface were recorded. Samples were incubated with cell viability stain and visualized with confocal laser microscopy to determine tissue effect. Smoothing was quantitated by three surgeons using a visual analog scale (VAS) as well as a subjective rating regarding whether smoothing was "arthroscopically acceptable."

Results:

Tissue effect at the surgical endpoint of arthroscopically acceptable smoothing was 385 microns for MD versus 236 microns for RFE, a significant difference ($P < .0001$). Mean post-treatment VAS for MD was 2.8 points less smooth than for RFE ($P < .0001$). Overall, arthroscopically acceptable smoothing was achieved in 90% of RFE samples compared to 49% of MD samples.

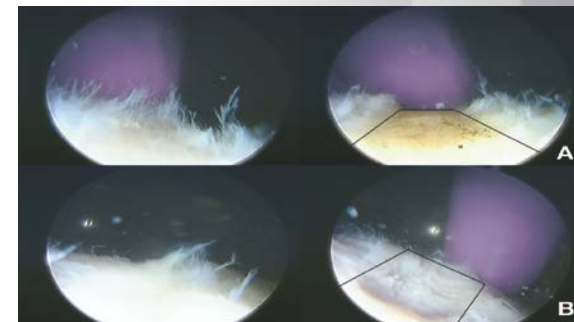
Conclusion:

Chondroplasty using a RFE probe results in greater smoothing of chondromalacic cartilage in fewer treatment passes and with decreased total tissue effect than MD using a rotary shaver blade. If safety and efficacy can be shown in vivo, thermal chondroplasty may represent an alternative for treatment of symptomatic chondromalacia.

Study Limitations:

- Ex-vivo evaluations cannot determine long term clinical outcome. As such, the long term consequences of cell death are unknown.
- VAS smoothing scores and arthroscopically acceptable smoothing are subjective observations.
- Interobserver error existed between the three surgeons in this study.
- Significant differences in pretreatment VAS smoothing scores exist between the MD and RFE groups.

Human Ex-Vivo
Prospective, Randomized
Non-ArthroCare Device



Arthroscopic images of pretreatment chondromalacic cartilage (left) and post-treatment cartilage (right) treated with a (A) radiofrequency energy (RFE) probe for 3 passes and (B) mechanical debridement (MD) device for 10 passes. Treatment area is outlined in black.

Radiofrequency (Electrosurgical) Ablation of Articular Cartilage: A Study in Sheep

Turner AS, et al. *Arthroscopy*. 1998 Sep;14(6):585-91. (P/N 44324)

Purpose:

Examine the effect of a bipolar ablation probe on experimentally roughened articular cartilage and compare it with the traditional mechanical shaving technique using the knee joint of sheep.

Methods:

Twenty-eight skeletally mature ewes were divided randomly into two groups: one group was treated with a rotating shaving device and another group was treated using the bipolar ablation probe (Bipolar Arthroscopic Probe; ElectroScope, Inc, Boulder, CO). Animals were killed at 0, 6, 12 and 24 weeks, and histological sections of the experimental limbs were compared with sections of the opposite limb using a modified Mankin scale.

Results:

Bipolar ablative probe-treated limbs had 14.29% favorable responses and 35.71% favorable or neutral responses, whereas shave-treated limbs had 0% favorable and only 7.14% favorable or neutral responses. For all variables, bipolar ablative probe-treated limbs had more favorable responses.

Conclusion:

The less severe histological change in the bipolar ablative probe-treated joints compared with the shave-treated joints suggests that bipolar ablation of articular cartilage may be a better treatment for chondromalacia than the usual shaving methods of debridement.

Study Limitations:

- Model used of manually roughening cartilage is not identical to naturally occurring chondromalacia.
- Standardization of defects created was subjective, not objective.
- Significance tests were of limited use in drawing conclusions from results of any one outcome measure (due to small sample size). Meaningful conclusions could be drawn from these data by looking jointly at all six outcome measures.

Animal In-Vivo

Prospective, Randomized

Non- ArthroCare Device

Estimated Probabilities and P Values for Significance of a Better Outcome for Bipolar Ablative Probe-Treated Sheep Versus Shave-Treated Sheep

Variable	Probability of Better Probe Result (%)	Bracketed Significance Probability
Surface	65.6	.05 < P < .10
Cells	66.8	.05 < P < .10
Hypocellularity	68.6	.05 < P < .10
Matrix (transitional zone)	70.2	.025 < P < .05
Matrix (radiate zone)	74.7	.01 < P < .025
Empty lacunae/hypereosinophilic cells	69.9	.025 < P < .05

Prospective Analysis of RF Versus Mechanical Debridement of Isolated Patellar Chondral Lesions

Owens BD, et al. Arthroscopy. 2002 Feb18(2):151-5. (P/N 44327)

Purpose:

Compare the clinical outcomes of debridement of patellar grade 2 and 3 chondral lesions using radiofrequency (J&J Mitek) and mechanical devices (S&N Dyonics).

Methods:

Consecutive female patients undergoing arthroscopy for symptomatic, isolated patellar cartilage lesions without evidence of instability, mal-alignment, or patellar tracking dysfunction were prospectively randomized into radiofrequency (at nonablative energy parameters) and mechanical debridement groups based on medical record number. All patients had failed a 6 month course of conservative treatment and had chondral pathology documented by magnetic resonance imaging. Patients were assessed before and after surgery using the Fulkerson Shea Patellofemoral Joint Evaluation Score.

Results:

See figures at right.

Conclusion:

This study presents clear evidence of superior clinical outcomes of debridement of patellar grade 2 and 3 chondral lesions with the use of bipolar radiofrequency versus a mechanical shaver.

Study Limitations:

- Because patient assessments were not performed by a blinded independent observer, there is the possibility of observer bias.
- The functional evaluation score used is a tool that has not been adequately validated or used extensively in reported studies.
- This study focuses on patellar chondral lesions in female patients. Because patellar cartilage is the thickest in the body, the results of this study may not be applicable to chondral pathology in other locations
- Extrapolation of results to other patient populations may not be appropriate; further study is needed.

Human In-Vivo

*Prospective, Randomized
Non- ArthroCare Device*

Patellofemoral Joint Scores

	Mechanical Shaver	Radiofrequency Treatment
N	19	20
Mean Age	37.5	36.9
Preoperative Score	59.2	59.6
Postoperative Score 12 Mos (P=.023)	80	87.9
Postoperative Score 24 Mos (P=.014)	77.5	86.6

Meniscal Debridement with an Arthroscopic Radiofrequency Wand Versus an Arthroscopic Shaver: Comparative Effects on Menisci and Underlying Articular Cartilage

Allen TR et al. *J Arthroscopic & Related Surgery*. 2006; 22(4):385–393. (P/N 44329)

Purpose:

Meniscal debridement with an arthroscopic radiofrequency (RF) wand versus an arthroscopic shaver and their comparative effects on menisci and underlying articular cartilage were studied.

Methods:

Six fresh bovine knees were harvested, the tibial plateau was dissected free from the femoral articulation and placed in a saline bath at 28 C, with 10%-15% of the posterior horn of the menisci debrided arthroscopically, and the surfaces debrided using a basket punch plus shaver, punch plus RF wand, RF wand alone, and an untreated control. Treatment time of each case was 24 seconds at wand power 7.

Results:

Chondrocyte viability of the tibial articular surface was 96%-98%. We saw no differences in the viability or injury zone (0-150 microns) among debrided groups or versus the control for any experimental surface, with no significant differences in metabolic activity in menisci debrided surfaces versus control. Meniscal viability was variable with analyses showing substantial levels (150 to 500 microns) of cell death in debrided and control groups. Metabolic activity in treated meniscus was lower than in cartilage specimens. No significant differences were observed among treatment groups versus control.

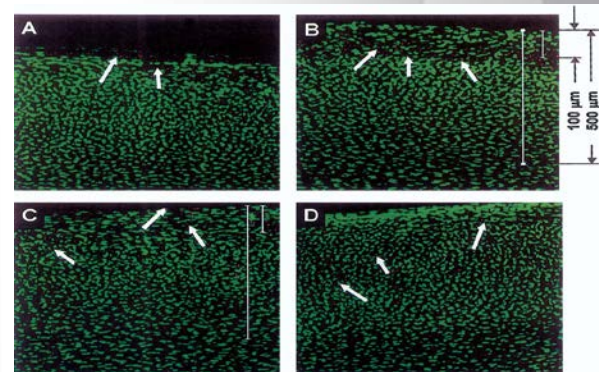
Conclusions:

Focal areas of chondrocyte cell death were not seen. Meniscal samples showed cell death (150 to 500 microns) throughout the tissue. Debridement of menisci with a bipolar RF wand produces levels of cell injury and death similar to those of debridement with a basket punch and mechanical shaver. The RF wand did not harm underlying articular surfaces and produced a precise cut to the meniscal surface.

Study Limitations:

- Only 1 RF wand device on 1 power setting was used.
- The femoral condyle was removed to gain better access to the tibial plateau.
- All debridements were performed by hand by 1 surgeon in a manner consistent with his clinical experience.
- Studies that compare clinical outcomes of debridement with an RF wand versus a mechanical shaver are needed to determine if short and long-term patient function is significantly different with RF wand treatments.

Animal Ex-Vivo
Prospective
ArthroCare Device



Confocal microscopy of calf articular cartilage. Living Cells 96%-98% in all experimental groups. Experimental groups (A) arthroscopic basket punch plus shaver, (B) basket punch plus Coblation, (C) Coblation only, (D) untreated control

An Ex Vivo Thermal Chondroplasty Model: The Association of a Char-Like Layer and Underlying Cell Death

Lotto ML, et al. Arthroscopy. 2006 Nov;22(11):1159-62. (P/N 44326)

Human Ex-Vivo
Prospective
Non-ArthroCare Device

Purpose:

Evaluate the relation between the char-like layer observed during radiofrequency energy (RFE) treatment of cartilage and the depth of underlying cell death.

Methods:

Healthy adult bovine patellae were treated with a monopolar RFE probe (Glider, Smith & Nephew) ex- vivo at generator settings of 20, 30, 40, 50, 60, 80, and 110 in cut mode. The presence or absence of a char-like layer and visual electrical discharge was noted. Treated tissue was incubated with cell viability stain, and the depth of cell death and matrix debridement was measured from confocal laser microscopy images.

Results:

At generator settings of 60 and above, a char-like layer, electrical discharge, and matrix debridement were consistently observed, and the depth of cell death was significantly less ($P < 0.05$) than when these features were not observed (≤ 30). Paradoxically, the least depth of cell death did not occur at the lowest generator settings in cut mode. It occurred at a generator setting of 60. an increase in impedance of the system and a decrease in current were also associated with reduced cell death.

Conclusion:

Formation of a char-like layer, visual electrical discharge, increased impedance, and reduced current were associated with less depth of cell death when cartilage was treated with monopolar RFE. This study suggests that a char-like layer and electrical discharge during RFE treatment of cartilage may be advantageous because, potentially, these features are associated with less depth of cell death (safety) and greater matrix debridement (efficacy).

Study Limitations:

- Healthy bovine cartilage was investigated, which is different from human chondromalacic cartilage.
- A long-term in vivo study would be an appropriate follow-up study.
- Single pass of RFE was used under controlled conditions; clinical application may vary.
- Visual observation of electrical discharge and the char-like layer were subjective observations whereby they either were or were not observed.
- Results are specific to the system and range of values tested.

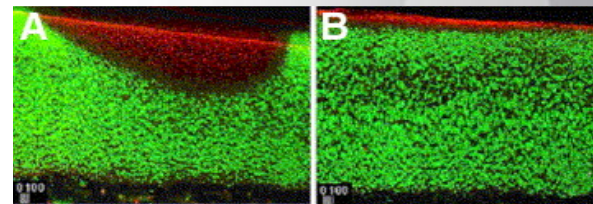


Figure 4. Representative confocal laser microscopic images of RFE-treated cartilage (top) and subchondral bone (bottom). The green dots represent viable chondrocytes, and the red dots represent dead chondrocytes. (A) Treated cartilage where a greater depth of cell death (and no char-like layer) was observed during treatment (40). (B) Treated cartilage where less depth of cell death (and a char-like layer) was observed (60). (Measurement bar, 100 μ m)

Risk of Osteonecrosis of the Femoral Condyle after Arthroscopic Chondroplasty using Radiofrequency: A Prospective Clinical Series

Human In-Vivo

Prospective

Non-ArthroCare Device

Cetik O, et al. *Knee Surg Sports Traumatol Arthrosc.* 2009 Jan; 17(1):24-9. (P/N 44328)

Purpose:

The current study searches for an answer whether surgical arthroscopic modalities using RF energy (J&J Mitek) causes osteonecrosis.

Methods:

Arthroscopic chondroplasty was applied on 50 patients, 27 female and 23 male, with a mean age of 45.54 (SD 10.63). All patients had stage II and III degenerative changes of the articular cartilage according to Outerbridge arthroscopic classification system for chondral lesions. Magnetic resonance imaging was performed for all patients pre- operatively and at six month follow up time period. Patients with preoperative MRI findings of osteonecrosis were also excluded from the study.

Results:

Of the 50 patients, chondroplasty was performed in 14 (28%), chondroplasty and partial meniscectomy in 23 (46%) and partial meniscectomy in 13 (26%) with RF. Postoperatively, among all 50 patients osteonecrosis was detected only in 2 patients (4%) for whom both chondroplasty and partial meniscectomy was performed.

Conclusion:

Bipolar RF energy used for arthroscopic chondroplasty does not cause subchondral osteonecrosis if proper surgical techniques are carried out.

Table 1 Outerbridge arthroscopic classification system for chondral lesions

Grade 0	Normal
Grade I	Softening of the cartilage
Grade II	Fibrillation
Grade III	Fissuring
Grade IV	Cartilage loss reaching the subchondral bone

Regional Planning – Coblation in the Knee

- RSM and NSM lead sales planning session
- Distilled tips and tricks, Key learning and takeaways

Mr James Robinson MS FRCS (Ortho)
Consultant Orthopaedic Surgeon
Avon Orthopaedic Centre, Bristol, UK

IN-Sight: A decade of evolution in ACL reconstruction





Coblation in the knee

Ben Price

If you see pulsing at the tip of a wand what should you consider doing?

A

Increase Suction until pulsing stops

B

Reduce Suction until pulsing stops

What effect will reducing suction have on the plasma field?

A

It will reduce the size of the plasma making for a more accurate removal of tissue

B

It will enable a more stable plasma to form around the tip of the wand

Coblation Workshop, ESSKA 2014, Amsterdam

Thursday 15th May 12.30-13.00

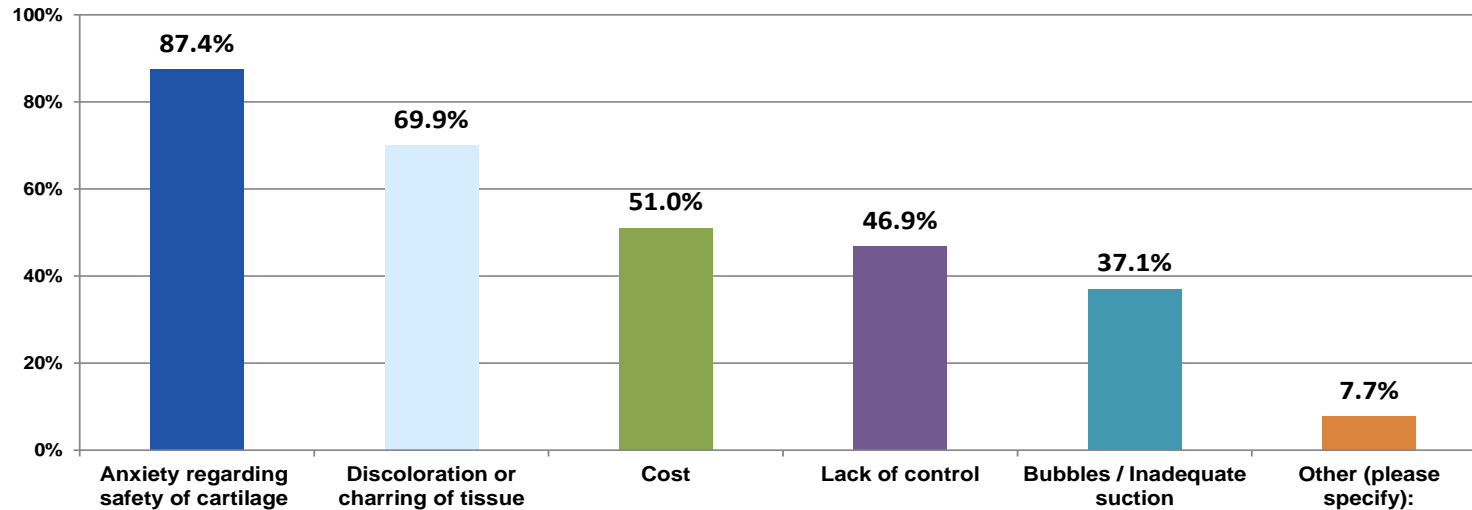
In-Sight: Knee Coblation

Addressing common myths associated with Radio
Frequency plasma technology

- Mr James Robinson
- Mr Martin Lind (TBC)
- Mr Jean Woloszko



What are the biggest problems you experience when using existing RF systems to debride articular cartilage lesions? (Please select the top 3 that are most problematic) [% Selected] - N=143



Coblation Market research. Actionable Research. August 2011

Tipping the Balance

Thank You

