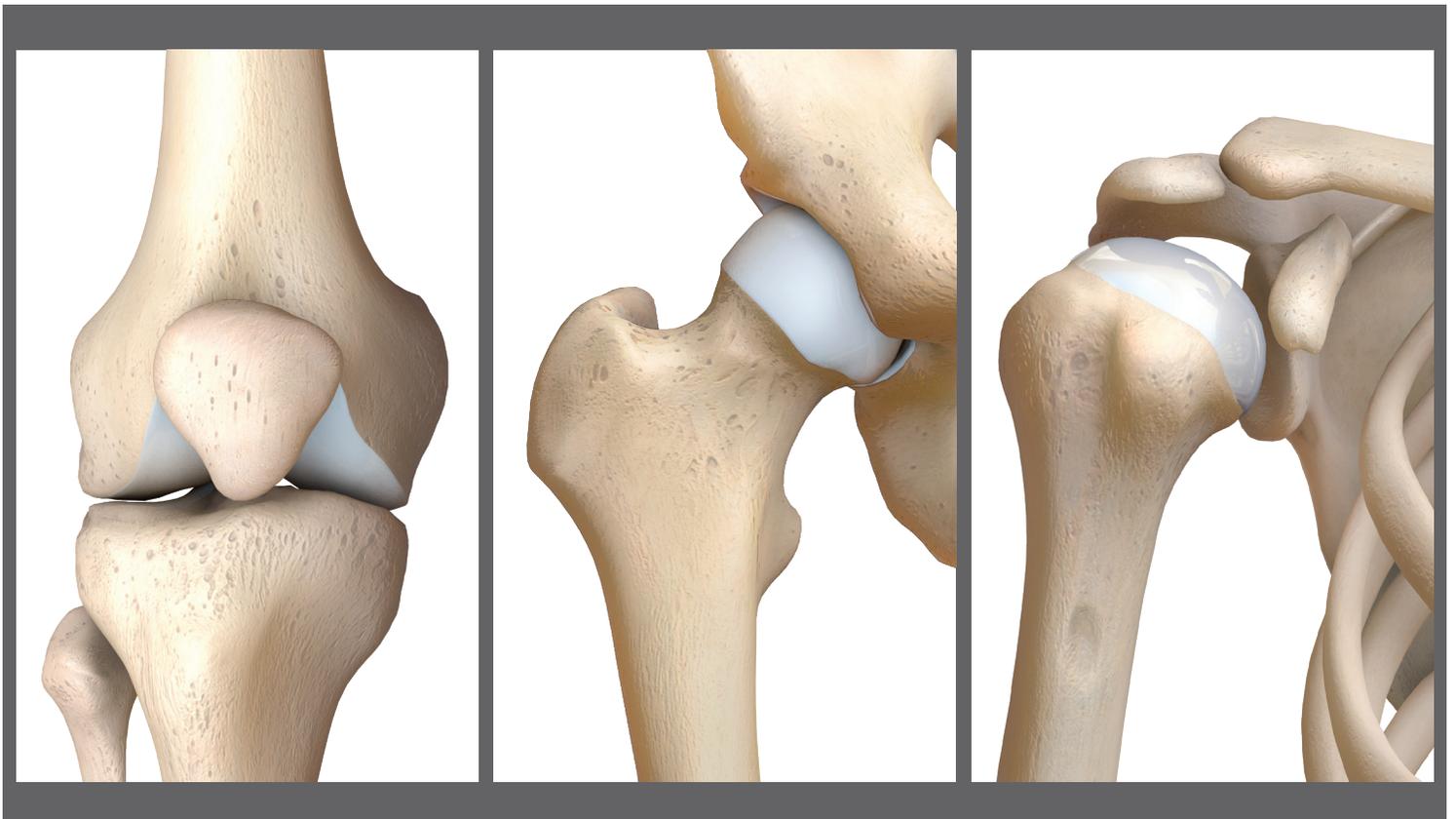


COOLIEF* COOLED RADIOFREQUENCY
CLINICAL RESEARCH SUMMARY:
KNEE, HIP, SHOULDER



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This bibliography includes excerpts from either clinical studies that involve the COOLIEF* Cooled Radiofrequency System or literature which supports the use of the system. It is an abridged grouping of available study excerpts, and readers are advised to review all relevant sources for complete information.

Selection Criteria for Included Study Excerpts:

- Published in peer-reviewed journal;
- Prospective or retrospective comparison with controls; review paper (meta-analysis); or technique paper;
- Published in 1994 or later;
- Includes use of radiofrequency denervation products for approved indications;

This grouping of excerpts aims to include a balance of positive, neutral and negative studies proportional to the number published in the literature. Clinicians are advised to refer to the product Instructions for Use (IFU) for both the device used and medications prescribed for complete information regarding indications, contraindications, cautions and warnings. There are inherent risks in all medical devices. Please refer to the product labeling for Indications, Cautions, Warnings and Contraindications. Failure to follow the product labeling could directly impact patient safety.

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COOLIEF* Knee Cooled Radiofrequency

Cooled radiofrequency system relieves chronic knee osteoarthritis pain: the first case series

Bellini M, Barbieri M. Anaesthesiology Intensive Therapy 2015;47:30-33. Pain Management Unit, San Carlo Clinic, Paderno Dugnano, Milan, Italy.

OBJECTIVE: Knee osteoarthritis is a frequent cause of chronic knee pain. Therapeutic solutions include intra-articular injections with short-term pain relief and surgical therapy. Radiofrequency (RF) of genicular nerves has been previously reported with varying success. Cooling tissue adjacent to the electrode (cooled RF) increases the radius of lesion. We present here the first retrospective data on pain relief and changes in function after such cooled RF denervation.

RESULTS: We observed an improvement in VAS pain scores 2 ± 0.5 at one month, 2.3 ± 0.7 at three months, 2.1 ± 0.5 at six months, and 2.2 ± 0.2 at 12 months after the procedure, and WOMAC score 20 ± 2 , at one month, 22 ± 0.5 at three months, 21 ± 1.7 at six months, and 20 ± 1.0 at 12 months.

CONCLUSION: The majority of patients with chronic knee pain experienced a clinically relevant degree of pain relief and improved function following cooled RF of genicular nerves at one, three, six and 12 months follow-up.

A Prospective, multi-center, randomized, crossover clinical trial comparing the safety and effectiveness of cooled radiofrequency ablation to corticosteroid injection in the management of osteoarthritic knee pain

Timothy Davis, Eric Loudermilk, Michael DePalma, Corey Hunter, David Lindley, Nilesh Patel, Daniel Choi, Marc Soloman, Anita Gupta, Asokumar Buvanendran, Mehul Desai, Leonardo Kapural Orthopedic Pain Specialists

OBJECTIVE: Chronic knee pain from conditions such as osteoarthritis (OA) is a significant cause of disability in the aging patient population. While total joint replacement is a well-established surgical treatment for late stage OA, not all patients are well-suited for this procedure due to issues of age, health, or other factors. Cooled radiofrequency ablation (CRFA) has emerged as a minimally invasive option for pain control for patients with knee OA. This study sought to evaluate the safety and effectiveness of cooled RFA (CRFA) when compared to intraarticular steroid injection (IAS) in an OA knee population.

RESULTS: The two treatment groups were homogenous for demographic, pain and functional parameters at baseline. Mean NRS (Numeric Rating Scale) at Baseline was 7.3 ± 1.2 (Mean \pm SD) for the CRFA group and 7.2 ± 1.0 for the IAS group. One hundred and twenty-six (126) patients remained in the study and were evaluated at 6-months post treatment ($n = 58$ CRFA and 68 IAS). In the CRFA group, 74.1% of patients had $\geq 50\%$ reduction in NRS pain score compared to 16.2% in the IAS group at the 6-month follow up evaluation ($p < 0.0001$, primary endpoint). At 6 months, the mean NRS was 2.5 ± 2.3

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for the CRFA group and 5.9 ± 2.2 for the IAS group ($p < 0.0001$), representing a 4.9 point drop in NRS for the CRFA group. The mean Oxford Knee Score was 35.7 ± 8.8 in the CRFA group at 6 months compared to 22.4 ± 8.5 in the IAS group ($p < 0.0001$). At 6 months, 91.4% of subjects in the CRFA group reported improvement in Global Perceived Effect compared to 23.9% in the IAS group ($p < 0.0001$). No serious adverse events related to either procedure were noted, and overall adverse event profiles were similar.

CONCLUSION: These results demonstrate that cooled RFA is a safe and effective nonnarcotic option for managing pain and improving physical function and quality of life for patients suffering from OA knee pain. CRFA treated patients demonstrated a significant improvement in both pain relief and overall function when compared to patients treated with IAS. Further follow up from this study will evaluate the long-term durability of cooled RFA in this patient population.

Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial

Tim Davis, Eric Loudermilk, Michael DePalma, Corey Hunter, David A Lindley, Nileskumar Patel, Daniel Choi, Marc Soloman, Anita Gupta, Mehul Desai, Elizabeth Cook, Leonardo Kapural.
Regional Anesthesia & Pain Medicine: first published as 10.1136/rapm-2018-100051 on 16 February 2019.

OBJECTIVE: As a follow-up to the 6-month report,¹² this study investigated the analgesic effect of cooled radiofrequency ablation (CRFA) in patients with knee osteoarthritis (OA) 12 months postintervention and its ability to provide pain relief in patients who experienced unsatisfactory effects of intra-articular steroid injection (IAS).

RESULTS: At 12 months, 65% of the original CRFA group had pain reduction $\geq 50\%$, and the mean overall drop was 4.3 points ($p < 0.0001$) on the numeric rating scale. Seventy-five per cent reported 'improved' effects. The cross-over group demonstrated improvements in pain and functional capacity ($p < 0.0001$). No unanticipated adverse events occurred.

CONCLUSION: This study demonstrates that analgesia following CRFA for OA knee pain could last for at least 12 months and could rescue patients who continue to experience intolerable discomfort following IAS

Cooled radiofrequency ablation of the genicular nerves for chronic pain due to knee osteoarthritis: six-month outcomes

Zachary L. McCormick, MD, Marc Korn, MD, Rajiv Reddy, MD, Austin Marcolina, BS, David Dayanim, MD, MS, MHA, Ryan Mattie, MD, Daniel Cushman, MD, Meghan Bhawe, MD, Robert J. McCarthy, PharmD, Dost Khan, MD, Geeta Nagpal, MD, and David R. Walega, MD

OBJECTIVE: Determine outcomes of cooled radiofrequency ablation (C-RFA) of the genicular nerves for treatment of chronic knee pain due to osteoarthritis (OA).

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RESULTS: *Thirty-three patients (52 discrete knees) met inclusion criteria. Thirty-five percent (95% confidence interval [CI] 5 22-48) of procedures resulted in the combined outcome of 50% or greater reduction in NRS score, reduction of 3.4 or more points in MQSIII score, and PGIC score consistent with “very much improved/improved.” Nineteen percent (95%CI 5 10-33) of procedures resulted in complete pain relief. Greater duration of pain and greater than 80% pain relief from diagnostic blocks were identified as predictors of treatment success. The accuracy of the model was 0.88 (95% CI 5 0.78-0.97, P < 0.001).*

CONCLUSION: *Genicular C-RFA demonstrated a success rate of 35% based on a robust combination of outcome measures, and 19% of procedures resulted in complete relief of pain at a minimum of six months of follow-up. Report of 80% or greater relief from diagnostic blocks and duration of pain of less than five years are associated with high accuracy in predicting treatment success. Further prospective study is needed to optimize the patient selection protocol and success rate of this procedure*

Radiofrequency techniques to treat chronic knee pain: a comprehensive review of anatomy, effectiveness, treatment parameters, and patient selection

David E Jamison, Steven P Cohen. Journal of Pain Research 2018;11 1879-1888

OBJECTIVE: *The use of radiofrequency ablation (RFA) procedures to treat chronic knee pain has surged in the past decade, though many questions remain regarding anatomical targets, selection criteria, and evidence for effectiveness. A comprehensive literature review was performed on anatomy, selection criteria, technical parameters, results of clinical studies, and complications.*

RESULTS: *We identified nine relevant clinical trials, which included 592 patients, evaluating knee RFA for osteoarthritis and persistent postsurgical pain. These included one randomized, placebo-controlled trial, one randomized controlled trial evaluating RFA as add-on therapy, four comparative-effectiveness studies, two randomized trials comparing different techniques and treatment paradigms, and one non-randomized, controlled trial. The results of these studies demonstrate significant benefit for both reduction and functional improvement lasting between 3 and 12 months, with questionable utility for prognostic blocks. There was considerable variation in the described neuroanatomy, neural targets, radiofrequency technique, and selection criteria.*

CONCLUSION: *RFA of the knee appears to be a viable and effective treatment option, providing significant benefit to well-selected patients lasting at least 3 months. More research is needed to better identify neural targets, refine selection criteria to include the use of prognostic blocks, optimize treatment parameters, and better elucidate relative effectiveness compared to other treatments.*

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A Prospective Randomized Trial of Prognostic Genicular Nerve Blocks to Determine the Predictive Value for the Outcome of Cooled Radiofrequency Ablation for Chronic Knee Pain Due to Osteoarthritis

Zachary L. McCormick, MD; Rajiv Reddy, MD; Marc Korn, MD; David Dayanim, MD, MS, MHA; Raafay H. Syed, MD; Meghan Bhave, MD; Mikhail Zhukalin, DO; Sarah Choxi, MD; Ali Ebrahimi, MD; Mark C. Kendall, MD; Robert J. McCarthy, PharmD; Dost Khan, MD; Geeta Nagpal, MD; Karina Bouffard, MD, MPH; and David R. Walega, MD, MSCI. Pain Medicine, 2017; 0:1-11.

OBJECTIVE: *Genicular nerve radiofrequency ablation is an effective treatment for patients with chronic pain due to knee osteoarthritis; however, little is known about factors that predict procedure success. The current study evaluated the utility of genicular nerve blocks to predict the outcome of genicular nerve cooled radiofrequency ablation (cRFA) in patients with osteoarthritis.*

RESULTS: *Twenty-nine participants (36 knees) had cRFA following a prognostic block, and 25 patients (35 knees) had cRFA without a block. Seventeen participants (58.6%) in the prognostic block group and 16 (64.0%) in the no block group had >50% pain relief at six months (P50.34). A 15-point decrease in the Western Ontario and McMaster Universities Osteoarthritis Index at six months was present in 17 of 29 (55.2%) in the prognostic block group and 15 of 25 (60%) in the no block group (P50.36).*

CONCLUSION: *This study demonstrated clinically meaningful improvements in pain and physical function up to six months following cRFA. A prognostic genicular nerve block using a local anesthetic volume of 1mL at each injection site and a threshold of >50% pain relief for subsequent cRFA eligibility did not improve the rate of treatment success.*

Long-Term Retrospective Assessment of Clinical Efficacy of Radiofrequency Ablation of the Knee Using a Cooled Radiofrequency System

Leonardo Kapural, MD, PhD¹, Nicholas Lee¹, Kevin Neal, MD, and Michael Burchell, MD. Pain Physician, 2019; 22:489-494.

OBJECTIVE: *This large, real-life, retrospective study evaluated the long-term effectiveness of CRFA in the general chronic knee pain population.*

RESULTS: *The average age of the 183 patients was 61 (28-95) years, body mass index 34 (18.5-57), and there were 105 women and 78 men. A total of 137 patients had unilateral knee pain, whereas 46 patients had bilateral knee pain. Eighty percent (146/183) reported at least one or more additional sources of chronic pain (back, shoulder, and others). The average opioid use at baseline was 50 mg morphine sulfate equivalents (median 30 mg). The average baseline pain scores were 8.5, which decreased to 2.2 after the geniculate local anesthetic block, and to 4.2 after CRFA. A total of 65% of the patients claimed > 50% pain relief, whereas 77% had 2 or more Visual Analog Scale points decrease, and 26 (14%) patients reported no pain at all after CRFA. The mean duration of > 50% pain relief after CRFA was 12.5 months (range 0-35 months). There was no significant*

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decrease of opioid use. Patients who underwent a repeated procedure (n = 43) achieved a similar pain relief (P = 0.402). We could not find a statistical difference in geniculate CRFA outcomes between the group who had total knee arthroplasty (TKA; n = 21) and maintained chronic knee pain and patients who had no prior surgery (P = 0.542).

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COOLIEF* Hip Cooled Radiofrequency

Cooled radiofrequency neurotomy of the articular sensory branches of the obturator and femoral nerves – combined approach using fluoroscopy and ultrasound guidance: technical report, and observational study on safety and efficacy

Leonardo Kapural, MD, PhD, Suneil Jolly, MD, Joao Mantoan, MD, Harish Badhey, MD, and Ty Ptacek, MD.

OBJECTIVE: We describe a novel anterior approach to cooled radiofrequency (RF) hip denervation under combined ultrasound (US) and fluoroscopy guidance to avoid the neurovascular femoral bundle and reach proper landmarks.

RESULTS: A total of 62 patients underwent 2 diagnostic blocks. Fifty-two of them had greater than 50% relief and agreed to RF ablation. Until now, the ablation was conducted in 23 patients. There were no adverse events, except one case of neuritis. Expectedly, the needle approach to the lateral articular branches of the femoral nerve was easily achieved with more than a 1 cm passage distance from the femoral nerve in all 52 RF cases (median) 2.5 range 1-3.5 cm). Placement of the second trocar to the incisura acetabuli was more challenging; in 21 RF cases the passing distance was less than 1 cm (range 0.5 to 1.9 cm, median 0.8). Motor stimulation (2 Hz) at less than 1 V was positive for the obturator nerve in 26 cases, which resulted in electrode repositioning more laterally (2-5 mm). Change in the pain scores was from the baseline 7.61 ± 1.2 to 2.25 ± 1.4 after the RF ablation ($P < 0.01$). The time interval of pain relief was much longer for RF ablation.

CONCLUSION: An anterior needle approach to the lateral articular branches of the femoral and obturator nerves, and subsequently RF denervation of these nerves, is a safe procedure when US needle guidance is combined with identification of landmarks using fluoroscopy.

Clinical efficacy assessment of cooled radiofrequency ablation of the hip in patients with avascular necrosis. Case Series.

Jeremy Naber; Nicholas Lee & Leonardo Kapural. Pain Management, online June 19, 2019.

OBJECTIVE: This pilot case series examined feasibility of anterior radiofrequency approach under combined ultrasound and fluoroscopy guidance to control pain from avascular necrosis of the hip.

RESULTS: The average age was 56 (28-66), BMI 29.5 (16.5-34), in four women and three men. Their average opioid use was 92 mg MSO4 equivalents (median 35 mg). The pain score decreased to 3.3 after the CRFA. Five patients claimed more than 50% of pain relief. The average time interval of greater than 50% of pain relief from the CRFA was 70-250 days.

CONCLUSION: CRFA may be an effective treatment of chronic pain from avascular necrosis.

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COOLIEF* Shoulder Cooled Radiofrequency

Cadaveric Study of the Articular Branches of the Shoulder Joint

M. Eckmann MD, B. Bickelhaupt MD, J. FehI MD, J. Benfield DO, J. Curley MD, O. Rahimi PhD, A. Nagpal MD, MS, Med. Regional Anesthesia and Pain Medicine 2017;42:5.

OBJECTIVE: *The purpose of this cadaveric study was to investigate the anatomic relationships of the articular branches of the suprascapular (SN), axillary (AN), and lateral pectoral nerves (LPN), which are potential targets for shoulder analgesia.*

RESULTS: *Thirty-three shoulders from 17 total cadavers were studied. In a series of 16 shoulders, 16 (100%) of 16 had an intact SN branch innervating the posterior head of the humerus and shoulder capsule. Suprascapular sensory branches coursed laterally from the spinoglenoid notch then toward the glenohumeral joint capsule posteriorly. Axillary nerve articular branches innervated the posterolateral head of the humerus and shoulder capsule in the same 16 (100%) of 16 shoulders. The AN gave branches ascending circumferentially from the quadrangular space to the posterolateral humerus, deep to the deltoid, and inserting at the inferior portion of the posterior joint capsule. In 4 previously dissected and 17 distinct shoulders, intact LPNs could be identified in 14 (67%) of 21 specimens. Of these, 12 (86%) of 14 had articular branches innervating the anterior shoulder joint, and 14 (100%) of 14 LPN articular branches were adjacent to acromial branches of the thoracoacromial blood vessels over the superior aspect of the coracoid process.*

CONCLUSION: *Articular branches from the SN, AN, and LPN were identified. Articular branches of the SN and AN insert into the capsule overlying the glenohumeral joint posteriorly. Articular branches of the LPN exist and innervate a portion of the anterior shoulder joint.*

Anatomical study of the innervation of glenohumeral and acromioclavicular joint capsules: implications for image-guided intervention

John Tran, Philip W H Peng, Anne M R Agur. Regional Anesthesia & Pain Medicine: first published as 10.1136/rapm-2018-100152 on 11 January 2019.

OBJECTIVE: *The purpose of this cadaveric study was to determine the origin, course, relationships to bony landmarks, and frequency of articular branches innervating the glenohumeral and acromioclavicular joints.*

RESULTS: *In all specimens, the posterosuperior quadrant of the glenohumeral joint was supplied by suprascapular nerve; posteroinferior by posterior division of axillary nerve; anterosuperior by superior nerve to subscapularis; and anteroinferior by main trunk of axillary nerve. Less frequent innervation was found from lateral pectoral nerve and posterior cord. The acromioclavicular joint was found to be innervated by the lateral pectoral and acromial branch of suprascapular nerves in all specimens. Bony and soft tissue landmarks were identified to localize each nerve.*

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CONCLUSION: *The frequency map of the articular branches supplying the glenohumeral and acromioclavicular joints, as well as their relationship to bony and soft tissue landmarks, provide an anatomical foundation to develop novel shoulder denervation and perioperative pain management protocols*

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