

CLINICAL RESEARCH SUMMARY

COOLIEF* SINERGY* Sacroiliac Cooled Radiofrequency
COOLIEF* TRANSDISCAL* Disc Biacuplasty Cooled Radiofrequency
COOLIEF* Thoracic Cooled Radiofrequency
COOLIEF* Knee Cooled Radiofrequency
COOLIEF* Hip Cooled Radiofrequency
GENERAL

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Table of Contents

COOLIEF* SINERGY* Sacroiliac Cooled Radiofrequency.....7

Cohen SP, et al, Anesthesiology 2008; <i>Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain</i>	7
Kapur L, et al, Pain Medicine 2008; <i>Cooled radiofrequency system for the treatment of chronic pain from sacroiliitis: the first case-series</i>	7
Cohen SP, et al, Regional Anesthesia and Pain Medicine 2009; <i>Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation</i>	8
Kapur L, et al, Pain Medicine 2010; <i>Cooled radiofrequency (RF) of L5 dorsal ramus for RF denervation of the sacroiliac joint: technical report</i>	9
Vanelderen P, et al, Pain Practice 2010; <i>Sacroiliac joint pain</i>	9
Karaman H, et al, Acta Neurochirurgica 2011; <i>Cooled radiofrequency application for treatment of sacroiliac joint pain</i>	10
Patel N, et al, Pain Medicine 2012; <i>A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain</i>	11
Cheng, J, MD, PhD, et al, The Clinical Journal of Pain 2013; <i>Comparative outcomes of cooled versus traditional radiofrequency ablation of the lateral branches for sacroiliac joint pain</i>	11
Ho KY, et al, Journal of Pain Research 2013; <i>Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases</i>	12
Ramasubba C, et al, Pain Physician 2013; <i>Cooled sacroiliac radiofrequency denervation for the treatment of pain secondary to tumor infiltration: a case-based focused literature review</i>	12
Stelzer W, et al, Pain Medicine 2013; <i>Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series</i>	13
Cox Rachel, et al, Pain Physician 2014; <i>The Anatomy of the Lateral Branches of the Sacral Dorsal Rami: Implications for Radiofrequency Ablation</i>	13
Roberts SL, et al, Regional Anesthesia and Pain Medicine 2014; <i>Cadaveric study of sacroiliac joint innervation: implications for diagnostic blocks and radiofrequency ablation</i>	14
Stolzenberg D, et al, Pain Medicine 2014; <i>Incidence of neuropathic pain after cooled radiofrequency ablation of sacral lateral branch nerves</i>	14
Patel N, Pain Practice 2015; <i>Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac region pain</i>	15

Simopoulos TT1, et al, Pain Physician 2015; <i>Systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions</i>	15
Biswas, B, et al, Journal of Anaesthesiology Clinical Pharmacology 2016; <i>Water-cooled radiofrequency neuroablation for sacroiliac joint dysfunctional pain</i>	16
Cheng, J, MD, PhD, et al, Pain Physician 2016; <i>A new radiofrequency ablation procedure to treat sacroiliac joint pain</i>	17
Stelzer, W, et al, Journal of Pain Research 2017; <i>Influence of BMI, gender, and sports on pain decrease and medication usage after facet–medial branch neurotomy or SI joint lateral branch cooled RF-neurotomy in case of low back pain: original research in the Austrian population</i>	17
Tinnirello, A, MD, et al, Pain Medicine 2017; <i>Conventional (Simplicity III) and cooled (SInergy) radiofrequency for sacroiliac joint denervation: one-year retrospective study comparing two devices</i>	18
Sun H, et al, Medicine 2018; <i>The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain</i>	19

COOLIEF* TRANSDISCAL* Disc Biacuplasty Cooled Radiofrequency 20

Kapural L, et al, Pain Practice 2007; <i>Novel intradiscal biacuplasty (IDB) for the treatment of lumbar discogenic pain</i>	20
Kapural L, et al, Pain Medicine 2008; <i>Histological changes and temperature distribution studies of a novel bipolar radiofrequency heating system in degenerated and nondegenerated human cadaver lumbar discs</i>	20
Kapural L, et al, Pain Medicine 2008; <i>Intervertebral disc biacuplasty for the treatment of lumbar discogenic pain: results of a six-month follow-up</i>	21
Pauza K, MD, Pain Physician 2008; <i>Cadaveric intervertebral disc temperature mapping during disc biacuplasty</i>	21
Petersohn JD, et al, Pain Medicine 2008; <i>Acute histologic effects and thermal distribution profile of disc biacuplasty using a novel water-cooled bipolar electrode system in an in vivo porcine model</i>	22
Kapural L, et al, Pain Practice 2009; <i>Successful treatment of lumbar discogenic pain using intradiscal biacuplasty in previously discectomized disc</i>	22
Karaman H, et al, International Journal of Medical Sciences 2010; <i>6-month results of TransDiscal Biacuplasty on patients with discogenic low back pain: preliminary findings</i>	23
Kapural L, et al, Pain Medicine 2014; <i>Radiofrequency intradiscal biacuplasty for treatment of discogenic lower back pain: a 12-month follow-up</i>	23
Lu Y, et al, Spine 2014; <i>Nonoperative management of discogenic back pain. A systematic review</i>	24

Desai MJ, et al, Pain Physician 2015; <i>Intervertebral disc temperature mapping during disc biacuplasty in the human cadaver</i>	24
Desai MJ, et al, Spine 2015; <i>A prospective, randomized, multi-center, open-label clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain</i>	25
Desai MJ, et al, Pain Medicine 2016; <i>Twelve-month follow-up of a randomized clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain</i>	26
Helm S, et al, Pain Physician 2017; <i>Effectiveness of Thermal Annular Procedures in Treating Discogenic Low Back Pain</i>	26

COOLIEF* Thoracic Cooled Radiofrequency..... 28

Mekhail N, et al, Clinical Journal of Pain 2011; <i>Temperature mapping of cooled radiofrequency lesion of human cadaver thoracic facet medial branches</i>	28
Walega D, Pain Practice 2014; <i>Third-degree burn from cooled radiofrequency ablation of medial branch nerves for treatment of thoracic facet syndrome</i>	28

COOLIEF* Knee Cooled Radiofrequency 30

Dellon A, et al, Plastic and Reconstructive Surgery 2009; <i>Partial joint denervation II: knee and ankle</i>	30
Bellini M, et al, Anaesthesiology Intensive Therapy 2015; <i>Cooled radiofrequency system relieves chronic knee osteoarthritis pain: the first case-series</i>	30
Franco CD, et al, Regional Anesthesia and Pain Medicine 2015; <i>Innervation of the anterior capsule of the human knee: implications for radiofrequency ablation</i>	31
Menzies RD, Pain Practice 2015; <i>Analgesia and improved performance in a patient treated by cooled radiofrequency for pain and dysfunction post-bilateral total knee replacement</i>	32
Farrell M, et al, PM&R 2016; <i>Demonstration of lesions produced by cooled radiofrequency neurotomy for chronic osteoarthritic knee pain: a case report</i>	32
Reddy R, et al, Anesthesiology and Pain Med 2016; <i>Cooled radiofrequency ablation of genicular nerves for knee osteoarthritis pain: a protocol for patient selection and case series</i>	33
Rojhani S, et al, American Journal of Physical Medicine and Rehabilitation, 2016; <i>Water-cooled radiofrequency provides pain relief, decreases disability, and improves quality of life in chronic knee osteoarthritis</i>	33

Alberca A, et al, Clin Trials Degener Dis. 2017; <i>Pain treatment with cooled radiofrequency in osteoarthritis and total knee arthroplasty: case series in Hospital Universitario de Son Espases</i>	34
Davis T, et al, RAPM 2017; <i>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</i>	34
McCormick Z, MD, et al, Pain Medicine 2017; <i>Cooled radiofrequency ablation of the genicular nerves for chronic pain due to knee osteoarthritis: six-month outcomes</i>	35
McCormick Z, MD et al, Pain Medicine 2017; <i>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</i>	36
Walega D, MD et al, Pain Medicine 2017; <i>Third-Degree Skin Burn from Conventional Radiofrequency Ablation of the Inferiomedial Genicular Nerve</i>	37

COOLIEF* Hip Cooled Radiofrequency 38

Kim D, MD, MS, et al, Pain Physician 2017; <i>Ultrasound-guided radiofrequency lesioning of the articular branches of the femoral nerve for the treatment of chronic post-arthroplasty hip pain</i>	38
Kapural L, et al, Pain Physician 2018; <i>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</i>	38

GENERAL 40

Ball RD, Pain Physician 2014; <i>The science of conventional and water-cooled monopolar lumbar radiofrequency rhizotomy: an electrical engineering point of view</i>	40
Salmasi V, et al, Techniques in Regional Anesthesia and Pain Medicine 2014; <i>Application of cooled radiofrequency ablation in management of chronic joint pain</i>	40
Vallejo R, et al, Regional Anesthesia and Pain Medicine 2014; <i>An ex vivo comparison of cooled-radiofrequency and bipolar-radiofrequency lesion size and the effect of injected fluids</i>	41
Wang H, MD, et al, Spine 2016; <i>Effects of anesthetic fluid injectates on lesion sizes in cooled radiofrequency ablation</i>	42
Cedeno D, et al, Pain Physicians 2017; <i>Comparisons of Lesion Volumes and Shapes Produced by a Radiofrequency System with a Cooled, a Protruding, or a Monopolar Probe</i>	42

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

This bibliography includes excerpts from either clinical studies that involve the Halyard Health 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;
- Search terms: cooled radiofrequency, low back pain, sacroiliac joint, biacuplasty, lumbar medial branch, lumbar zygapophysial joint pain, thoracic facet joint pain.

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.

COOLIEF* SINERGY* Sacroiliac Cooled Radiofrequency

Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain

Cohen SP, Hurley RW, Buckenmaier CC 3rd, Kurihara C, Morlando B, Dragovich A. Anesthesiology 2008;109:279-288.

Department of Anesthesiology and Critical Care Medicine, Johns Hopkins School of Medicine, Baltimore, MD.

BACKGROUND: *Sacroiliac joint pain is a challenging condition accounting for approximately 20% of cases of chronic low back pain. Currently, there are no effective long-term treatment options for sacroiliac joint pain.*

RESULTS: *One, 3, and 6 months after the procedure, 11 (79%), 9 (64%), and 8 (57%) radiofrequency-treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the crossover group (n = 11), 7 (64%), 6 (55%), and 4 (36%) experienced improvement 1, 3, and 6 months after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief.*

CONCLUSION: *These results provide preliminary evidence that L4 and L5 primary dorsal rami and S1-S3 lateral branch radiofrequency denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain. Larger studies are needed to confirm these results and to determine the optimal candidates and treatment parameters for this poorly understood disorder.*

Cooled radiofrequency system for the treatment of chronic pain from sacroiliitis: the first case-series

Kapural L, Nageeb F, Kapural M, Cata JP, Narouze S, Mekhail N. Pain Medicine 2008;11:53-57.

Department of Pain Management, Cleveland Clinic, Cleveland, OH.

BACKGROUND AND OBJECTIVES: *Sacroiliitis and sacroiliac (SI) joint dysfunction are frequent causes of the chronic lower back pain. Therapeutic solutions include intra-articular injections with short-term pain relief and surgical fusion, which appears ineffective. Radiofrequency (RF) of the joint capsule or lateral branches has been previously reported with variable successes. Cooling tissue adjacent to the electrode (cooled RF) increases the*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

radius of lesion. We present here the first retrospective data on pain relief and changes in function after such RF denervation. We reviewed electronic records of 27 patients with chronic low back pain (median 5 years) who underwent cooled RF of S1, S2, and S3 lateral branches and of dorsal ramus (DR) L5 following two diagnostic SI joint blocks (>50% of pain relief). Patient sample consisted of 20 women and 7 men, 38 to 92 years old. Pain disability index (PDI), visual analog scale (VAS) pain scores, global patient satisfaction (GPE) and opioid use before and 3-4 months after the procedure were analyzed. One patient had an incomplete chart. Observed were improvements in function (PDI) from 32.7 +/- 9.9 to 20.3 +/- 12.1 (P < 0.001) and VAS pain scores 7.1 +/- 1.6 to 4.2 +/- 2.5 (P < 0.001) at 3-4 months after the procedure. Opioid use decreased from median 30 to 20 mg morphine equivalent. Eighteen patients rated their improvement in pain scores using GPE as improved or much improved, while eight claimed minimal or no improvement. The majority of patients with chronic SI joint pain experienced a clinically relevant degree of pain relief and improved function following cooled RF of sacral lateral branches and DR of L5 at 3-4 months follow-up.

Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation

Cohen SP, Strassels SA, Kurihara C, Crooks MT, Erdek MA, Forsythe A, Marcuson M. Regional Anesthesia and Pain Medicine 2009;34:206-214.

Department of Anesthesiology & Critical Care Medicine, Johns Hopkins School of Medicine, Baltimore, MD.

BACKGROUND AND OBJECTIVE: *Sacroiliac (SI) joint pain is a challenging condition characterized by limited treatment options. Recently, numerous studies have reported excellent intermediate-term outcomes after lateral-branch radiofrequency (RF) denervation, but these studies are characterized by wide variability in technique, selection criteria, and patient characteristics. The purpose of this study was to determine whether any demographic or clinical variables can be used to predict SI joint RF denervation outcome.*

RESULTS: *Forty patients (52%) obtained a positive outcome. In multivariate analysis, preprocedure pain intensity, age older than 65 years, and pain radiating below the knee were significant predictors of failure. A trend was noted whereby patients receiving regular opioid therapy were more likely to experience a negative outcome. The use of cooled, rather than conventional RF, was associated with a higher percentage of positive outcomes.*

CONCLUSION: *Whereas several factors were found to influence outcome, no single clinical variable reliably predicted treatment results. The use of more stringent selection criteria was not associated with better outcomes.*

Cooled radiofrequency (RF) of L5 dorsal ramus for RF denervation of the sacroiliac joint: technical report

Kapural L, Stojanovic M, Sessler DI, Bensitel T, Zovkic P. Pain Medicine 2010;11:1874.

Department of Pain Management, Cleveland Clinic, Cleveland, OH.

BACKGROUND AND OBJECTIVES: *The sacroiliac joint is a common source of chronic low back pain. We recently described the use of cooled radiofrequency (RF) electrodes for performing lateral branch neurotomy to treat sacroiliac joint pain. The procedure involves lesioning the lateral branches of the posterior primary rami at S1-S3, and the L5 dorsal ramus (L5DR). While the cooled RF electrode has been adopted as a means for lesioning the lateral branches, conventional RF electrodes are used to lesion the L5DR. The objective of this technical report is to evaluate the acute safety of denervating the L5DR using cooled RF electrode.*

RESULTS: *Of 100 procedures 82 were completed using cooled electrode for sacral lateral branches and L5DR. Of the 82 procedures completed using cooled RF to L5DR, 24 were reported to be of high difficulty and 19 with poor visualization (bowel gas). There were no major complications related to the procedure. Four patients reported increased pain: two from the conventional RF of L5DR group and two from the cooled RF group. All of the pains were transient and returned to the baseline within 6 weeks. There were two patients experiencing localized numbness over the upper medial quadrant of the buttock, both in cooled RF group. There was no reported weakness of the lower extremity. Two patients complained of increased lower back pain and two of prolonged itching.*

CONCLUSION: *This review demonstrates the acute safety of using cooled RF for L5DR denervation with no report of significant or unusual patient complications. To establish frequency of complication associated with the treatment, a larger registry is required.*

Sacroiliac joint pain

Vanelderden P, Szadek K, Cohen SP, De Witte J, Lataster A, Patijn J, Mekhail N, van Kleef M, Van Zundert J. Pain Practice 2010;10:470-478.

Department of Anesthesiology, Intensive Care Medicine, Multidisciplinary Pain Centre, Ziekenhuis Oost-Limburg, Genk, Belgium.

The sacroiliac joint accounts for approximately 16% to 30% of cases of chronic mechanical low back pain. Pain originating in the sacroiliac joint is predominantly perceived in the gluteal region, although pain is often referred into the lower and upper lumbar region, groin, abdomen, and/or lower limb(s). Because sacroiliac joint pain is difficult to distinguish from other forms of low back pain based on history, different provocative maneuvers have been advocated. Individually, they have weak predictive value, but combined batteries of tests can help ascertain a diagnosis. Radiological imaging is important to exclude "red

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

flags” but contributes little in the diagnosis. Diagnostic blocks are the diagnostic gold standard but must be interpreted with caution, because false-positive as well as false-negative results occur frequently. Treatment of sacroiliac joint pain is best performed in the context of a multidisciplinary approach. Conservative treatments address the underlying causes (posture and gait disturbances) and consist of exercise therapy and manipulation. Intra-articular sacroiliac joint infiltrations with local anesthetic and corticosteroids hold the highest evidence rating (1 B+). If the latter fail or produce only short-term effects, cooled radiofrequency treatment of the lateral branches of S1 to S3 (S4) is recommended (2 B+) if available. When this procedure cannot be used, (pulsed) radiofrequency procedures targeted at L5 dorsal ramus and lateral branches of S1 to S3 may be considered (2 C+).

Cooled radiofrequency application for treatment of sacroiliac joint pain

Karaman H, Kavak GO, Tüfek A, Çelik F, Yildirim ZB, Akdemir MS, Tokgöz O. Acta Neurochirurgica 2011;153:1461-1468.

Pain Management Center, Department of Anesthesiology, Dicle University, 21280 Diyarbakir, Turkey.

BACKGROUND: *The unavailability of an effective and long-lasting treatment for sacroiliac-based pain has led researchers to study the efficacy of radiofrequency in denervation. In this study, we aimed to investigate the efficacy and safety of novel cooled radiofrequency application for sacral lateral-branch denervation.*

RESULTS: *Cooled radiofrequency was applied on a total of 15 patients. Prior to the procedures, the median VAS score (interquartile range) was 8 (7-9), but at the 1st, 3rd and 6th month, this had fallen to 3 (1-4), 2 (1-3) and 3 (2-4). The baseline median ODI score (interquartile range) was 36 (32-38), while at the 1st, 3rd and 6th month, it was 16 (8-20), 12 (9-18) and 14 (10-20), respectively. At the final control, while 80% of the patients reported at least a 50% decline in pain scores, 86.7% of those reported at least a ten-point reduction in ODI scores.*

CONCLUSION: *It was seen that the cooled radiofrequency used for sacroiliac denervation was an effective and safe method in the short to intermediate term.*

A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain

Patel N, Gross A, Brown L, Gekht G. Pain Medicine 2012;13:383-398.

Advanced Pain Management, Green Bay, WI.

OBJECTIVE: *The objective of this study was to compare the efficacy of lateral branch neurotomy using cooled radiofrequency to a sham intervention for sacroiliac joint pain.*

RESULTS: *Statistically significant changes in pain, physical function, disability, and quality of life were found at 3-month follow-up, with all changes favoring the lateral branch neurotomy group. At 3-month follow-up, 47% of treated patients and 12% of sham subjects achieved treatment success. At 6 and 9 months, respectively, 38% and 59% of treated subjects achieved treatment success.*

CONCLUSION: *The treatment group showed significant improvements in pain, disability, physical function, and quality of life as compared with the sham group. The duration and magnitude of relief was consistent with previous studies, with current results showing benefits extending beyond 9 months.*

Comparative outcomes of cooled versus traditional radiofrequency ablation of the lateral branches for sacroiliac joint pain

Jianguo Cheng, MD, PhD, Jason E. Pope, MD, Jarrod E. Dalton, MA, wz Olivia Cheng, BA, and Albatoul Bensitel, MDz, *Clin J Pain* 2013;29:132–137

OBJECTIVE: *Sacroiliac joint pain is a common cause of low back pain (LBP). Cooled radiofrequency ablation (c-RFA) of the lateral branches was recently introduced with the hypothesis that it creates larger lesions to overcome the anatomic variability of the lateral branches and achieve better outcomes as compared with the traditional radiofrequency approach (t-RFA). The objective of this comparative study is to determine if c-RFA is superior over t-RFA in providing longer pain relief.*

RESULTS: *Among the 88 patients, 30 received t-RFA and 58 received c-RFA. We did not find a significant univariable relationship between RFA technique and duration of pain relief either before ($P=0.76$, Sun test) or after ($P=0.95$, Wald test) adjusting for the potentially confounding variables. Both cooled and traditional RFAs provided >50% pain reduction for 3 to 6 months in majority of the patients.*

CONCLUSION: *This study did not reveal evidence that c-RFA of the lateral branches provides longer relief of sacroiliac joint pain as compared with t-RFA.*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases

Ho KY, Hadi MA, Pasutharnchat K, Tan KH. Journal of Pain Research 2013;6:505-511.

Pain Management Centre, Raffles Hospital, Singapore.

BACKGROUND: *Sacroiliac joint pain is a common cause of chronic low back pain. Different techniques for radiofrequency denervation of the sacroiliac joint have been used to treat this condition. However, results have been inconsistent because the variable sensory supply to the sacroiliac joint is difficult to disrupt completely using conventional radiofrequency. Cooled radiofrequency is a novel technique that uses internally cooled radiofrequency probes to enlarge lesion size, thereby increasing the chance of completely denervating the sacroiliac joint. The objective of this study was to evaluate the efficacy of cooled radiofrequency denervation using the SInergy™ cooled radiofrequency system for sacroiliac joint pain.*

RESULTS: *Fifteen of 20 patients showed a significant reduction in pain (a decrease of at least three points on the Numeric Rating Scale). Mean Numeric Rating Scale for pain decreased from 7.4 ± 1.4 to 3.1 ± 2.5 , mean Patient Global Impression of Change was "improved" (1.4 ± 1.5), and Global Perceived Effect was reported to be positive in 16 patients at two years following the procedure.*

CONCLUSION: *Cooled radiofrequency denervation showed long-term efficacy for up to two years in the treatment of sacroiliac joint pain.*

Cooled sacroiliac radiofrequency denervation for the treatment of pain secondary to tumor infiltration: a case-based focused literature review

Ramasubba C, Cohen SP. Pain Physician 2013;16:1-8.

Johns Hopkins School of Medicine, Baltimore, MD.

OBJECTIVE: *To describe a patient with terminal breast cancer and tumor infiltration of the sacroiliac joint who was treated with cooled RF of the sacral lateral branches as an end-of-life palliative measure. The objectives of this review are to provide insight into the innervation of the SI joint; address controversial issues surrounding the targeted nerves in a patient with transitional anatomy; outline risk-mitigation strategies; and highlight the need for individually tailored treatment plans.*

RESULTS: *Treatment was tailored to facilitate the rapid treatment of this terminal patient by performing the prognostic blocks and RF ablation at the same visit. Until her death 5 days post-procedure, the patient reported significant pain relief and began to ambulate and use the bathroom on her own, activities she could not do before treatment. In addition to functional improvement, she was also able to significantly reduce her opioid intake.*

CONCLUSION: *This is the first report of cooled SI joint RF ablation to treat cancer pain. Our patient's positive response to the procedure suggests the possibility that the lateral branches innervate not only the posterior ligaments, but also the bony articulation. The decision to proceed with RF ablation on the same day as a prognostic lateral branch block was based on our patient's terminal condition, and the fact that cooled RF does not require sensory stimulation to ensure proximity to the target nerves. Because of her transitional anatomy, we elected to target L4.*

Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series

Stelzer W, Aiglesberger M, Stelzer D, Stelzer V. Pain Medicine 2013;14:29-35. Medizinisches Zentrum SchmerzLOS, Baden/Vienna, Austria.

OBJECTIVE: *To retrospectively evaluate the use of cooled RF lateral branch neurotomy (LBN) to treat chronic SIJ-mediated low back pain in a large European study population.*

RESULTS: *When stratified by time to final follow-up (4-6, 6-12, and >12 months, respectively): 86%, 71%, and 48% of subjects experienced \geq 50% reduction in VAS pain scores, 96%, 93%, and 85% reported their quality of life as much improved or improved, and 100%, 62%, and 67% of opioid users stopped or decreased use of opioids.*

CONCLUSION: *The current results show promising, durable improvements in pain, quality of life, and medication usage in a large European study population, with benefits persisting in some subjects at 20 months after treatment. These results are consistent with previous study findings on the use of cooled RF to treat SIJ-mediated low back pain.*

The anatomy of the lateral branches of the sacral dorsal rami: implications for radiofrequency ablation

Rachel C Cox, BA1 and Joseph D Fortin, DO2

OBJECTIVE: *Our objective was to clarify the lateral branches' innervation of the SIJ and their specific locations in relation to the dorsal sacral foramina, which are the standard RFA landmark.*

RESULTS: *There was a broad range of exit points from the dorsal sacral foramina: ranging from 12:00 – 6:00 position on the right side and 6:00 – 12:00 on the left positions. Nine of 12 of the hemipelvises showed anastomosing branches from L5 dorsal rami to the S1 lateral plexus.*

CONCLUSION: *Widespread variability of lateral branch exit points from the dorsal sacral foramen and possible contributions from L5 dorsal rami and superior gluteal nerve were*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

disclosed by the current study. Hence, SIJ RFA treatment approaches need to incorporate techniques which address the diverse SIJ innervation.

Cadaveric study of sacroiliac joint innervation: implications for diagnostic blocks and radiofrequency ablation

Roberts SL, Burnham RS, Ravichandiran K, Agur AM, Loh EY. Regional Anesthesia and Pain Medicine 2014;39:456-464.

Department of Anatomy, Department of Surgery, University of Toronto, Toronto, Ontario, Canada.

BACKGROUND AND OBJECTIVES: *Optimization of clinical outcomes of lateral branch radiofrequency ablation or blocks for sacroiliac joint (SIJ) pain requires precise nerve localization; however, there is a lack of comprehensive morphological studies. The objectives of this cadaveric study were to document SIJ innervation relative to bony landmarks in 3 dimensions and to identify reference points visible under ultrasound and fluoroscopy for optimal needle placement.*

RESULTS: *The SIJ was innervated by the posterior sacral network: S1-S2 contributed in all specimens, S3 in 88%, L5 in 8%, and S4 in 4%. Most frequently, the lateral branch(es) emerged from the inferolateral S1, superolateral and inferolateral S2, and superolateral S3 quadrants. All TSTs were easily identifiable elevations that were used to landmark the nerves innervating the SIJ. The majority of branches of the posterior sacral network crossed the lateral sacral crest between TST1-3, with the greatest concentration between TST2-3. Only 3 specimens had a branch superior or inferior to these landmarks.*

CONCLUSION: *Based on the innervation pattern and using bony landmarks identifiable under ultrasound and fluoroscopy, 2 radiofrequency ablation techniques were proposed. Further research is required to determine the accuracy and reliability of needle placement and to evaluate clinical outcomes.*

Incidence of neuropathic pain after cooled radiofrequency ablation of sacral lateral branch nerves

Stolzenberg D, Gordin V, Vorobeychik Y. Pain Medicine 2014;15:1857-1860.

Department of Anesthesiology, Penn State Medical Center, Hershey, PA.

OBJECTIVE: *To determine the incidence of neuropathic pain after cooled radiofrequency ablation (RFA) of the sacral lateral branches for the treatment of chronic posterior sacroiliac joint complex pain.*

RESULTS: *Forty-eight separate procedures were performed, with a total of 193 levels and 430 lesions. Three patients had transient postprocedure neuropathic pain yielding a 0.7%*

(95% confidence interval [CI] \pm 0.4%) rate of this complication per lesion. This proportion increases to 6.2% (95% CI \pm 3.5%) per procedure and to 9.4% (95% CI \pm 5.2%) per patient.

CONCLUSION: *The incidence of postprocedural neuropathic pain after cooled RFA for posterior sacroiliac joint complex denervation is low and in a similar range to that in the lumbar spine. We consider this procedure safe to be utilized by pain medicine practitioners.*

Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac region pain

Patel N. Pain Practice 2016;16:154-167.

Advanced Pain Management, Green Bay, Brown County, Wisconsin, U.S.A; Orthopedic Center of Florida, Ft. Myers, Florida, U.S.A; Coastal Orthopedics, Pain and Rehabilitation, Bradenton, Florida, U.S.A.

OBJECTIVE: *The objective of this study was to report the long-term outcomes of cooled radiofrequency (CRF) lateral branch neurotomy (LBN) as a treatment for sacroiliac (SI) region pain. Whereas the 1-, 3-, 6-, and 9-month outcomes of this procedure compared to sham treatment were previously reported, this current report shows the 12-month outcomes of CRF/LBN treatment for SI region pain.*

RESULTS: *In the original CRF/LBN treatment group, 12-month outcomes compared to baseline were favorable, with a mean 2.7 point drop in the NRS score, a 13.9 decrease in the ODI, and a 15.8 increase in SF-36BP. In the crossover study group, 6-month outcomes were also favorable, with a mean NRS score decrease of 2.5 points, a reduction in ODI of 8.8, and an increase in SF36-BP of 11.9.*

CONCLUSION: *These favorable 12-month results illustrate the durability of effective CRF/LBN-mediated treatment of SI region pain for selected patients. Furthermore, successful CRF/LBN treatments in unblinded crossover study subjects demonstrate the unlikelihood that such positive outcomes are attributable to a “placebo” effect, and suggest that CRF/LBN is an effective therapeutic option for alleviating pain, and improving physical function and quality of life, with few complications.*

Systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions

Simopoulos TT1, Manchikanti L2, Gupta S3, Aydin SM4, Kim CH5, Solanki D6, Nampiaparampil DE7, Singh V8, Staats PS9, Hirsch JA10. Pain Physician 2015;18:E713-E756.

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COOLIEF* Cooled Radiofrequency

Clinical Research Summary

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OBJECTIVE: *To evaluate the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions.*

RESULTS: *A total of 11 diagnostic accuracy studies and 14 therapeutic studies were included. The evidence for diagnostic accuracy is Level II for dual diagnostic blocks with at least 70% pain relief as the criterion standard and Level III evidence for single diagnostic blocks with at least 75% pain relief as the criterion standard. The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is Level II to III. The evidence for conventional radiofrequency neurotomy, intra-articular steroid injections, and periarticular injections with steroids or botulinum toxin is limited: Level III or IV.*

CONCLUSION: *The evidence for the accuracy of diagnostic and therapeutic effectiveness of sacroiliac joint interventions varied from Level II to Level IV.*

Water-cooled radiofrequency neuroablation for sacroiliac joint dysfunctional pain

Binay Kumar Biswas, Samarjit Dey¹, Saumya Biswas², Varinder Kumar Mohan³

Departments of Anesthesiology, Pain and Perioperative Medicine, ESI-Post Graduate Institute of Medical Sciences and Research, Maniktala, Kolkata, ²Malda Medical College, Maldah, West Bengal, ¹North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, Meghalaya, ³All India Institute of Medical Sciences, New Delhi, India

Sacroiliac (SI) joint dysfunction is a common source of chronic low-back pain. Recent evidences from different parts of the world suggest that cooled radiofrequency (RF) neuroablation of sacral nerves supplying SI joints has superior pain alleviating properties than available existing treatment options for SI joint dysfunctional pain. A 35-year-old male had intractable bilateral SI joint pain (numeric rating scale [NRS] - 9/10) with poor treatment

response to intra-articular steroid therapy. Bilateral water cooled = RF was applied for neuroablation of nerves supplying both SI joints. Postprocedure pain intensity was 5/10 and after 7 days it was 2/10. On 18th-month follow-up, he is pain free except for mild pain (NRS 2/10) on occasional extreme twisting of the back. This case attempts to highlight that sacral neuroablation based on cooled RF technique can be a long lasting remedial option for chronic SI joint pain unresponsive to conventional treatment.

A new radiofrequency ablation procedure to treat sacroiliac joint pain

Jianguo Cheng, MD, PhD, See Loong Chen, MD, Nicole Zimmerman, MS, Jarrod E. Dalton, PhD, Garret LaSalle, MD, and Richard Rosenquist, MD, *Pain Physician* 2016; 19:603-615

OBJECTIVE: *We aimed to develop a new RFA technique to relieve low back pain secondary to sacroiliac joint disorders.*

RESULTS: *The new technique allowed reduction of operating time by more than 50%, x-ray exposure time and dose by more than 80%, and cost by more than \$1,000 per case. The percent of patients who achieved > 50% pain reduction was significantly higher in the b-RFA group at 3, 6, and 12 months follow-up, compared to the cooled radiofrequency group. No complications were observed in either group.*

CONCLUSION: *Compared to the cooled radiofrequency ablation (c-RFA) technique, the new b-RFA technique reduced operating time by more than 50%, decreased x-ray exposure by more than 80%, and cut the cost by more than \$1000 per case. The new method was associated with significantly improved clinical outcomes despite the limitations of the study design. Thus this new technique appeared to be safe, efficacious, and cost-effective.*

Influence of BMI, gender, and sports on pain decrease and medication usage after facet–medial branch neurotomy or SI joint lateral branch cooled RF-neurotomy in case of low back pain: original research in the Austrian population

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¹Medizinisches Zentrum SchmerzLOS Linz and Baden/Vienna, Vienna, ²Johannes Kepler University Linz, Linz, Austria

OBJECTIVE: *This retrospective original research was designed to illustrate the general outcome after radiofrequency (RF) neurotomy of lumbar medial branch (MB) and posterior ramus of the sacroiliac joint of 160 patients with chronic low back pain (LBP) 1, 6, and 12 months after treatment.*

RESULTS: *A VAS decrease of 4 points on a 10-point scale (from 8 to 4) in the overall group*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

was seen after 6 months and of 4.5 after 12 months. Lower medication usage was reported, with opi-oids decreased by 40% and nonsteroidal anti-inflammatory drugs (NSAIDs) by 60%. Decreased pain lasted for 12 months. Significantly better outcomes were reported by patients with BMIs <30. No gender-specific differences occurred in the reported decrease in VAS. Analysis of the “no-sports” group versus the more active (1–3 times weekly sports) group showed a better pain decrease after 1 year in the active group.

CONCLUSION: The data suggest RF treatment for chronic LBP that can lead to long-term improvement. Patients with a BMI >30 are less likely to report decreased pain. The better long-term pain relief in the sports participating group is a motivation for the authors to keep the patients in motion.

Conventional (Simplicity III) and cooled (SInergy) radiofrequency for sacroiliac joint denervation: one-year retrospective study comparing two devices

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*Department of Anesthesiology, Intensive care and Pain Management, ASST Franciacorta, Chiari (BS), Italy; †Young Against Pain Group, Parma, Italy;

OBJECTIVE: To compare two radiofrequency (RF) devices, Simplicity III (conventional RF), and SInergy (cooled RF), which are specifically designed to denervate the sacroiliac joint (SIJ).

RESULTS: Average SInergy group NRS and ODI scores were consistently less than those in the Simplicity III cohort at each post-RF denervation follow-up, and such differences were statistically significant at six and 12 months. The Simplicity III procedure was completed approximately 2.5 times faster than the SInergy procedure, and one minor adverse event was reported in the SInergy group.

CONCLUSION: The study results suggest that SInergy safely afforded patients with greater and more durable analgesia and disability relief than Simplicity III for SIJ-derived pain. The Simplicity III procedure may be more conducive than SInergy for bilateral procedures and for patients who have limited tolerance to be in an RF procedure–required prone position. Randomized controlled trials are needed to confirm the implication made in this study that SInergy is the preferred RF denervation option for treating SIJ-derived pain and the disability associated with it.

The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain

A PRISMA-compliant meta-analysis

Hui-Hui Sun, MPhila,b, Su-Yang Zhuang, PhDa, Xin Hong, MDa, Xin-Hui Xie, PhDa, Lei Zhu, MPhila, Xiao-Tao Wu, PhDa,*

BACKGROUND: Cooled radiofrequency procedure is a novel minimally invasive surgical technique and has been occasionally utilized in managing chronic sacroiliac joint (SIJ) pain. A meta-analysis was conducted to systematically assess the efficacy and safety of using cooled radiofrequency

RESULTS: Totally 7 studies with 240 eligible patients were enrolled. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, $P < .001$] and 3.78 (95% CIs: 3.31–4.25, $P < .001$) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, $P < .001$) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00–0.05, $P < .001$). Only mild complications were observed in the 7 studies, including transient hip pain, soreness, and numbness.

CONCLUSION: Cooled radiofrequency procedure can significantly relieve pain and disability with no severe complications, and majority of patients are satisfied with this technique. Thus, it is safe and effective to use this procedure in managing patients with chronic SIJ pain. More high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

COOLIEF* TRANSDISCAL* Disc Biacuplasty Cooled Radiofrequency

Novel intradiscal biacuplasty (IDB) for the treatment of lumbar discogenic pain

Kapurall, Mekhail N. Pain Practice 2007;7:130-134.

Department of Pain Management, The Cleveland Clinic Foundation, Cleveland, OH.

Reported here is the treatment of severe axial discogenic pain in a young man utilizing the new minimally invasive transdiscal radiofrequency technique called intradiscal biacuplasty (Baylis Medical Inc., Montreal, Canada). The new procedure is detailed and step-by-step fluoroscopic imaging presented. There were no intra- and postoperative complications, and significant improvements in patient functional capacity, and pain scores were noted. Visual analog scale pain score decreased from 5 to 1 cm at 6-month follow-up, Oswestry disability scores improved from 14 (28% or moderate disability) to 6 points (12% or minimal disability) and SF-36-PF (physical function) score changed from 67 to 82. Potential advantages of cooled, bipolar radiofrequency to heat the posterior annulus are discussed.

Histological changes and temperature distribution studies of a novel bipolar radiofrequency heating system in degenerated and nondegenerated human cadaver lumbar discs

Kapurall, Mekhail N, Hicks D, Kapurall M, Sloan S, Moghal N, Ross J, Petriner D. Pain Medicine 2008;9:68-75.

Department of Pain Management, The Cleveland Clinic Foundation, Cleveland, OH.

OBJECTIVE: *The purpose of this experimentation was to investigate the safety of a novel cooled bipolar radiofrequency system by examining histology and monitoring temperature distribution in the disc, epidural space, and adjacent to the nerve roots. In our study we used two human cadaver lumbar spines, one moderately to severely degenerated and the other mildly degenerated.*

RESULTS: *Temperatures developed in the posterior annulus of the disc were on average 52.35 +/- 5.07 degrees C, while in the intervertebral foramen and in the spinal canal were 38.84 +/- 1.7 degrees C and 38.29 +/- 2.04 degrees C, respectively. There was no histological evidence of damage to any other structures including vertebral end plates, epidural space, or nerve roots. Additionally, there were no histological changes in the posterior annulus that were consistent with heat-induced changes to collagen structure.*

CONCLUSION: *Temperatures reached in the posterior annulus during transdiscal biacuplasty were greater than required (45 degrees C) for neuroablation. Temperatures reached at the neural foramina and epidural were low enough to avoid neural damage.*

Intervertebral disc biacuplasty for the treatment of lumbar discogenic pain: results of a six-month follow-up

Kapur L, Ng A, Dalton J, Mascha E, Kapur M, de la Garza M, Mekhail N. Pain Medicine 2008;9:60-67.

Department of Pain Management, The Cleveland Clinic, Cleveland, OH.

OBJECTIVE: *Intradiscal biacuplasty (IDB) is a novel bipolar cooled radiofrequency system for the treatment of degenerative disk disease. We present the results of a pilot trial with 6-month follow-up.*

RESULTS: *Median visual analog scale pain scores were reduced from 7 (95% confidence interval [CI] 6, 8) to 4 (2, 5) cm at 1 month, and remained at 3 (2, 5) cm at 6 months. The Oswestry improved from 23.3 (SD 7.0) to 16.5 (6.8) points at 1 month and remained similar after 6 months. The SF-36 Physical Functioning scores improved from 51 (18) to 70 (16) points after 6 months, while the SF-36 Bodily Pain score improved from 38 (15) to 54 (23) points. Daily opioid use did not change significantly from baseline: from 40 (95% CI 40, 120) before IDB to 5 (0, 40) mg of morphine sulfate equivalent 6 months after IDB. No procedure-related complications were detected.*

CONCLUSION: *Patients showed improvements in several pain assessment measures after undergoing IDB for discogenic pain. A randomized controlled study is warranted and needed to address the efficacy of the procedure.*

Cadaveric intervertebral disc temperature mapping during disc biacuplasty

Kevin Pauza, MD

OBJECTIVE: *To assess temperature profiles created by disc biacuplasty in human cadaver discs.*

RESULTS: *At 13 minutes, with the settings used in this study, the posterior longitudinal ligament (PLL) temperature reached $40 \pm 3^{\circ}\text{C}$. The anterior disc reached $41 \pm 3^{\circ}\text{C}$. The outer layer of the posterior annulus fibrosus was heated to $54 \pm 6^{\circ}\text{C}$ and the inner two-thirds of the posterior annulus fibrosus reached temperatures of $60 \pm 6^{\circ}\text{C}$.*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

CONCLUSION: *The anterior disc and PLL remained at safe temperatures below 45°C while temperatures throughout the center posterior and posterolateral disc were all raised above 45°C, sufficient for neural ablation.*

Acute histologic effects and thermal distribution profile of disc biacuplasty using a novel water-cooled bipolar electrode system in an in vivo porcine model

Petersohn JD, Conquergood LR, Leung M. Pain Medicine 2008;9:26-32.

PainCare, P.C. Linwood, NJ.

BACKGROUND: *Thermal treatment of the lumbar intervertebral disc has been suggested for the treatment of chronic discogenic pain. Disc biacuplasty (D-BAC) is a novel procedure that uses two water-cooled radiofrequency electrodes in a bipolar configuration to heat a large volume of the posterior annulus fibrosus.*

RESULTS: *Temperature monitoring at designated safety zones outside the disc demonstrated maintenance of near-physiologic conditions while temperature in the inner posterior annulus reached 65 degrees C. Histologic sections of treated discs demonstrated no evidence of thermal damage to the dorsal root ganglia or spinal nerve roots when compared with controls. Increased coarseness of the fibrillar matrix and loss of cellular detail were noted in the nucleus pulposus of treated discs.*

DISCUSSION: *Disc biacuplasty, in a porcine model, achieves suitable temperatures to induce thermal transition of collagen and thermoneurolysis while showing no evidence of damage to neural tissue in safety zones surrounding the disc.*

Successful treatment of lumbar discogenic pain using intradiscal biacuplasty in previously discectomized disc

Kapural L, Cata JP, Narouze S. Pain Practice 2009;9:130-134.

Department of Pain Management, The Cleveland Clinic Foundation, Cleveland, OH.

Discogenic back pain is frequently present in patients after discectomy. Here, we describe a case of a young woman, previously discectomized, who was treated by a novel annuloplasty procedure, intradiscal biacuplasty (IDB). The improvement in functional capacity and pain scores were profound 12 months after the IDB. Visual analog pain scores (0-10) changed from 5 to 3. Oswestry scale showed functional improvement from 52%, or severe disability, to 14%, or minimal disability, and the SF-36 physical function scale score changed from 55 to 95. IDB may be an effective treatment for patients with discogenic pain from previously discectomized discs.

6-month results of transdiscal biacuplasty on patients with discogenic low back pain: preliminary findings

Karaman H, Tüfek A, Kavak GÖ, Kaya S, Yildirim ZB, Uysal E, Celik F. International Journal of Medical Sciences 2010;8:1-8.

Pain Management Center, Department of Anesthesiology, Dicle University, Diyarbakir, Turkey.

OBJECTIVE: *Our aim is to investigate the efficacy and safety of TransDiscal Biacuplasty.*

RESULTS: *15 patients were treated at one or two levels. The mean patient age was 43.1 ± 9.2 years. We found the mean symptom duration to be 40.5 ± 45.7 months. At the sixth month, 57.1% of patients reported a 50% or more reduction in pain, while 78.6% of patients reported a reduction of at least two points in their VAS values. In the final check, 78.6% of patients reported a 10-point improvement in their Oswestry Disability scores compared to the initial values. No complications were observed in any of the patients.*

CONCLUSION: *TransDiscal Biacuplasty is an effective and safe method.*

Radiofrequency intradiscal biacuplasty for treatment of discogenic lower back pain: a 12-month follow-up

Kapural L, Vrooman B, Sarwar S, Krizanac-Bengez L, Rauck R, Gilmore C, North J, Mekhail N. Pain Medicine 2014;16:425-431.

Center for Clinical Research; Carolinas Pain Institute, Winston-Salem, North Carolina; Pain Management Department and Evidence-Based Pain Management Research, Cleveland Clinic, Cleveland, Ohio, USA.

INTRODUCTION: *Discogenic low back pain (LBP) affects a considerable number of patients suffering from chronic LBP. Recently, a growing interest has emerged in minimally invasive treatment options for discogenic LBP. Intradiscal biacuplasty (IDB), which uses cooled radiofrequency technology to ablate nociceptors in the posterior aspect of the intervertebral disc, is one such option. We previously presented 6-month results of a randomized, double-blinded, sham-controlled study. Now, we present the unblinded, 12-month follow-up data for treatment patients and 6-month data for cross-over subjects from the original sham group.*

RESULTS: *Twenty-two out of 27 subjects in the original active treatment group were followed until 12 months and had clinically significant improvements in physical function ($\Delta = 22$) and pain ($\Delta = -2.9$). Out of 30 subjects originally in the sham group, 24 chose to cross over, and 20 cross-over patients completed follow-up at 6 months. In cross-over patients, improvements in physical function and pain did not differ statistically from those of patients originally randomized to IDB treatment. No complications or adverse events related to the procedure were reported.*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

CONCLUSION: *Clinically significant improvements after IDB initially reported at 6 months were maintained at 9 and 12 months. The cross-over subjects had similar improvement in all outcome measures at all observed time points.*

Nonoperative management of discogenic back pain

A systematic review

Lu Y, Guzman JZ, Purmessur D, Iatridis JC, Hecht AC, Qureshi SA, Cho SK. Spine 2014;39:1314-1324.

OBJECTIVE: *A systematic evaluation of the literature was performed to investigate current nonoperative management of the treatment of discogenic low back pain.*

RESULTS: *The 11 RCTs investigated traction therapy, injections, and ablative techniques. Results from 5 RCTs investigating methylene blue injection, steroid injection, ramus communicans ablation, intradiscal electrothermal therapy, and biacuplasty favored intervention over sham therapy. However, results from the study on methylene blue injections have not been replicated in other RCTs. Evaluation of the selection criteria used in the studies on ramus communicans ablation and intradiscal biacuplasty and a stratified analysis of results from the RCTs on intradiscal electrothermal therapy casts doubt on whether the conclusions from these RCTs can be applied to the general patient population with discogenic pain.*

CONCLUSION: *There are few high-quality studies evaluating nonoperative treatments for reducing discogenic low back pain. Although conclusions from several studies favor intervention over sham, it is unclear whether these interventions confer stable longterm benefit. There is some promise in newer modalities such as biacuplasty; however, more inclusive studies need to be performed.*

Intervertebral disc temperature mapping during disc biacuplasty in the human cadaver

Desai MJ, Ollerenshaw J, Harrison R, Yu L, Sayal P, Crone T, Dine A. Pain Physician 2015; 18:E217-E223.

International Spine, Pain & Performance Center, Silver Springs, MD.

OBJECTIVE: *The purpose of this study is to map the intradiscal and peridiscal temperatures when IDB is performed at increased temperature using a modified lesion approach. The resulting temperature profiles are used to assess the safety and theoretical efficacy of this approach to ablate nociceptors in the posterior annulus.*

RESULTS: Higher maximum temperature was reached intradisally, and a larger volume of tissue was exposed to neuroablative temperature ($> 45^{\circ}\text{C}$). Temperature at the nerve roots and in the epidural space increased by $2.4^{\circ}\text{C} \pm 2.6^{\circ}\text{C}$ and $4.9^{\circ}\text{C} \pm 1.9^{\circ}\text{C}$ (mean \pm SD), respectively, during bipolar lesion. Similarly, temperature increased by $2.2^{\circ}\text{C} \pm 1.9^{\circ}\text{C}$ and $0.8^{\circ}\text{C} \pm 1.3^{\circ}\text{C}$ at the nerve roots and in the epidural space, respectively, during monopolar lesion.

CONCLUSION: The modified treatment paradigm showed intradiscal heating is achieved and is concentrated in the posterior annulus, suggesting minimal risk of thermal damage to the neighboring neural structures. Clinical benefits should be evaluated.

A prospective, randomized, multi-center, open-label clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain

Desai MJ, Kapural L, Petersohn JD, Vallejo R, Menzies R, Creamer M, Gofeld M. Spine 2015 [Epub ahead of print].

George Washington University Medical Center, Washington, DC, USA; International Spine, Pain, and Performance Center, Washington, DC, USA; Center for Clinical Research, Winston-Salem, NC, USA; PainCare, Linwood, NJ, USA; Millennium Pain Center, Bloomington, IL, USA; JPS Orthopedic and Sports Medicine, Arlington, TX, USA; Compass Research, Orlando FL, USA; Department of Anesthesia, St. Michael's Hospital, Toronto, Ontario, Canada.

OBJECTIVE: The objective was to demonstrate the superiority of IDB over CMM in the treatment of discogenic pain with respect to the primary outcome measure.

RESULTS: In the IDB cohort the mean VAS score reduction exceeded that in the CMM cohort (-2.4 vs. -0.56 ; $p=0.02$), and the proportion of treatment responders was substantially greater (50% vs. 18%). Differences in secondary measures favored IDB. No differences in opioid utilization were noted between groups.

CONCLUSION: Superior performance of IDB with respect to all study outcomes suggests that it is a more effective treatment for discogenic pain than CMM-alone.

Twelve-month follow-up of a randomized clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain

Desai MJ, Kapural L, Petersohn JD, Vallejo R, Menzies R, Creamer M, Gofeld M. Pain Medicine 2016 [Epub ahead of print].

George Washington University Medical Center, Washington, DC, USA; International Spine, Pain, and Performance Center, Washington, DC, USA; Center for Clinical Research, Winston-Salem, NC, USA; PainCare, Linwood, NJ, USA; Millennium Pain Center, Bloomington, IL, USA; JPS Orthopedic and Sports Medicine, Arlington, TX, USA; Compass Research, Orlando FL, USA; Department of Anesthesia and Pain Medicine, University Health Network, Toronto, Canada.

OBJECTIVE: *This report conveys 12-month outcomes of subjects treated with intradiscal biacuplasty (IDB) and conservative medical management (CMM) for chronic low back pain of discogenic origin, and results for subjects who elected to receive IDB+CMM 6 months after CMM-alone.*

RESULTS: *Pain reduction at 12 months was statistically significant and clinically meaningful in the original IDB+CMM group compared to baseline. Functional and disability outcomes were also improved statistically and clinically. Fifty-five percent of the IDB+CMM patients responded to treatment with a mean VAS reduction of 2.2 points at 12 months. Furthermore, 50% and 64% of subjects reported clinically significant improvements in SF36-PF and in ODI, respectively. There was a 1.7-point reduction (improvement) on a 7-point PGIC scale, and a 0.13-point increase (improvement) in the EQ-5D Health Index. Fifty-percent of cross-over subjects responded to IDB+CMM intervention. Mean outcome scores for cross-over subjects were similar to those of the originally-treated subjects, and functional and disability endpoints were improved statistically and clinically compared to respective baseline values.*

CONCLUSION: *The study demonstrated long-term clinical effectiveness of IDB+CMM for treating chronic lumbar discogenic pain. Furthermore, the cross-over study subjects experienced similar improvements in pain, function, disability, and satisfaction.*

Effectiveness of thermal annular procedures in treating discogenic low back pain

Standiford Helm, MD1, Thomas T. Simopoulos, MD2, Milan Stojanovic, MD3, Salahadin Abdi, MD, PhD4, and Mohamed Ahamed El Terany, MD5

OBJECTIVE: *The aim of this study is to evaluate and update the efficacy of TAPs to treat chronic refractory discogenic pain.*

RESULTS: *For this systematic review, 49 studies were identified. Of these, there were 4 RCTs and no observational studies which met the inclusion criteria.*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

Based upon 2 RCTs showing efficacy, with no negative trials, there is Level I, or strong, evidence of the efficacy of biacuplasty in the treatment of chronic, refractory discogenic pain.

Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit, there is Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain.

The evidence supporting the use of discTRODE is level V, or limited.

CONCLUSION: *The evidence is Level I, or strong, that percutaneous biacuplasty is efficacious in the treatment of chronic, refractory discogenic pain. Biacuplasty may be considered as a first-line treatment for chronic, refractory discogenic pain.*

COOLIEF* Thoracic Cooled Radiofrequency

Temperature mapping of cooled radiofrequency lesion of human cadaver thoracic facet medial branches

Mekhail N, Cheng J. *Clinical Journal of Pain* 2011;27:56-61.

Cleveland Clinic, Cleveland, OH.

OBJECTIVE: *Thoracic facet joint pain constitutes 34% to 48% of chronic thoracic spinal pain. Variable medial branch paths in the thoracic region, particularly at branches T5 to T8 levels, make the clinical outcomes of conventional radiofrequency (RF) ablation inconsistent. The internally cooled-RF electrodes can achieve ablation of larger tissue volumes and may increase the probability of capturing the targeted thoracic medial branch nerves.*

RESULTS: *The 3.5 mm active electrode raised the temperatures to 74°C, 54°C, 43°C, 33°C, 27°C, and 36°C at distances of 1, 2, 3, 4, 5, and 6 mm, respectively, whereas the 5.5 mm active electrode achieved temperatures of 49°C, 55°C, 62°C, 63°C, and 35°C at distances of 2, 3, 4, 5, and 6 mm, respectively. Thus, the 5.5 mm active electrode is able to achieve temperatures sufficient for neural tissue ablation within a 5 mm radius tissue volume.*

CONCLUSION: *Cooled RF may offer an effective and reliable method for treating thoracic facet joint pain despite of the variable anatomic paths of the thoracic facet medial branches.*

Third-degree burn from cooled radiofrequency ablation of medial branch nerves for treatment of thoracic facet syndrome

David Walega, MD; Christiana Roussis, MD

Radiofrequency ablation of medial branch nerves is considered a safe and effective treatment for chronic facet joint pain in the cervical, thoracic, and lumbosacral spine. Cooled radiofrequency ablation (C-RFA) is gaining popularity over conventional thermal radiofrequency ablation (RFA) in pain management. However, complications of C-RFA have not been reported in the literature. We present a first report of third-degree skin burn resulting from C-RFA electrode use for the treatment of facet syndrome.

A 61-year-old woman (BMI of 21.8 kg/m²) with thoracic facet syndrome underwent C-RFA of the T1–4 medial branch nerves (Thoracool System, Baylis Medical Company, Montreal, QC, Canada). Lesioning at the superior-lateral aspect of the thoracic transverse processes at each level was performed. During lesioning of the T2 MBN on the T3 transverse process, skin blanching 15 mm in diameter was noted around the introducer needle with patient complaints of severe, localized pain. Postprocedurally the skin injury at this level worsened in appearance, with a 20 mm x 4mm skin defect, which took nearly 5 months to heal.

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

With C-RFA, internally cooled electrodes are capable of creating large volume spherical lesions, a size advantage over conventional RFA. Although C-RFA lesion size may overcome the anatomic variability of target nerve location and potentially improve pain outcomes, added vigilance is required in thin patients and in anatomic regions of minimal subcutaneous tissue between the lesion target and the dermis. Skin burns at the site of the RF electrode are a potential risk under such conditions.

COOLIEF* Knee Cooled Radiofrequency

Partial joint denervation II: knee and ankle

A. Lee Dellon, M.D., Ph.D. Baltimore, Md.

BACKGROUND: *Partial joint denervation is the concept of preservation of joint function and relief of joint pain by interrupting neural pathways that transmit the pain message from the joint to the brain. Partial denervation of painful wrist, elbow, and shoulder joints was described in part I. Application of these principles to the knee and ankle is described in part II.*

RESULTS: *The results obtained for partial joint denervation of the upper ex-tremity can be applied successfully to the knee and ankle joints. If anesthetic block of joint innervation results in a reduction of 5 or more the visual analogue scale, 90 percent of the patients can expect good to excellent pain relief from partial joint denervation.*

CONCLUSION: *For patients with a structurally intact joint but with chronic knee or ankle pain after trauma or arthroplasty, this approach provides an outpatient, ambulatory operative approach that is joint sparing and can be rehabilitation-free. Partial joint denervation in the lower extremity offers plastic surgeons the opportunity to help our colleagues in orthopedic surgery, podiatric medicine, and pain management with some of their most difficult pain-related lower extremity patient problems.*

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.

Innervation of the anterior capsule of the human knee: implications for radiofrequency ablation

Franco CD, Buvanendran A, Petersohn JD, Menzies RD, Menzies LP. Regional Anesthesia and Pain Medicine 2015;40:363-368.

Rush University Medical Center, Department of Anesthesiology and Pain Management, Chicago IL.

OBJECTIVE: Chronic knee pain is a common problem in all age groups. Some patients who fail conservative therapy benefit from radiofrequency neurotomy. Having an understanding of the anatomy is critical to ensure a successful outcome. The purpose of this study was to reanalyze the innervation to the anterior knee capsule from the perspective of the interventional pain practitioner.

RESULTS: Literature review revealed a lack of consensus on the number and origin of nerve branches that innervate the anterior knee capsule. All dissections revealed the following 6 nerves: superolateral branch from the vastus lateralis; superomedial branch from the vastus medialis; middle branch from the vastus intermedius; inferolateral (recurrent) branch from the common peroneal nerve; inferomedial branch from the saphenous nerve and a lateral articular nerve branch from the common peroneal nerve. Nerve branches showed variable proximal trajectories but constant distal points of contact with femur and tibia. The inferolateral peroneal nerve branch was found to be too close to the common peroneal nerve making it inappropriate for radiofrequency neurotomy.

CONCLUSION: The innervation to the anterior capsule of the knee joint seems to follow a constant pattern making at least 3 of these nerves accessible to percutaneous ablation. Well-aligned radiographs to guide lesion placement is critical for procedural success.

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

Analgesia and improved performance in a patient treated by cooled radiofrequency for pain and dysfunction post-bilateral total knee replacement

Menzies RD. Pain Practice 2015;15:E54-E58.

JPS Orthopedics and Sports Medicine. JPS Health System, Arlington, TX.

OBJECTIVE: *While total knee replacement (TKR) results are generally satisfactory, a significant proportion of patients experience persistent pain, defined as lasting greater than 3-months following surgery, even after an operation that appears technically acceptable. Individuals suffering such difficulties may ironically find themselves using some of the same presumably insufficient analgesic or physical therapies that originally led them to opt for TKR. Here, the clinical experience of a patient that originally presented to an orthopedic surgeon with osteoarthritis of both knees is revealed to demonstrate the alternative utility of a relatively non-invasive pain management strategy, namely cooled radiofrequency (CRF) ablation of sensory nerves, to treat persistent knee pain and dysfunction following TKR.*

RESULTS: *Following CRF neurotomy, the patient reported marked OKS improvements for both knees (left knee, pain score: 0 to 4 in 3-months; total score: 24 to 42 in 3-months and right knee, pain: 1 to 4 in 1-month; total: 30 to 42 in 1-month). Pain relief and better knee function occurred up to 9- and 6-months, for the left and right knees, respectively. Moreover, the patient reported a significant improvement in quality of life, as illustrated by minimal knee pain, less reliance on analgesics, and ability to walk more freely, including on stairs.*

CONCLUSION: *Ablation of these targeted genicular nerves by CRF may be an effective treatment for patients who continue to experience knee pain and dysfunction following TKR.*

Demonstration of lesions produced by cooled radiofrequency neurotomy for chronic osteoarthritic knee pain: a case report

Michael E. Farrell, DC, Genaro Gutierrez, MD, Mehul J. Desai, MD MPH

Farrell ME, Gutierrez G, Desai MJ, Demonstration of Lesions Produced by Cooled Radiofrequency Neurotomy for Chronic Osteoarthritic Knee Pain: A Case Report, PM&R (2016), doi: 10.1016/j.pmrj.2016.09.001.

OBJECTIVE: *This is a case demonstrating radiographic evidence of lesions created following cooled radiofrequency (cRF) neurotomy of the knee. A 67-year-old man presents with chronic left knee osteoarthritis, pain, and disability. After failed trial of conservative treatments, the patient underwent diagnostic genicular nerve blocks, and subsequent cRF neurotomy, of the left knee. Shortly after cRF, magnetic resonance imaging (MRI) of the left knee was obtained. On MRI, lesions created by cRF ablation were identified. The images presented in this case offer a visual correlation for the success of cRF in the treatment of knee osteoarthritis.*

CONCLUSION: *This case provides the first in vivo images of the lesions created by cRF ablation. The patient experienced 3 months of pain reduction after undergoing cRF neurotomy of the left knee. A plausible explanation for the duration of his pain relief is the creation of the large spherical lesions demonstrated in the images presented.*

Cooled radiofrequency ablation of genicular nerves for knee osteoarthritis pain: a protocol for patient selection and case series

Rajiv D. Reddy, Zachary L. McCormick, Ben Marshall, Ryan Mattie, and David R. Walega

OBJECTIVE: *We describe a standardized protocol for selecting patients for cooled radiofrequency ablation (C-RFA) of the genicular nerves, as well as the clinical outcomes of four patients ages 63-65 years.*

RESULTS: *C-RFA of the genicular nerves after using the described selection protocol resulted in > 90% pain reduction, improved function and avoidance of surgery at 6 months in all four cases. All opioid and analgesic medication use decreased or was unchanged in all cases. No serious adverse events occurred.*

CONCLUSION: *The accompanying case series suggests that this protocol is deserving of randomized, prospective study.*

Water-cooled radiofrequency provides pain relief, decreases disability, and improves quality of life in chronic knee osteoarthritis

Rojhani S, Qureshi Z, Chhatre A. American Journal of Physical Medicine and Rehabilitation, 2016, [Epub ahead of print].

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Chronic osteoarthritis (OA) is a widespread source of pain and disability and represents a growing economic burden across aging populations. Representing a major focus of arthritis care, OA of the knee is especially concerning as it has the potential to restrict mobility and significantly impair quality of life. Chronic OA is often poorly managed both pharmacologically and nonpharmacologically, with surgical management representing the definitive treatment. Those who are not surgical candidates or simply opt for minimally invasive treatments are usually faced with a lack of alternatives. An additional treatment presents itself in the form of water-cooled radiofrequency ablation, which involves the use of thermal lesions to interrupt the active pain pathways. An 81-year-old woman with bilateral severe knee OA was initially seen and evaluated in an outpatient physiatry clinic

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

after multiple previous workups of her ongoing knee pain. With a known diagnosis of end-stage knee OA, the patient chose to proceed with bilateral water-cooled radiofrequency ablation. At 6 weeks and 3 months after the procedure, the patient maintained adequate levels of pain relief, markedly improved function, and enhanced quality of life. Water-cooled radiofrequency ablation has the potential to create lasting pain relief and with minimal adverse effects in patients with chronic knee OA.

Pain treatment with cooled radiofrequency in osteoarthritis and total knee arthroplasty: case series in Hospital Universitario de Son Espases

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OBJECTIVE: Cooled radiofrequency (RF) for neurotomy of genicular nerves has been proved to be efficient in shortterm (12 weeks) to relieve the knee pain in severe osteoarthritis (OA) and total knee arthroplasty (TKA). This study is aimed to analyze the results of cooled radiofrequency in patients with chronic knee pain after one year of follow-up.

RESULTS: Regarding SF-36, a significant improvement in pain, general health and overall outcome was obtained. Preoperative average VAS score was 8.5; 1 year after surgery this score was 5.3. Significant differences were found at the knee score (KS) in KSS but not in the function score (FS) in KSS.

CONCLUSION: Cooled RF for neurotomy of genicular nerves is still effective after 1 year of the procedure in the treatment of chronic knee pain due to osteoarthritis. The rate of conversion to arthroplasty is low. This technique could be a good alternative for chronic pain management in patients in whom TKA is not the first option of treatment.

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 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.

DISCUSSION: These results demonstrate that cooled RFA is a safe and effective non-narcotic 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.

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).

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

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

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 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.*

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

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BACKGROUND: *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.

Third-degree skin burn from conventional radiofrequency ablation of the inferiomedial genicular nerve

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OBJECTIVE: *We report a case of a third-degree skin burn at the site of the inferiomedial genicular nerve following a conventional thermal RFA procedure. A 50-year-old man (BMI 24.2 kg/m²) with five years of right knee pain and radiographic evidence of moderate to severe tri-compartmental OA, who experienced no meaningful relief from conservative management and corticosteroid injections, underwent superiomedial, superiolateral, and inferiomedial genicular nerve RFA using an accepted protocol*

CONCLUSION: *Based on this case, we speculate that RFA lesion extension to the dermis with subsequent superficial necrosis is possible at the inferiomedial genicular nerve site in patients with minimal subcutaneous tissue overlying the medial tibial flare. Based on ex vivo studies, the RFA parameters used in this case would result in a lesion 13.4mm in length and 9.9mm in width, yet lesion size may be larger in vivo and when local anesthetic is used prior to lesioning. Indeed, third-degree skin burns have been reported in the literature in patients with slender body habitus in association with RFA of relatively superficial targets including a thoracic medial branch nerve and a thyroid nodule.*

In order to prevent this potential complication, careful individualized selection of RFA electrode size and length, lesioning time, and temperature must be considered, specifically in relation to patient body habitus and depth of the lesion target.

COOLIEF* Hip Cooled Radiofrequency

Ultrasound-guided radiofrequency lesioning of the articular branches of the femoral nerve for the treatment of chronic post-arthroplasty hip pain

David J. Kim, MD, MS, Shiqian Shen, MD, and George M. Hanna, MD

OBJECTIVE: We evaluate the effectiveness of cooled (60°C) radiofrequency lesioning of the articular branches of the femoral nerve (ABFN) as a minimally invasive treatment for patients suffering from chronic post-arthroplasty hip pain. This treatment has never been described previously in this population.

RESULTS: Prior to intervention, the patient reported severe disruption in daily activities, sleep, and relationships; NRS scores at rest and with activity were 4/10 and 10/10, respectively. At 4 weeks following intervention, the patient reported significant improvement in functional ability and NRS scores decreased to 1/10 and 2/10, respectively. At 6 months, the patient's NRS scores at rest and with activity were 0/10 and 1/10, respectively. At 24-month follow-up, the patient continued to endorse significant pain relief with NRS scores at rest and with activity of 0 – 1/10 and 1 – 2/10, respectively. There were no side effects or complications including motor weakness, sensory loss, and neuralgias.

CONCLUSION: Cooled (60°C) radiofrequency lesioning of the ABFN under ultrasound guidance is both an effective and minimally invasive intervention for chronic post-arthroplasty hip pain.

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

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

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.

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

GENERAL

The science of conventional and water-cooled monopolar lumbar radiofrequency rhizotomy: an electrical engineering point of view

Ball RD. Pain Physician 2014;17:E175-211.

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Radiofrequency ablation (RFA) is a safe and effective pain therapy used to create sensory dysfunction in appropriate nerves via thermal damage. While commonly viewed as a simple process, RF heating is actually quite complex from an electrical engineering standpoint, and it is difficult for the non-electrical engineer to achieve a thorough understanding of the events that occur. RFA is highly influenced by the configuration and properties of the peri-electrode tissues. To rationally discuss the science of RFA requires that examples be procedure-specific, and lumbar RFA is the procedure selected for this review. Adequate heating of the lumbar medial branch has many potential failure points, and the underlying science is discussed with recommendations to reduce the frequency of failure in heating target tissues. Important technical details of the procedure that are not generally appreciated are discussed, and the status quo is challenged on several aspects of accepted technique. The rationale underlying electrode placement and the limitations of RF heating are, for the most part, commonly misunderstood, and there may even need to be significant changes in how lumbar radiofrequency rhizotomy (RFR) is performed. A new paradigm for heating target tissue may be of value. Foremost in developing best practices for this procedure is avoiding pitfalls. Good RF heating and medial branch lesioning are the rewards for understanding how the process functions, attention to detail, and meticulous attention to electrode positioning.

Application of cooled radiofrequency ablation in management of chronic joint pain

Salmasi V, Chaiban G, Eissa H, Tolba R, Lirette L, Maged N, Guirguis MN. Techniques in Regional Anesthesia and Pain Medicine 2014;18:137-144.

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Department of Pain Management, Ochsner Health System, New Orleans, Louisiana.

Radiofrequency ablation (RFA) is a minimally invasive neurotomy technique that can provide sensory ablation in patients with chronic pain. Cooled RFA, however, can create larger lesions compared with traditional RFA. Size of lesions plays a more important role in neurotomy of articular nerves where neural anatomy is not as predictable. We review the literature present about cooled radiofrequency neurotomy of articular branches of joints in patients with chronic pain of sacroiliac, hip, or knee joints. Sacroiliac joint pain is a significant etiology of low-back pain whereas low-back pain can be experienced by up to a third of

the population. Chronic hip and knee pain can result in huge healthcare expenses as well as disability. The patients with chronic hip and knee pain might not be good candidates for arthroplasty surgeries because of their other comorbidities. Moreover, they might have persistent pain postoperatively. We also explain the technique used for neurotomy of articular branches in these joints.

An ex vivo comparison of cooled-radiofrequency and bipolar-radiofrequency lesion size and the effect of injected fluids

Vallejo R, Benyamin R, Tilley DM, Kelley CA, Cedeño DL. Regional Anesthesia and Pain Medicine 2014;39:312-321.

From the Millennium Pain Center, Bloomington, IL; School of Biological Sciences, and Department of Chemistry, Illinois State University, Normal, IL.

BACKGROUND AND OBJECTIVE: *Radiofrequency (RF) neuroablation is a common therapy for alleviating chronic pain. Larger lesion volumes lead to higher chance of ablating small sensory nerves; therefore, bipolar-RF and cooled-RF are improved alternatives to conventional monopolar-RF. This work provides an ex vivo comparison of bipolar-RF to cooled-RF lesioning in the presence of bone structure using some conventional temperature and time programs and in conjunction with injection of a variety of clinically used substances.*

RESULTS: *The volume of bipolar-RF lesions is dependent on IED, being more favorable at IED equals 10 mm. The injection of some fluids induces significant ($P < 0.05$) changes in bipolar-RF lesion volume, although the changes are dependent on IED. Cooled-RF induces larger lesions than bipolar-RF, with no changes in volume induced by injecting fluids.*

CONCLUSION: *Cooled-RF yields larger lesions than bipolar-RF under the conditions used in this study. The spherical shape of cooled-RF lesions provides larger volume coverage than lesions obtained with bipolar-RF at IED equals 5, 10, or 15 mm under similar electrode tip temperature and lesioning time.*

COOLIEF* Cooled Radiofrequency

Clinical Research Summary

Effects of anesthetic fluid injectates on lesion sizes in cooled radiofrequency ablation

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OBJECTIVE: *This is an ex vivo study using pork chops to simulate human vertebra to determine the effects of various anesthetic fluids injectates and concentrations on lesion size and shape created when using cooled radiofrequency ablation. Secondary objective is to determine the effects of various time durations of applied lesion on lesion size created. Our final objective is to determine the effects of fluid injectates on tissue temperature and impedance.*

RESULTS: *There was no significant difference in the size of the lesion created when using different injectates and concentrations. There was no significant difference in the size of the lesion created when applying a 90 second duration lesion compared to a 150 second duration lesion.*

CONCLUSION: *Applying a 90 second duration lesion can be considered in clinical use for cooled radiofrequency ablation. The use of an injectate did not significantly alter the size or desired spherical shape of the lesion created, did not significantly alter the time required to create the lesion, and did not significantly lower the temperature threshold. The study is limited by the use of ex vivo tissue which does not account for the effects of tissue perfusion. The use of an injectate prior to cooled radiofrequency ablation can be made at the interventionalist's discretion.*

Comparisons of lesion volumes and shapes produced by a radiofrequency system with a cooled, a protruding, or a monopolar probe

David L. Cedeño, PhD1,2, Alejandro Vallejo, HS1,3, Courtney A. Kelley, BS1,2, Dana M. Tilley, PhD1,2, and Nitesh Kumar, BS2

OBJECTIVE: *This study compares lesion volumes of 3 commercially available RF systems: cooled-RF, "V" shaped active cannula and protruding electrode (18 g and 20 g), and monopolar RF (MRF; 16 g, 18 g, and 20 g).*

RESULTS: *Mean lesion volume with cooled RF (595 mm³) is significantly larger than any other mean volume measured. The second largest volume is produced with MRF using a 16 g introducer (360 mm³), which is significantly larger than those obtained with 18 g or 20 g. This is also significantly larger than the one obtained with PERF using an 18 g introducer. Mean lesion volume produced with PERF (80°C for 90 seconds) and an 18 g diameter tip (215 mm³) is significantly larger than the respective one produced with MRF (169 mm³).*

COOLIEF* Cooled Radiofrequency Clinical Research Summary

Increasing lesioning time to 150 seconds significantly increases the volume (283 mm³). Using a 20 g tip produces the smallest lesions at 80°C for 90 seconds with either PERF or MRF, although a lesioning time of 150 seconds makes it significantly larger (207 mm³).

CONCLUSION: *The results indicate that the lesion produced with a cooled-RF system (17 g, 4 mm tip) is significantly larger than that produced with either of the other systems trialed (18 g or 20 g, 10 mm active tip protruding electrode or 16 g, 18 g, or 20 g monopolar electrode). Interestingly, a 16 g, 10 mm active tip monopolar electrode produced a larger lesion than the one produced with the 18 g protruding electrode.*

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