Washington State Health Care Authority

Peripheral nerve ablation for the treatment of limb pain

Draft key questions: public comment and response

August 23, 2018

Health Technology Assessment Program (HTA)
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Peripheral nerve ablation for the treatment of limb pain

Draft Key Questions: Public Comment and Response

Provided by:

Center for Evidence-based Policy
Oregon Health & Science University

August 23, 2018

Responses to public comment on draft key questions

The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

Draft key question document comments received:

- Fielding Greaves, Director State Government and Regional Affairs, Advanced Medical Technology Association (AdvaMed)
- Asokumar Buvanendran, MD, President, American Society of Regional Anesthesia and Pain Medicine (ASRA)
- Todd Sitzman, MD, President; David Kloth, Past President; David Provenzano, Director-at-Large, Policy & Advocacy Committee, Co-Chair; Jason Pope, Director-at-Large, Policy & Advocacy Committee, Co-Chair; Corey W Hunter, MD Director-at-Large, North American Neuromodulation Society (NANS)
- Jeffrey S. Welch, DO
- David Westerdahl, MD
- Jeffrey Lyman, MD
- Mark C. Lavigne, PhD, Global Clinical Affairs, Avanos Medical
- Jiang Wu, MD
- Brett R. Stacey, MD
- Daniel Kwon, MD

Specific responses pertaining to submitted comments are shown in Table 1.

Table 1. Responses to comments on Draft key questions for Peripheral nerve ablation for the treatment of limb pain

	Comments	Response
Commenter: Fielding Greaves, Advanced Medical Technology Association (AdvaMed)		
Public comment process	The Advanced Medical Technology Association (AdvaMed), the national association of medical technology providers, is deeply concerned about the process involved with the Health Technology Assessment Program (program) as it relates to the current proceeding examining Peripheral Nerve Ablation technology or Radiofrequency Ablation (RFA). We again urge you to provide the public with more time to comment or extend the comment period so that the public can study these complex questions, develop thorough, comprehensive responses and meaningfully engage with program staff to best serve the interests of the program. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed encourages public policies that assure patient access to the benefits of medical technology. AdvaMed has been very interested in Washington's health technology assessment program since its inception. During the legislative debate that led to the creation of the program and the assessment program's subsequent activities, AdvaMed has advocated for efforts to ensure transparency and adequate public comment. AdvaMed appreciates the opportunity to provide comment on the draft key questions regarding the review of RFA technology by the Health Technology Assessment. Although this proceeding considers only key questions for consideration, the questions stand to deeply influence the program's ultimate conclusions and we urge the program to extend this and future comment periods to fall in line with other customary comment periods to ensure adequate public participation. For federal rulemaking 30-60 days is the normal minimum comment period. 180 days is provided for complex rules. California provides for a minimum comment period of 45 days for all rulemaking. However, the current public comment period for the RFA questions provides only 15 days, beginning with publication on July 26 and ending August 9. AdvaMed is concerned that this short comment period (just 11 business days) will limit the depth and value of public consideration and comment that may be provided to the program. There is significant technical evidence and information relative to RFA technology and the current two-week public	Thank you for your comments. The Washington Health Technology Assessment process includes a 14-day public comment period for the Key Questions and a 30-day public comment period for the draft evidence report.

	Comments	Response
	comment period fails to provide enough time to effectively respond to the draft key questions. AdvaMed respectfully requests a delay in the deadline for the public comment submissions to the draft key questions as we look to carefully and thoughtfully respond to the program's questions.	
Commenter: Asokumar Buvanendran, MD, American Society of Regional Anesthesia and Pain Medicine (ASRA)		
Evidence review	Comments included a review of studies related to peripheral nerve ablation and other interventions for chronic knee pain.	Thank you for your comments. Articles cited in this public comment will be considered for inclusion in the evidence review, using the criteria outlined in the Key Questions.
Commenter: North American Neuromodulation Society (NANS)		
Coverage decision	Submitted comments consisted of a letter to Cigna regarding Cigna's recent coverage decision on peripheral nerve ablation for chronic knee pain.	Thank you for your comments. Articles cited in this public comment will be considered for inclusion in the evidence review, using the criteria outlined in the Key Questions.
Commenter: Jeffrey S. Welch, DO		
Coverage decision	I am a board certified interventional pain management physician working at the Providence Pain Management clinic for the last 6 years. We are extremely fortunate to have the Halyard Coolief Radio-Frequency generator which allows us to perform Coolief procedures. The most frequently requested procedure by far in our clinic is the geniculate nerve ablation for knee pain. Since the FDA endorsement of this procedure in the spring of 2017 our referrals have exploded. We are receiving dozens of referrals weekly and are struggling to keep up with the demand. These referrals are from local orthopedic surgeons who have recognized how beneficial this procedure has been for their patients. This procedure is working much better than cortisone and Synvisc injections and is lasting far longer. It has been a godsend for patients with severe knee pain who are not candidates for knee replacement surgery or have already had surgery but still suffer with pain . Virtually all of my patients have had these other procedures previously and failed to get long term benefit. My patients are reporting a 75% reduction in pain scores with an extremely low failure rate (less than 5%). Recent studies have demonstrated that patients who have had this procedure prior to surgery are requiring significantly lower doses of opioid pain medications post-operatively. This alone is a good reason	Thank you for your comments.

	Comments	Response
	to support efforts to help all citizens of our state to have access to this procedure.	
Commenter: David Westerdahl, MD		
Coverage decision	My patients have greatly benefited from the use of cooled radio frequency ablation to treat knee arthritis pain. I have found it especially helpful for those with moderate to severe knee osteoarthritis who are not candidates for a knee replacement. These patients may be younger in age, overweight, or not able to have a knee replacement due to time lost from work or their role as a caregiver for other family members. I have found that my patients have achieved moderate pain relief for months to over a year. Most of my patients approximately 80% would say that they are satisfied or very satisfied with the release from this procedure. My patients have achieved moderate pain relief for several months to over a year. Most of my patients approximately 80% would say that they are satisfied or very satisfied with the release from this procedure.	Thank you for your comments.
Commenter: Jeffrey Lyman, MD		
In-process study	This letter is in support of the use of cooled radio frequency (cRFA) in the State of Washington for medical purposes. I am a practicing board certified, fellowship trained, knee Orthopedic surgeon practicing in Coeur d'Alene, Idaho. I have been studying the use of cRFA for the nonoperative management of knee arthritis and for the potential benefits of pain management after knee arthroplasty. We have been studying the effect of this technology on pain management via an IRB approved, prospective double blinded level one clinical trial. The trial is multicentered, and has three surgeons involved. We recently performed a scheduled midterm limited biopsy of our data which demonstrated a statistically significant 30% reduction in analog pain scores 2 weeks after knee arthroplasty for patients having undergone cRFA compared to placebo. When completed, our study will describe the effects this technology has on narcotic usage, hospital LOS, patient reported pain and functional scores, and physical therapy usage and milestones. Based on our limited biopsy we are anticipating that the technology will demonstrate benefits that could potentially change the standard of care for patients have knee arthroplasty surgery. Cooled RFA has already been shown to be an effective technology to manage arthritis-related knee pain and for	Thank you for your comments. The evidence review is limited to published studies. The report will also include a section that notes ongoing, registered trials from the ClinicalTrials.gov registry database.

	Comments	Response
	some patients may be the only non-narcotic option for this condition. My opinion is that it would be a mistake to exclude this technology from being utilized in the State of Washington.	
Commenter: Mark C. Lavigne, PhD, Avanos Medical		
Evidence review	Submitted comment was A Presentation of Investigations of Radiofrequency Ablation to Treat Chronic Pain Emanating from the Knee and Hip.	Thank you for your comments. Articles cited in this public comment will be considered for inclusion in the evidence review, using the criteria outlined in the Key Questions.
Commenter: Jiang Wu, MD		
Evidence review	The comments include a review of studies related to COOLIEF Cooled Radiofrequency thermal treatment device for knee osteoarthritis.	Thank you for your comments. Articles cited in this public comment will be considered for inclusion in the evidence review, using the criteria outlined in the Key Questions.
Commenter: Brett R. Stacey, MD		
Evidence review	The comments include a review of studies related to radiofrequency ablation of peripheral nerves to treat limb/joint pain.	Thank you for your comments. Articles cited in this public comment will be considered for inclusion in the evidence review, using the criteria outlined in the Key Questions.
Commenter: Daniel Kwon, MD		
Coverage decision	I am writing this letter in support of peripheral nerve ablation for the treatment of limb pain. I work as a physician dealing with chronic pain and will encounter patients who have end stage arthritis of peripheral joints including the knee. Fortunately many of these patients are able to undergo total knee arthroplasty (or other surgical procedures) with orthopedic surgery and able to resume a functional life. However there are situations where the patient may not be a good surgical candidate due to medical or other co-morbidities. Radiofrequency ablation of the genicular nerves for the knee has been a useful option for some of these patients. The decision of loss of mobility/ambulation vs. pursuing genicular nerve radiofrequency is a question that we occasionally face. The challenge is limited published evidence for this procedure, but over time we have seen more data coming out in favor of this procedure. The benefit can be significant pain reduction and improved functional mobility, and the risks are very low for this procedure.	Thank you for your comments.

	Comments	Response
	I hope that Washington State and the HTCC will carefully consider this option in a select/specific group of patients that would otherwise have no other options.	

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July 30, 2018

Sue Birch
Director, Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Dear Director Birch:

The Advanced Medical Technology Association (AdvaMed), the national association of medical technology providers, is deeply concerned about the process involved with the Health Technology Assessment Program (program) as it relates to the current proceeding examining Peripheral Nerve Ablation technology or Radiofrequency Ablation (RFA). We again urge you to provide the public with more time to comment or extend the comment period so that the public can study these complex questions, develop thorough, comprehensive responses and meaningfully engage with program staff to best serve the interests of the program.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed encourages public policies that assure patient access to the benefits of medical technology. AdvaMed has been very interested in Washington's health technology assessment program since its inception. During the legislative debate that led to the creation of the program and the assessment program's subsequent activities, AdvaMed has advocated for efforts to ensure transparency and adequate public comment.

AdvaMed appreciates the opportunity to provide comment on the draft key questions regarding the review of RFA technology by the Health Technology Assessment. Although this proceeding considers only key questions for consideration, the questions stand to deeply influence the program's ultimate conclusions and we urge the program to extend this and future comment periods to fall in line with other customary comment periods to ensure adequate public participation. For federal rulemaking 30-60 days is the normal minimum comment period. 180 days is provided for complex rules. California provides for a minimum comment period of 45 days for all rulemaking. However, the current public comment period for the RFA questions provides only 15 days, beginning with publication on July 26 and ending August 9. AdvaMed is concerned that this short comment period (just 11 business days) will limit the depth and value of public consideration and comment that may be provided to the program.

There is significant technical evidence and information relative to RFA technology and the current two-week public comment period fails to provide enough time to effectively respond to the draft key questions. AdvaMed respectfully requests a delay in the deadline for the public comment submissions to the draft key questions as we look to carefully and thoughtfully respond to the program's questions.

Thank you for considering our concerns. Please contact me if you have any questions.

Sincerely,

Fielding Greaves
Director, State Government & Regional Affairs

American Society of Regional Anesthesia and Pain Medicine
Advancing the science and practice of regional anesthesiology and pain medicine to improve patient outcomes through research, education, and advocacy
Four Penn Center West | Suite 401 | Pittsburgh, PA 15276 | www.asra.com

On behalf of the American Society of Regional Anesthesia and Pain Medicine's 5,000 members we would like to take the opportunity to express our concerns regarding those who have denied coverage for patients receiving radiofrequency ablation (RFA) to treat chronic knee pain. We strongly insurance providers to reconsider your policies to provide coverage of RFA for your members who are treated by our members.

With a lifetime prevalence rate of approximately 45%,[1] knee pain is one of the most common conditions and causes of disability and reduced quality of life in adults.[2,3] The leading cause of chronic knee pain is osteoarthritis, in addition to other etiologies including rheumatoid arthritis, trauma, and persistent post-surgical pain.[4,5] The clinical and economic burden associated with chronic knee pain is substantial and is projected to increase as the population ages and obesity rates rise.[6]

Available treatments for knee pain vary depending on the etiology and diagnosis but broadly include physical therapy, injections, and surgery.[7] Intra-articular injections encompass a wide range of medications to include anti-inflammatory corticosteroids, pro-inflammatory prolotherapy, and platelet-rich plasma solutions, viscosupplements, and stem cell preparations.[8-11] All intra-articular injections require the presence of an intact joint, and are therefore not applicable following total arthroplasty. Knee surgery is similarly heterogeneous and ranges from minimally invasive arthroscopic procedures to open partial or total arthroplasties.[12,13]

Currently, chronic knee pain is not effectively managed by pharmacologic or surgical treatment, with some patients developing refractory, disabling chronic knee pain. For example, pain due to severe osteoarthritis is not reliably responsive to conservative therapies, and intra-articular injections may be ineffective or provide only limited or short-term pain relief. Furthermore, the adverse impacts associated with the long-term use of steroids are well documented. In a randomized, placebo-controlled study of 140 patients with knee osteoarthritis, the long-term use of intra-articular steroid injections resulted in significantly greater cartilage volume loss and no significant difference in knee pain compared with intra-articular saline.[8]

Another growing concern about pharmacologic therapies to treat chronic knee pain is related to the potential for tolerance and possible addiction to opioids A retrospective cohort study by Wright and colleagues (2014) showed a significant increase in opioid prescribing between 2003 and 2009 for Medicare beneficiaries with knee osteoarthritis.[14] In light of the escalating opioid crisis, safe and efficacious alternatives are needed in the treatment of chronic knee pain.

Surgery to treat pain due to osteoarthritis is associated with a significant failure rate, with chronic pain persisting in up between 12% and 40% of patients who undergo joint replacement, being characterized as severe in 15% of cases.[15-17] Knee surgery is also a considerable expense for our healthcare system. In 2012, the total cost for all total knee arthroplasty (TKA) procedures in the United States was over $11 billion.[6] In addition, TKA is associated with a risk of serious complications; a large cohort study of 32,754 patients undergoing TKA demonstrated the annual incidence of venous thromboembolism, myocardial infarction, stroke, and 90-day mortality to all be significantly higher than the general population.[18]

Delivery of radiofrequency (RF) energy to the knee's nerve supply is a relatively new intervention that can be safely done in the presence of an artificial joint and may offer an alternative to surgery or surgical

revision.[19] RFA entails the discrete delivery of thermal energy produced by an alternating current to neural tissue, thereby degrading its ability to conduct pain signals.[20]

As reported in several publications, RFA is an effective treatment alternative to surgery, nonsteroidal anti-inflammatory drugs, opioids, and steroid injections. Strong evidence for the use of RFA is found in the literature consisting of 3 clinical studies, which evaluated knee RFA for osteoarthritis and persistent postsurgical pain and included a total of 217 patients. These studies compared knee RFA to sham or other treatments, with all demonstrating superior pain relief and function in the RFA groups.[21-23]

- In a randomized controlled trial of 38 patients with chronic knee pain due to osteoarthritis, Choi and colleagues (2011) found that that RFA significantly lowered visual analog scale scores at all time periods compared with sham.[21] Ten of the 19 RFA patients achieved at least 50% pain reduction at 12 weeks, compared with no patients in the control group. Oxford Knee Score (OKS) and patient satisfaction were also significantly improved in the RFA group.
- A double-blind, randomized study by Qudsi-Sinclair and colleagues (2017) compared RFA to analgesic block with corticosteroid for the treatment of chronic knee pain in 28 patients with a history of TKA.[22] The results showed superior pain relief with RFA at all time periods as assessed by the Numeric Rating Scale between 0 and 10.
- The most recent randomized trial by Davis and colleagues (2018) consisted of 151 patients with knee pain from osteoarthritis and is also the largest and the first to employ cooled RFA (CRFA).[23] Pain relief with CRFA was superior to that obtained with intra-articular steroids at all time periods. At 6-month follow-up, 74% of the CRFA group had at least 50% relief versus 16% of the intra-articular steroid group. Function (as measured by OKS) and global perception were also superior in the CRFA cohort.

The results of these studies demonstrate the significant benefit of RFA for both pain reduction and functional improvement lasting between 3 and 12 months in well-selected patients with chronic knee pain.

Additional evidence supporting the use of RFA in chronic knee pain is provided by a retrospective chart review and two systematic reviews.

- In a retrospective chart review of 31 patients who received RFA for chronic knee pain from osteoarthritis, Iannaccone and colleagues (2017) found that RFA provided greater than 60% pain relief for as long as 6 months.[24] At 3-month follow-up, the average pain relief was 67% improved from baseline knee pain, and the average pain score was 2.9 out of 10. Of those who described pain relief at 3 months, 95% reported pain relief at 6 months, with an average pain relief of 64% from baseline knee pain and an average pain score of 3.3 out of 10.
- A systematic review by Bhatia and colleagues (2016) noted a high success rate with radiofrequency procedures in relieving chronic knee pain at 1 to 12 months after the procedures. [25]. Thirteen publications were included and showed evidence for improvement in function and a lack of serious adverse events with RF treatments.[25]
- Similar results were reported in a systematic review by Gupta and colleagues (2017).[26] Seventeen publications were included in this systematic review. According to the authors, the studies showed promising results for RFA in the treatment of severe chronic knee pain at up to 1 year with minimal complications. The authors concluded that RFA offers substantial clinical and functional benefit to patients with chronic knee pain due to osteoarthritis or post total knee arthroplasty.

RFA serves a large unmet need for a minimally invasive treatment to bring relief to patients suffering from debilitating chronic knee pain. Shown to provide significant benefit to well-selected patients, RFA relieves knee pain, increases functionality, and decreases the need for pain medication, thus offering an effective solution that helps patients manage pain without the risk of addiction. RFA is amenable to an outpatient setting, involves a short treatment time, and may be performed without the risks of general anesthesia or surgical infection.

Based on the review of the literature, RFA has demonstrated clinical benefit in the treatment of chronic knee pain. Given the current opioid epidemic it is irresponsible to place these patients on opioids when treatment options such as RFA can be used for chronic pain. If RFA is denied, this may contribute the opioid crisis in the U.S. Withholding access to RFA is a major disservice to your members and potentially harmful and is contrary to providing coverage that is patient-oriented and evidence-based. We respectfully request that you reconsider your coverage policy to ensure that your members have access to all appropriate treatment options including RFA. If you would like to discuss this issue further, please do not hesitate to contact us.

Thank you for your time and consideration of our request.

Sincerely,

Asokumar Buvanendran, MD

President, ASRA (2017-2019)

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June 25, 2018

Dr. Julie Kessel
National Medical Director Coverage Policy
900 Cottage Grove Road,
Bloomfield, CT 06002

Re: Response to new policy statement on "Peripheral Nerve Destruction/Pain Condition" – effective 2-15-18

Dear Dr. Kessel,

This letter is on behalf of the North American Neuromodulation Society (NANS) and its 1500 members in response to the new policy statement released by Cigna regarding "Peripheral Nerve Destruction" to treat chronic intractable knee pain due to end stage knee arthritis or post-replacement pain. We feel quite strongly that this particular therapy has a legitimate place in the treatment of knee pain and should be covered by Cigna as an option for patients to avoid potentially harmful opioid pain medication. The opioid epidemic we are experience in this country demands a more careful consideration of any potential "opioid-sparing therapies" aimed at treating chronic pain, like this geniculate neurotomy.

OVERVIEW

While surgery is considered to be the accepted treatment option for patients with advanced joint disease, many individuals have comorbidities that may prevent them from being an appropriate surgical candidate. Others may simply want to avoid surgery, as they may be unable to take off the necessary time from work for the procedure and post-operative recovery period. Chronic knee pain ultimately leads to secondary pain problems from the altered gait including back and hip problems, deconditioning, weight gain and a multitude of other problems which Cigna will then be responsible to cover. In these cases, radiofrequency neurotomy of the genicular nerves is a safe, efficacious, appropriate and medically indicated alternative to joint replacement.

In addition, despite the general efficacy of knee replacements, not everyone is a candidate and those that are may continue to suffer from persistent pain after surgery.[1] Traditionally, in these unfortunate cases, patients had few options, if any, that did not involve additional surgery that was rarely successful or a lifetime of opioid pain medications. With the advent of genicular

nerve neurotomy, patients can achieve significant pain relief and improved function without further surgery.

Benefits

Chronic knee (OA) is on the most common diseases of advanced age. Greater than 12% of the American population experiences pain and functional limitations from chronic knee OA.[2]. With up to 20 million adults in the United States suffering from OA the knee, [3] close to 700,000 cases progress to total knee replacement.[4] As described above, this procedure has its limitations – genicular ablation bridges the gap with respect to those limitations[5]

Radiofrequency ablation of the genicular nerves has been shown to significantly reduce chronic knee pain in patients without the need for a major surgery to replace the knee or revise an already existing joint replacement. One of the most impressive aspects of this procedure is its ability to offer immediate pain relief thus allowing patients to participate in physical therapy, restore function and return to their normal daily activities.

It is a minimally invasive, nonsurgical treatment option with the potential to relieve pain where other more conventional therapies have failed, and in the case of surgery – avoid it altogether. When compared to a total knee replacement:

Genicular Nerve Neurotomy	Traditional Joint Replacement
Inexpensive	Extremely expensive
Performed in your doctor's office	Performed in hospital
Outpatient procedure	Inpatient admission
Can be done with only local anesthetic	Required general anesthesia and regional anesthesia
Minimal risk of infection	Risk of post-surgical or nosocomial infection
No need for blood thinners	Requires 4 weeks of blood thinners (anticoagulation)
Virtually non-existent recovery period	Long postoperative recovery period requiring inpatient rehab
Most patients are back to work the next day or by the week's end	Can be weeks to months before returning to work
Little to no postoperative pain, typically controlled with NSAIDs	Significant postoperative pain
Can return to normal activities in a matter of days	May be several months before being able to perform normal activities

For many patients who have to wait several months for surgery, genicular nerve neurotomy can significantly reduce their pain making the waiting period more tolerable.

After the procedure, the degree of pain relief can vary, depending on the cause and location of the pain. In most cases, pain relief from RFA can last 12 months or longer; During the pain relief period, patients are typically able to participate in physical therapy and improve their overall activity level.

Evidence

For those patients where a knee replacement is seemingly inevitable, radiofrequency (RF) neurotomy of the genicular nerves can offer a substantial amount of pain relief without the need for an invasive surgery. Simply put, an ablation is performed at the superior lateral (SL), superior medial (SM), and inferior medial (IM) branches. The procedure generally takes 30 to 45 minutes and can provide pain relief for over a year. There are a number of publications in the literature that support its overall efficacy.

- Choi et al (2011)[5]: 38 patients with severe OA were enrolled, 19 received the ablation. The authors reported a statistically significant decrease in pain in the ablation group of 59%, 65% and 59% reporting at least 50% decrease in pain at 1 week, 4 weeks and 12 weeks respectively.
- Protzman et al (2013)[6]: Proved efficacy in patients with persistent pain after total knee arthroplasty
- Sari et al (2016)[7]: 40 patients received genicular ablation and followed for up to 3 months. Authors reported significant reductions in both VAS and WOMAC out to 3- months (LEVEL-I evidence)
- Davis et al (2017)[8]: 151 patients enrolled in a randomized, controlled trial (RCT). The authors reported statistically significant reductions in NRS, pain reduction, Oxford Knee Score, Global Perceived Effect as well as a mean change in medication usage. Moreover, treatment group performed better than the control (cortisone injection) at 6-months and there were no procedure-related serious adverse events reported. (LEVEL-I evidence)

REVIEW OF THE REPORT

We carefully examined the rationale leading to Cigna's decision to declare Radiofrequency Neurolysis of the Knee a non-covered treatment. With all due respect, the review is flawed, fraught with double standards, conveniently leaves out key publications and seems to pick out only key statements from the publications it does cite to make its point only to leave out the primary points of the articles, themselves.

Cigna's review states the following points to rationalize its decision regarding Genicular Nerve Ablation:

- **Variable Technique:** This is far from true or a legitimate reason. There is no one way to perform an epidural steroid injection. No 2 doctors will perform it the same yet it is covered treatment. Nerve blocks performed anywhere in the body are performed in a variety of ways, typically dependent on the operators place of training and comfort level with a particular technique. One can perform a nerve block using fluoroscopic guidance, under ultrasound or blind using landmarks to guide him/her. The same is true here – the genicular nerves are in a predictable location and the only variability that may exist lies in which of the aforementioned 3 techniques the operator may choose to place the needle in the correct location. Once there, the standard and accepted rules for performing a "nerve block" apply. Such concern over "variable technique" has never been an issue with any other of the 50 plus nerve blocks physicians perform regularly, why is it an issue now?

- **Small sample population:** Cigna's review conveniently omitted the prospective randomized, controlled trial by Davis, et al from 2017 in the Journal of Regional Anesthesia and Pain Medicine. This was an FDA-approved clinical trial, registered with clinicaltrials.gov on 151 patients with osteoarthritis of the knee. The study compares the used of Genicular Nerve Ablation to a standard cortisone injection as the control. The group receiving the ablation reported statistically significant improvements in pain at 6-months, where as the control group only statistically significant improvements at 1-month with pain returning close to baseline by 6- months. Cortisone injections are an approved treatment, yet Genicular Nerve Ablation is not despite the fact that is demonstrated superiority? Furthermore, to claim a "small sample population" as rationale for declaring this a non-covered treatment is inconsistent considering the sample size for Hyalgan (a covered treatment under Cigna) clinical trial from 1995 cited less than half (75) of the patients in the Davis study.

- **Differences surrounding selection criteria:** This is a curious statement considering all payers establish their own selection criteria surrounding any particular treatment – the same could be done here if Cigna so chose. Like with neurolysis of the medial branches, Cigna has clear guidelines as to how many test blocks must be performed, what kinds of conservative treatments must have been attempted first, etc. Why not do the same here? There are already clear guidelines for how to diagnose, establish and stage osteoarthritis of the knee. Such summaries already exist in your guidelines as it pertains to viscosupplementation of the knee. Why is that these guidelines and selection criteria are appropriate for viscosupplementation yet not appropriate for Genicular Nerve Ablation, especially when it purports to treat exactly the same pathology?

- **Lack of society guidelines:** Correct, there are no society guidelines. Given this procedure only became mainstream in the last 5 years, the pain management, orthopedic and physiatry communities have not yet had time to create any. However, if one were to speak of society guidelines as a means to decide whether or not a particular treatment should supported, then perhaps it would be worth mentioning the relevant guidelines put forth by the American Academy of Orthopedic Surgery (AAOS) in 2008 – "Treatment of Osteoarthritis of the Knee – 2nd Edition." Genicular Nerve Ablation is not mentioned in these guidelines as the procedure had not yet been discovered, however a number of other treatments were: cortisone injection, viscosupplementation and opioids for knee pain ALL were discussed.
  - RECOMMENDATION 7B: Opioids – inconclusive recommendation. Despite a clear lack of "society guidelines," Cigna does not appear to have any issue with approving oxycodone or hydrocodone for those suffering with knee pain, nor is there a prior approval process for generic versions of these drugs
  - RECOMMENDATION 8: Intra-articular Steroid – inconclusive recommendation. Yet another procedure that is clearly covered by Cigna, despite lack of societal support for said treatment
  - RECOMMENDATION 9: Recommend AGAINST Hyaluronic Acid – STRONG. The AAOS makes a strong recommendation against this treatment yet it is an approved treatment, across-the-board, on all Cigna policies. One of the largest medical societies in the United States makes a clear recommendation against the use of one treatment and it is approved, yet Genicular Nerve Ablation is denied because it has not been mentioned?

- **Concerns over safety given the proximity of genicular nerves to blood vessels:** proximity of blood vessels to nerves being targeted for neurolysis is not specific to genicular nerve ablation – there are blood vessels in close proximity to each and every procedure we perform as interventionalists, this procedure does not carry any inherent increased risk in that regard, to make such a claim is either intentionally misleading or due to a lack of knowledge of the risks by the authors. I would note that the literature does not support these concerns as the Davis study in 2017 showed the procedure to be safe and to have a low incidence of adverse

events.

- **Insufficient peer-reviewed evidence:** the literature search provided in Cigna's review appears to be painfully incomplete and intentionally omits a number of well- performed studies.

Cigna Lit Review	Study	Year	N
X	Franco	2015	8
X	Bellini	2015	9
Missed	Menzies	2015	1
Missed	Rojhani	2016	1
Missed	Farrell	2016	1
Missed	Reddy	2017	4
Missed	McCormick	2017	33
Missed	Davis	2017	151
Missed	McCormick	2017	54
X	Choi	2009	38
X	Ikeuchi	2009	35
Missed	Protzman	2014	1
X	Sari	2016	73
Missed	Shen	2017	54
Missed	Kirdemir	2017	49
X	Iannaconne	2017	31
X	Santana	2017	20
X	Gupta	2017	
X	Qudzi	2017	14

**The most egregious of these omissions is neglecting to include TWO LEVEL-I studies (Davis and Sari).*

Conclusion

This country is experiencing an opioid epidemic that is having a huge financial and social cost on Americans and insurance carriers. One of the biggest dilemmas this country faces in attempting to dig our way out of this epidemic is to discover additional ways to treat pain without using addictive pain medications. Geniculate Neurotomy is an effective treatment backed by Level-I evidence with a limited side-effect/risk profile that can be offered as an alternative to opioids for those in pain. To deny this treatment makes no sense and is a disservice to both your beneficiaries and shareholders as the alternative options are typically not only inferior but markedly more costly. NANS and its 1500 members urge Cigna to reconsider this non-coverage decision for geniculate neurotomy.

Sincerely,

[redacted]

Todd Sitzman, MD
President, NANS

[redacted]

David Kloth
Past President, NANS

[redacted]

David Provenzano
Director-at-Large, NANS
Policy & Advocacy Committee, Co-Chair

[redacted]

Jason Pope
Director-at Large, NANS
Policy & Advocacy Committee, Co-Chair

[redacted]

Corey W Hunter, MD
Director-at-Large, NANS

REFERENCES

[1] Lui SS, et al. A Cross-Sectional Survey on Prevalence and Risk Factors for Persistent Postsurgical Pain 1 Year After Total Hip and Knee Replacement. Regional Anesthesia and Pain Medicine. 2012; 37(4): 415-422

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Masters, Christine V. (HCA)

From: Weaver, Diane <Diane.Weaver@hyh.com>
Sent: Tuesday, August 7, 2018 7:19 PM
To: HCA ST Health Tech Assessment Prog
Cc: Weaver, Diane
Subject: Dr. Jeffrey S. Welch testimonial

Dr. Jeffrey S. Welch
Providence Pain Management
Providence Holy Family Hospital
Spokane, WA 99208
August 7, 2018

To whom it may concern;

I am a board certified interventional pain management physician working at the Providence Pain Management clinic for the last 6 years. We are extremely fortunate to have the Halyard Coolief Radio-Frequency generator which allows us to perform Coolief procedures. The most frequently requested procedure by far in our clinic is the geniculate nerve ablation for knee pain. Since the FDA endorsement of this procedure in the spring of 2017 our referrals have exploded. We are receiving dozens of referrals weekly and are struggling to keep up with the demand. These referrals are from local orthopedic surgeons who have recognized how beneficial this procedure has been for their patients.

This procedure is working much better than cortisone and Synvisc injections and is lasting far longer. It has been a godsend for patients with severe knee pain who are not candidates for knee replacement surgery or have already had surgery but still suffer with pain . Virtually all of my patients have had these other procedures previously and failed to get long term benefit. My patients are reporting a 75% reduction in pain scores with an extremely low failure rate (less than 5%). Recent studies have demonstrated that patients who have had this procedure prior to surgery are requiring significantly lower doses of opioid pain medications post-operatively. This alone is a good reason to support efforts to help all citizens of our state to have access to this procedure.

Thanks for your time and interest in this matter.

Sincerely,

Jeffrey S. Welch, D.O.

Diplomate, American Board of Anesthesiologists Diplomate, American Board of Pain Medicine

Sent from my iPad

_____

Masters, Christine V. (HCA)

From: Weaver, Diane <Diane.Weaver@hyh.com>
Sent: Tuesday, August 7, 2018 2:37 PM
To: HCA ST Health Tech Assessment Prog
Cc: Weaver, Diane
Subject: Tech Assessment - Peripheral Nerve Ablation for the treatment of Limb Pain - Cooled RF

This email comes to you in support of the tech assessment for Peripheral Nerve Ablation for the Treatment of Limb Pain from Dr. David Westerdahl, MD. -

---

From: David Westerdahl [mailto:dnwesterdahl@hotmail.com]
Sent: Tuesday, August 07, 2018 2:10 PM
To: Weaver, Diane <Diane.Weaver@hyh.com>
Subject: [EXTERNAL] Cooled RF

Dear WA State Health Care Authority;
My patients have greatly benefited from the use of cooled radio frequency ablation to treat knee arthritis pain. I have found it especially helpful for those with moderate to severe knee osteoarthritis who are not candidates for a knee replacement. These patients may be younger in age, overweight, or not able to have a knee replacement due to time lost from work or their role as a caregiver for other family members. I have found that My patients have achieved moderate pain relief for months to over a year. Most of my patients approximately 80% would say that they are satisfied or very satisfied with the release from this procedure. My patients have achieved moderate pain relief for several months to over a year. Most of my patients approximately 80% would say that they are satisfied or very satisfied with the release from this procedure.
Sincerely,
David Westerdahl,MD

Orthopedic SPECIALTY INSTITUTE

Wednesday, August 8, 2018

To whom it may concern:

This letter is in support of the use of cooled radio frequency ablation(cRFA) in the State of Washington for medical purposes.

I am a practicing board certified, fellowship trained, knee Orthopedic surgeon practicing in Coeur d'Alene, Idaho. I have been studying the use of cRFA for the nonoperative management of knee arthritis and for the potential benefits of pain management after knee arthroplasty.

We have been studying the effects of this technology on pain management via an IRB approved, prospective, double blinded level one clinical trial. The trial is multicentered, and has three surgeons involved. We recently performed a scheduled midterm limited biopsy of our data which demonstrated a statically significant 30% reduction in analog pain scores 2 weeks after knee arthroplasty for patients having undergone cRFA compared to placebo. When completed, our study will describe the effects this technology has on narcotic usage, hospital LOS, patient reported pain and functional scores, and physical therapy usage and milestones.

Based on our limited biopsy we are anticipating that the technology will demonstrate benefits that could potentially change the standard of care for patients have knee arthroplasty surgery.

Cooled RFA has already been shown to be an effective technology to manage arthritis-related knee pain and for some patients may be the only non-narcotic option for this condition.

My opinion is that it would be a mistake to exclude this technology from being utilized in the State of Washington.

Sincerely,

[redacted]

Dr. Jeffrey Lyman

Masters, Christine V. (HCA)

From: Weaver, Diane <Diane.Weaver@hyh.com>
Sent: Wednesday, August 8, 2018 2:37 PM
To: HCA ST Health Tech Assessment Prog
Cc: Weaver, Diane
Subject: WA Health Technology Assessment - Peripheral Nerve Ablation for The Treatment of Limb Pain
Attachments: WA State_reimbursement_MCL_08082018 - edits by Anne - Final - approved (002).docx

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Washington State Health Care Authority Technology Committee;

Please take into consideration the attached evidence for your assessment on the topic of "Peripheral Nerve Ablation for The Treatment of Limb Pain".

Best regards,
Mark Lavigne, PhD

Diane F. Weaver, MS
Sr. Manager, Health Economics & Health Policy
Cell Phone: (Corporate Line) 1 (442) 217-8794
Cell Phone: (858) 776-7682
Diane.Weaver@hyh.com

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A Presentation of Investigations of Radiofrequency Ablation to Treat Chronic Pain Emanating from the Knee and Hip

Mark C. Lavigne, PhD
Global Clinical Affairs
Avanos Medical

August 8, 2018

Introduction

Chronic osteoarthritis is a prevalent and disabling condition currently affecting an estimated 40 to 50 million Americans, with approximately 10% to 30% of those afflicted having significant pain, impaired function, and decreased quality of life.[1-3] The socioeconomic burden of knee and hip OA alone averages more than $12,000 annually in both direct and indirect costs of disease.[4] A common approach to this clinical challenge is to first address the major symptom of disease, pain, rather than the disease itself, which would likely warrant surgery. Traditional strategies for reducing joint pain include so-called conservative therapies to reduce inflammation and/or pressure in the affected area by using oral analgesics such as NSAIDs and/or opioids, corticosteroid injections, or injection of biological agents such as hyaluronate (viscosuplementaion) or PRP. However, chronic use of NSAIDs can introduce gastrointestinal, cardiovascular, and renal complications,[5] opioids present the risk of tolerance and addiction with escalating dosage over time,[6] physical therapy requires routine visits that increase healthcare expenditures, corticosteroid injections have limited duration of efficacy,[7,8] viscosupplementation efficacy is equivocal,[9,10] as is PRP compared to viscosupplementation,[11,12] and bracing may not be cost-effective.[13] Knee and hip replacement may be indicated in lieu of these conservative therapies, but not every patient may be considered “operative”, due to comorbid health issues that would preclude them from surgery or increase the risk profile for undergoing surgery. Thus, a treatment option that is relatively non-invasive, but is more effective than conservative treatments for chronic pain of the knee and hip, is warranted.

Thermal radiofrequency ablation (both standard RF and cooled thermal RF) is a safe, target-specific treatment that can be performed on an outpatient basis with minimal sedation required, and in a short period of time (typically less than 45 minutes). Both standard and cooled radiofrequency ablation denervate nervous tissue at ≥ 80° Celsius. In their 3-month follow-up to RFA of the genicular nerves (sensory nerves of the knee), Iannaccone et al. determined that the average pain relief was 67% improvement from baseline knee pain, with 0% being no relief and 100% being complete relief, and average 0 (no pain)-10 (worst pain) pain score was 2.9. At the 6-month follow-up, of those who described pain relief at 3 months, 95% still described analgesia. This group’s average percent pain relief was 64 and average day’s 0-10 pain score 3.3. The authors concluded that, based on patient interviews and data collection, RFA of genicular nerves could supply on average greater than 60% pain relief in their patient population for as long as 6 months. As ablated peripheral nerves regenerate,[14] knee and hip pain and disability may reemerge. As has been reported with medial branch neurotomy,[15] repeat neuroablative procedures reinstate pain relief. Therefore, if knee pain eventually did return, repeating RFA would be reasonable and sensible, especially if in the interim, the patient enjoys reduction in pain, disability, and the need for less oral analgesics.

The data provided in this report are intended to address the questions shown immediately below regarding the application of RFA of sensory nerves of the knee and hip to primarily relieve affected patients of chronic pain associated with these joints.

1. *What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*
2. *What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*
3. *Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:*
    a. *Indication*
    b. *Patient characteristics*

Glossary of Acronyms and Terms used in this Report

Acronym or Term	Meaning and/or Definition
AE	Adverse event
AKSS	American Knee Society Score - a widely used functional outcome score for knee arthroplasty. Grading for the Knee Society Score Score 80-100 – Excellent; Score 70-79 – Good; Score 60-69 – Fair; Score below 60 - Poor
ALGC	Analgesics
BMI	Body mass index
CI	Confidence interval
cm	centimeter
CON	Control (group)
CR	Case Report
CRFA	Cooled radiofrequency ablation
Harris Hip Score	Used to assess the results of hip surgery, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. Grading for the Harris Hip Score Successful result =post-operative increase in Harris Hip Score of > 20 points + radiographically stable implant + no additional femoral reconstruction or <70 – Poor; 70-79 – Fair; 80-89 – Good; 90-100 - Excellent
hr	Hour
hypoesthesia	Reduced sense of touch or sensation, or a partial loss of sensitivity to sensory stimuli (i.e., numbness).
IAS	Intra-articular steroid injection
IPBSN	Infrapatellar branch of the saphenous nerve
iv	Intravenous
Kellgren-Lawrence	A scoring tool used to assess the severity of knee osteoarthritis on a plain radiograph. GRADE DESCRIPTION: 0 - No radiographic features of osteoarthritis 1 - Possible joint space narrowing and osteophyte formation 2 - Definite osteophyte formation with possible joint space narrowing 3 - Multiple osteophytes, definite joint space narrowing, sclerosis and possible bony deformity 4 - Large osteophytes, marked joint space narrowing, severe sclerosis and definite bony deformity
kg/m	Kilograms/meter
mg	Milligram
ml	Milliliter
MRI	Magnetic resonance imaging
MUA	Manipulation under anesthesia

MQS3	Medication Quantification Scale; an instrument with clinical and research applications for quantifying medication regimen use in chronic pain populations. It co-quantifies three relevant aspects of medications prescribed for chronic nonmalignant pain: drug class, dosage, and detriment (risk). The 2003 version (MQS III) is the third iteration of the scale, featuring new detriment weights determined by surveying all physician members of the American Pain Society in the United States via mail. Reduced scores indicate less medication use.
NB	Nerve block
NRS	Numeric rating scale (pain measurement); 0 score = no pain; 10 score = worst pain
NSAID	Nonsteroidal anti-inflammatory drug
OA	Osteoarthritis
OHS/OKS	Oxford Hip Score/Oxford Knee Score Score 0 to 19 - May indicate severe hip/knee arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an Orthopaedic Surgeon. Score 20 to 29 - May indicate moderate to severe hip/knee arthritis. See your family physician for an assessment and x-ray. Consider a consult with an Orthopaedic Surgeon. Score 30 to 39 - May indicate mild to moderate hip/knee arthritis. Consider seeing your family physician for an assessment and possible x-ray. You may benefit from non-surgical treatment, such as exercise, weight loss, and /or anti-inflammatory medication Score 40 to 48 - May indicate satisfactory joint function. May not require any formal treatment.
PB	Prognostic block
PBO	Placebo
PGIC	Patient Global Impression of Changes (in disease symptoms) The PGIC is based on a 7-point scale of subjects' responses, including "very much improved" (score of 1); "much improved" (2); "minimally improved" (3); "no change" (4); "minimally worse" (5); "much worse" (6); and "very much worse" (7), to express how treatment for their pain has affected their overall health satisfaction.
PRP	Platelet-rich plasma
RCT	Randomized controlled trial
RF	Radiofrequency
RFA	Radiofrequency ablation
SAE	Serious adverse event
SD	Standard deviation
SF-36	Short-Form Health Survey - Determines quality of life, with a higher score indicating better life quality.
SRFA	Standard radiofrequency ablation
TKA	Total knee arthroplasty
TKR	Total knee replacement
Tönnis Grades	Tönnis Classification of Osteoarthritis by Radiographic Changes GRADE DESCRIPTION: 0 - No signs of osteoarthritis 1 - Mild: Increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity 2 - Moderate: Small cysts, moderate narrowing of the joint space, moderate loss of head sphericity
VAS	Visual analog scale (pain measurement); 0 score = no pain; 10 score = worst pain
WOMAC	A widely used, proprietary set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints. The WOMAC measures five items for pain (score range 0–20), two for stiffness (score range 0–8), and 17 for functional limitation (score range 0–68). For each question, score of 0 = none; score of 4 = extreme.

Investigations of Radiofrequency Ablation to Treat Chronic Pain Emanating from the Knee

Question 1. *What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*

Radiofrequency ablation of sensory nerves of the knee to mitigate chronic pain derived from this joint has been examined in various study formats.

Four case reports were identified that used standard and cooled RF versions (Tables 2-5). The former produced significant analgesia and functional improvements up to six months post-intervention in one of the two patients who received this treatment. In contrast, one of the patients treated with CRFA enjoyed pain relief and enhanced knee function for up to 6 and 9 months, respectively, on the treated left and right knee, respectively. Two case series described use of CRFA (Table 6 and 7), with the majority of patients in each experiencing significant and clinically-relevant analgesia, improved function, and reduced pain medication use, up to 12-months post-procedure. Other non-comparator studies demonstrated 50% pain reduction (SRFA: 12 months; CRFA: 6 months), improved function, and "very much improved/improved" self-reported patient conditions following RFA for chronic knee pain (Tables 8-10).

In comparator non-RCT studies, SRFA was compared to nerve block, IAS, and PRP/viscosupplementation (sodium hyaluronate) as therapy for chronic knee pain. The SRFA significantly decreased knee pain, as measured by VAS for 12 weeks, compared to nerve block (control). More patients in the SRFA group responded (defined as a 50% or greater decrease in the pain VAS or the WOMAC pain subscale) to the treatment than in the control group for up to 12 weeks. Eight patients (44%) treated with SRFA rated the global assessment of her/his condition as "excellent" or "good", while three (18%) in the control group rated treatment as "good", although the difference was not significant (Table 11). The VAS- and WOMAC-measured improvements in knee pain and function were greater for SRFA than for IAS at the 3-month and 1-month follow-up, respectively (Table 12). Up to 3 months post-intervention, SRFA more effectively relieved refractory knee pain and promoted functional recovery compared to PRP/viscosupplementation (Table 13).

Two RCTs used SRFA, while CRFA was used in two others. The VAS and OKS results showed that SRFA yielded significantly less knee joint pain and improved function than placebo (SRFA arrangement, including probe placement, but without energy delivery to tissue) up to 12 weeks post-procedure, and 10/17 (59%), 11/17 (65%), and 10/17 (59%) in the SRFA cohort achieved at least 50% knee pain relief at 1, 4, and 12 weeks, respectively (Table 14). Prognostic block prior to CRFA did not enhance analgesia or functional improvements, however, at 6 months following CRFA, both the majority of pre-block and no-pre block groups experienced pain relief that was ≥50%, and at least a 15-point reduction (improvement) in WOMAC scores (Table 15). In an evaluation that compared CRFA to IAS, at 6 months post-intervention, patients in the ablation group had greater analgesia compared to those who received a single IAS injection in the affected knee. More pain relief in the CRFA group was accompanied by better functional improvements and perceptions of the treatment effects.

Non-opioid medication use declined in the CRFA cohort to a greater extent than that among IAS patients (Table 16). Compared to analgesics use only to address chronic knee pain, SRFA provided better pain relief and functional improvements, as VAS and WOMAC scores up to 6 months post-procedure indicated ablation to be more favorable. All participants noted quality of life improvement, and patient satisfaction in her/his condition was higher in the SRFA group at 6 months. The participants in the SRFA group did not need supplementary analgesia related to the treated joint during the entire follow-up period (Table 17).

Question 2. *What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*

Of the 17 studies detailed in this report pertaining to the knee, AEs were not reported in 12 (71%) of them. The investigations (Tables 5,10,11,13,17) that reported AEs did not need to halt their interventions because of such observations, and evidence of AEs were distributed between both SRFA and CRFA. The study-associated AEs were mostly minor, with little or no medical attention required for their resolution. The majority of AEs reported in Table 13 were deemed to have an "unrelated" or "unlikely" relationship with CRFA, and no SAEs were reported in this study. In their 2016 literature review, Kim et al. reported that vascular injuries after RFA of genicular nerves (sensory nerves of the knee) have not been reported, but genicular vascular complications are well-documented in the surgical literature.[17]

Question 3. *Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:*

a. Indication
b. Patient characteristics

The paucity of AEs reported in the studies herein make it difficult to definitively associate an indication or patient characteristic(s) with the likelihood of a particular AE occurring when RFA is used to treat chronic knee pain. As such, no indication or patient characteristic(s) was identified as being predictive of eliciting an AE upon SRFA or CRFA for chronic pain stemming from the knee.

No objective evidence of a specific indication for RFA of sensory nerves of the knee was provided in the bibliography of this report. Indeed, RFA of the knee was successful among a variety of patient clinical backgrounds and OA severity levels (Kellgren-Lawrence Grades 2-4). However, a consistent pattern of need for RFA was evident among patients who had previously engaged in conservative, relatively non-invasive treatments (e.g., physical therapy, intra-articular steroid injections, viscosupplementation, and autologous stem cell therapy), but without much success and satisfaction. The clinical backgrounds of such patients were variably prohibitive for surgery to resolve their disease and pain, thus these patients

were often referred to a pain clinic where the physician discussed the possibility of the intermediately invasive (relative to conservative therapies and surgery) RFA option as therapy. Because RFA patients often used oral analgesics, including opioids, to address non-joint related symptoms, it is difficult to determine whether RFA could reduce opioid use. One report indicated that 80% or greater relief from diagnostic blocks and duration of pain of less than five years are associated with high accuracy in predicting CRFA treatment success (Table 7). Other than these success qualifiers, there were no other evident patient characteristics or disease conditions revealed to predict the extent of RFA success for treating chronic knee pain.

Non-Comparator Studies

Case Reports

TABLE 1.

Title: Preoperative Pulse and Thermal Radiofrequency Facilitates Prehabilitation and Subsequent Rehabilitation of a Patient Scheduled For Total Knee Arthroplasty

Citation: Carli F, Chora D, Awasthi R, Asenjo JF, Ingelmo P. Can J Anaesth 2015;62:1355-1366.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	The patient had severe osteoarthritis of the knee requiring total knee arthroplasty. Significant knee pain unrelieved by opioid medication (codeine 30 mg/paracetamol 325 mg six times a day and pregabalin 50 mg twice a day), and had severely impaired functional activity, poor nutritional status, and moderate depression. In view of her relatively large opioid consumption, she agreed to RF denervation of the affected knee.	79	24	Not indicated.	Knee arthroplasty was performed under spinal anesthesia, and for postoperative analgesia, the patient received a continuous femoral blockade catheter with ropivacaine (0.2%) at 5 ml/hr^{-1} for two days and subsequently acetaminophen at 1 gram four times a day, Celebrex 200 mg twice a day, and tramadol 50 mg iv three times a day. Ambulation started with the help of a physiotherapist on the first post-operative day, and the physiotherapy continued until discharge on the fourth post-operative day. The Table below reports the changes in various domains during the pre-habilitation period and up to eight weeks following surgery. The excellent pre-operative analgesia allowed significant improvement in all the objective and self-reported outcome measures recorded during the six weeks before surgery and the eight post-operative weeks. The high quality of analgesia achieved with the SRFA had a major impact by facilitating the implementation of pre-habilitation and rehabilitation. In addition, the physical training likely played an important role in enhancing the patient's physical strength.	None reported.

From Carli et al.:

Table List of outcome measures

Outcome Measures	Baseline	Preoperative	4 weeks after surgery	8 weeks after surgery
TUG (sec)	16	8	10	10
6MWD (metres)	214	302	300	350
Energy Expenditure ($kcal \cdot kg^{-1} \cdot week^{-1}$)	18	37	8	64
36 Item Short Form Survey (SF-36®)				
PCS	20	25	22	39
MCS	38	60	51	68
HADS				
Anxiety	5	1	4	2
Depression	5	3	7	2
WOMAC				
Pain	15	8	10	6
Stiffness	4	4	5	3
Physical Function	53	38	37	25
VAS	8	1	6	1

6MWD = six minute walk distance: distance covered over 6 min; (patient's age-adjusted predicted value, 540 m); lower distance indicates decreased functional capacity

HADS = Hospital Anxiety and Depression Scale: score > 5 indicates moderate to severe state of anxiety and depression

PCS = Physical Component scale; MCS = Mental Component scale. The scales are indices of quality of life: scores > 50 indicate better health states

TUG = time up and go; time to start up walking 3 metres and come back; higher score than 10 sec indicates limited independent function

VAS = visual analogue pain scale (0-10); 0 = no pain; 10 = worst imaginable pain

WOMAC = Western Ontario and McMaster Osteoarthritis Index: pain score (0-20), stiffness score (0-8), physical function score (0-68); higher scores indicate worse pain, stiffness and functional limitations

TABLE 2.

Title: **Analgesia and Improved Performance in a Patient Treated by Cooled Radiofrequency for Pain and Dysfunction Postbilateral Total Knee Replacement**

Citation: Menzies RD, Hawkins JK. Pain Pract 2015;15:E54-E58.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Cooled	1	Physical therapy following TKR on the right knee failed to restore satisfactory range of motion; thus, MUA (4 months post-TKR) was performed on this knee. Although chronic pain in the right knee was unchanged, the range of motion improved following MUA. Pain, limited mobility, and unsatisfactory function, as evidenced by the patient's inability to walk more than 100 yards and complete inability to climb stairs, continued for both knees. The patient managed knee pain by taking Mobic (7.5 mg daily) and Norco (10 mg/325 mg) as needed every 6 hours. The patient was referred for nerve ablation by an orthopedic surgeon, and presented as a patient whose bilateral TKRs had unsatisfactory results, as indicated by his persistent knee pain, immobility, and reduced function. The surgeon had confirmed that the patient had no knee infections or loose hardware.	68	48.82	Not indicated.	The patient reported marked OKS improvements for both knees following CRFA. Indeed, pain and overall score ratings each increased after CRFA, indicating sustained pain relief and better knee function up to 9 and 6 months for the left and right knees, respectively. Moreover, after having CRFA of the knees, 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.	None reported.

TABLE 3.

Title: **Ultrasound-Guided Genicular Nerve Thermal Radiofrequency Ablation for Chronic Knee Pain**

Citation: Wong J, Bremer N, Weyker PD, Webb CA. Case Rep Anesthesiol 2016;2016:8292450.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	A patient with osteoporosis and chronic joint pain presented to the pain clinic for assistance in managing her chronic knee pain. Her 10-point VAS for pain was 8/10 with activity and 3/10 at rest. She was previously treated with a series of three intraarticular knee injections, which helped her pain for approximately one month. She was also prescribed acetaminophen and diclofenac 1% gel, but could not take oral NSAIDs due to a history of severe gastritis. A recent knee X-ray demonstrated severe medial femorotibial and mild lateral femorotibial compartment osteoarthrosis of the right knee. Physical exam during this visit was significant for bilateral mild knee edema, crepitus, and pain with flexion/extension of both knees. The patient was not interested in surgery, and was referred from her orthopedic surgeon for pain management.	88	Not indicated.	Not indicated.	The patient reported significant improvement in pain (VAS scores of 2/10 with activity and 0/10 at rest) and function with this block and was scheduled for continuous SRFA the following week. At the one-month follow-up visit, the patient had complete pain relief with VAS pain scores of 0/10 with activity and 0/10 at rest. Functionally, she could walk around home and to the store without limitations. At 6 months, she continued to be 100% pain-free (VAS pain scores ranging from 0 to 2 with activity and 0/10 at rest) without any functional limitations.	None reported.

TABLE 4.

Title: **Demonstration of Lesions Produced by Cooled Radiofrequency Neurotomy for Chronic Osteoarthritic Knee Pain: A Case Presentation**

Citation: Farrell ME, Gutierrez G, Desai MJ. PM R 2017;9:314-317.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Cooled	1	A patient with a significant past medical history of degenerative joint disease was referred by his orthopedic surgeon for pain management consultation to address severe left-sided knee pain. He presented with pain in his left knee rated 9/10 on a NRS, with daily discomfort limiting function, including severe limitations of walking and climbing stairs. His pain was refractory to treatment with medications, physical therapy, intra-articular steroid injections, viscosupplementation, and autologous stem cell therapy injection by his surgeon.	67	Not indicated.	Not indicated.	At 19 days after CRFA, the patient began experiencing pain in the posterior aspect of his knee. Magnetic resonance imaging with contrast was ordered to rule out infection. Although not the primary purpose, the MRI findings demonstrated evidence of the CRFA lesions at the superiomedial and superiolateral sites as well as a 4x5 cm cyst/effusion in his popliteal fossa, consistent with a Baker cyst. This was an unexpected finding following the procedure, as the authors are unaware of any evidence suggesting that RF neurotomy may lead to cyst/effusion formation. Aspiration was performed under ultrasound guidance without injection of corticosteroid, and yielded 20 ml of serosanguinous fluid that was culture negative. No further posterior knee pain was reported by the patient at subsequent visits. The patient was seen at 1-month and 3-month intervals following CRFA. At these visits, he continued to report significant pain reduction and improvement of his function. At the 1-month and 3-month follow-up visits, his average pain score was 3/10, with self-reported improvement in function. The patient did not return after 3 months.	None reported.

TABLE 5.

Title: **Water-Cooled Radiofrequency Provides Pain Relief, Decreases Disability, and Improves Quality of Life in Chronic Knee Osteoarthritis**

Citation: Rojhani S, Qureshi Z, Chhatre A. Am J Phys Med Rehabil 2017;96:E5-E8.

Study Design	Type of RFA	Number of Subjects	Indication	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain in Months	Results	Adverse Events
CR	Cooled	1	The patient presented with chronic intermittent bilateral knee pain and previously diagnosed chronic OA. Conservative management of OA consisted of trials of acetaminophen, heat, elevation, ice, immobilization, rest (non-weight bearing), and several courses of physical therapy with mild temporary improvement in pain. The patient continued use of acetaminophen (500 mg) up to five times weekly and naproxen (375 mg) twice daily, and required use of a straight cane to assist with community ambulation. In addition, treatment included bilateral intraarticular corticosteroid knee injections and subsequent hyaluronate injections over the course of two years prior to presentation. The patient's experience with injection therapy initially provided up to 75% relief for up to 6 months, although the patient ceased injection therapy with the previous provider because of waning therapeutic effect. The participant completed an outpatient physical therapy program in the year prior to CRF system and received home exercise strategies and disease education from therapy, physiatry, and primary care. The improvements initially manifested as increased walking distance and greater speed with stair ascension,	81	34	36	The patient tolerated the procedure well, and the procedure was without complications other than local post-procedure pain. She had completed physical therapy within the previous year and continued her home exercise program after the procedure. Six weeks and 3 months after bilateral CRFA, repeat NRS evaluation revealed a pain score of 0/10 bilaterally at the time of evaluation, and WOMAC scores of 22 and 26, reflecting a minimal level of disability and overall mild pain.	Post-procedure pain.

			although this had diminished to mere feet with increasing pain severity. At that time, the same provider who performed hyaluronate injections offered the patient bilateral TKA, which the patient refused because of personal fear of surgery.					

Case Series

TABLE 6.

Title: **Cooled Radiofrequency System Relieves Chronic Knee Osteoarthritis Pain: The First Case-Series**

Citation: Bellini M, Barbieri M. Anaesthesiol Intensive Ther 2015;47:30-33.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Mean Age (years) (SD)	Mean Body Mass Index (kg/m^2)	Pre-Procedure Mean Duration of Pain in Months (SD)	Results	Adverse Events
CS	Cooled	9	The study subjects comprised elderly patients with chronic knee pain (i.e. knee pain of at least moderate intensity on most days for > 3 months) and radiologic tibio-femoral OA. These patients did not respond to other treatments including physiotherapy, oral analgesics, and intra-articular injection with hyaluronic acids or steroids.	72 (4)	Not indicated.	67.8 (50)	The authors observed an improvement in VAS pain scores 2 (mean)±0.5 (SD) 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. The majority of patients with chronic knee pain experienced a clinically relevant degree of pain relief and improved function following CRFA of genicular nerves at one, three, six, and 12 months follow-up.	None reported.

TABLE 7.

Title: **Cooled Radiofrequency Ablation of Genicular Nerves for Knee Osteoarthritis Pain: A Protocol for Patient Selection and Case Series**

Citation: Reddy RD, McCormick ZL, Marshall B, Mattie R, Walega DR. Anesth Pain Med 2016;6:E39696.

Study Design	Type of RFA	Number of Subjects	Indication	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CS	Cooled	4	**Case 1:** A 65-year-old obese man, (BMI = 41) presented with progressive left knee pain of more than five years duration. Radiographs of the knee showed Kellgren-Lawrence grade 3 medial compartment OA. He reported 9/10 on the NRS, worsened by range of motion and weight bearing. He used a cane for ambulation. Non-steroidal anti-inflammatory medications, three intra-articular steroid injections, and physical therapy provided only modest transient pain reduction. Due to anemia of unknown etiology, TKA was contraindicated per orthopedic surgery. On examination, he demonstrated reduced knee range of motion in flexion, medial joint line tenderness to palpation, and an antalgic gait. **Case 2:** A 63-year-old morbidly obese man (BMI = 43) with disabling bilateral knee pain presented after several years of symptom progression following arthroscopic repair of a torn right meniscus. Radiographs of the knees confirmed tri-compartmental knee OA, Kellgren-Lawrence grade 3 on the left and grade 4 on the right. He reported 5/10 pain on the NRS, worsened with knee flexion. He noted limited ability to ambulate and perform stair climbing. Six periodic intra-articular steroid injections and physical therapy previously provided symptom relief, but were no longer effective. He had avoided use of opioids, but was taking ibuprofen up to 1200 mg daily. Physical examination revealed reduced end-range flexion range of motion bilaterally, medial and lateral knee joint line tenderness bilaterally, and antalgic gait. **Case 3:** A 66-year-old woman(BMI = 35) presented with 3 years of bilateral knee pain due to previously diagnosed OA. Radiographs of the knee showed Kellgren-Lawrence grade 3 and 4 medial compartment OA, on the left and right sides, respectively. She reported 7/10 pain in the right knee and 5/10 pain in the left knee on the NRS, worsened with prolonged walking. Her pain had been managed with	See "Indication" column.	See "Indication" column.	Not indicated.	All four patients reported 80%-100% improvement in knee pain at 6-12 months follow-up. All patients reported improved daily function, including walking and climbing stairs. One of the two patients taking opioids reduced use. Three patients had improved MSQ3 scores, while all four showed improved MSQ3 scores when excluding pain medications taken for an unrelated pain condition (low back and radicular pain in Case 1).	None reported.

			tramadol 100 mg daily. NSAIDs were contraindicated due to clopidogrel use for coronary artery disease. She had undergone physical therapy and five intra-articular steroid injections with diminishing benefit. She refused bilateral TKA due to concerns about her cardiac disease. Physical exam was remarkable for bilateral valgus deformities of the knees with decreased end-range flexion range of motion, medial and lateral joint line tenderness, and antalgic gait with use of a cane. **Case 4:** A 64 year-old man with Parkinson's disease (BMI = 24) and a remote history of right meniscectomy presented with progressive right knee pain. Radiographs of the knee demonstrated Kellgren-Lawrence grade 3 medial compartmental OA. He reported 5/10 pain on the NRS, worse with prolonged sitting. He had undergone four intra-articular steroid injections and physical therapy without sustained benefit. He was taking ibuprofen 200 mg as needed 1-2 times weekly. Physical exam was significant for crepitus with right knee range of motion, medial joint line tenderness, and an antalgic, shuffling Parkinsonian gait, for which he used a cane.					

From Reddy et al.:

Table 1. Summary of Case Presentations

Patient	1	2	3	4
Age	65	63	66	64
Sex	M	M	F	M
BMI	41	43	35	24
Unilateral (U) vs. Bilateral (B) RFA	U	B	B	U
Baseline NRS (Right/Left, if applicable)	6	5/4	7/5	3
Baseline MQS3/MEq	32.1/64	8/0	4.8/10	4/0
Percent reduction in pain with test block	100	100/100	86/100	100
Percent reduction in pain 3 month post-RFA	100	90/90	80/50	90
Percent reduction in pain 6 months post-RFA	100	90/90	85/80	90
Percent reduction in pain 9 months post-RFA	90	80/80	N/A	N/A
Reduction in MQS3 score at 6 months post-RFA	-6.9[2]	8	4.8	4
Reduction in Morphine equivalent consumption at 6 months post-RFA	-8[2]	N/A	10	N/A
Self-Reported Functional Change	Initially improvement walking with elimination of cane use and improved squat transfers	Improved prolonged ambulation and stair climbing	Improved transfers from sitting and prolonged ambulation	Improved prolonged standing and ambulation
Current Surgical Status (TKA or None)	None	None	None	None

[2] Rise in MSQ3 score related to low back and radicular pain, not knee pain.

TABLE 8.

Title: **The Genicular Nerve: Radiofrequency Lesion Application for Chronic Knee Pain**

Citation: Kirdemir P, Çatav S, Alkaya Solmaz F. Turk J Med Sci 2017;47:268-272.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Mean Age (years) (SD)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
Prospective	Standard	49	Patients were at Stage 2-4 according to the Kellgren–Lawrence classification of diagnostic criteria of the American Rheumatology Association, and had not responded to a 6-month period of conservative treatment, such as physiotherapy, analgesics, or intraarticular steroid or hyaluronic acid injection.	64 (10.6)	Not indicated.	Not indicated.	The mean VAS scores indicated reduced pain over time, as before the procedures mean VAS was 8.9±0.8 (SD), while 1, 4, and 12 weeks after the procedure, it was 4.73±3.23, 3.89±2.9, and 3.93±2.95, respectively. The mean WOMAC scores indicated reduced pain and improved function over time, as before the procedures the score mean was 64.26±7.29, while 1, 4, and 12 weeks after the procedures it was 44.93±13.18, 42.81±13.15, and 43.04±13.36, respectively.	None reported.

TABLE 9.

Title: **Cooled Radiofrequency Ablation of the Genicular Nerves for Chronic Pain due to Knee Osteoarthritis: Six-Month Outcomes**

Citation: McCormick ZL, Korn M, Reddy R, Marcolina A, Dayanim D, Mattie R, Cushman D, Bhave M, McCarthy RJ, Khan D, Nagpal G, Walega DR. Pain Med 2017;18:1631-1641

Study Design	Type of RFA	Number of Subjects	Clinical Background	Median Age (years) (IQR)	Median Body Mass Index (kg/m^2) (IQR)	Pre-Procedure Duration of Pain in Years	Results	Adverse Events
Retrospective cross-sectional survey	Cooled	33	Patients were included in the study if the following criteria were met: 1) age 18 to 89 years; 2) native symptomatic knee(s); 3) 50% or greater concordant pain relief of typical knee pain during walking and weight-bearing following a set of diagnostic superiomedial, superiolateral, and inferomedial genicular nerve blocks with 1 ml of 2% lidocaine at each location; 4) CRFA of the superiomedial, superiolateral, and inferomedial genicular nerves; 5) at least a 6-month time period since the genicular CRFA procedure was performed.	66 (62-77)	31 (24-38)	< 2 - > 5	Thirty-three patients (52 discrete knees) met inclusion criteria. At 6-months, thirty-five percent (95% CI = 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 MQS3 score, and PGIC score consistent with "very much improved/improved." Nineteen percent (95% CI = 10-33) of procedures resulted in complete pain relief. Greater duration of pain and greater than 80% pain relief from diagnostic blocks were identified as predictors of treatment success.	None reported.

From McCormick et al.:

Table 2 Pain NRS and MQSIII baseline values and change from baseline to follow-up and PGIC rating at follow-up after genicular nerve cooled radiofrequency ablation

						NRS Scores			MQSIII Value		PGIC Score
Patient	Knee	Symptom Duration, mo	Relief (%) from Diagnostic Block	Time to Follow-Up, mo	TKA	Preprocedure Baseline	Postprocedure Follow-Up (Minimum 6 mo)	Difference (Follow-Up Minus Baseline)	Baseline	Difference (Follow-Up Minus Baseline)	
1	1[†,‡]	36	100	15	No	8	2	6	4	3.5	Improved
1	2[†,‡]	36	100	15	No	8	1	7	3	0	Very much improved
2	3[†,‡]	60	90	8	No	10	2	8	7	3.4	Improved
2	4[†,‡]	60	75	8	No	10	1	9	7	3.4	Improved
3	5	45	100	7	No	8	8	0	14	7.2	Minimally improved
4	6	50	100	7	Yes	10	–	–	3	–	–
4	7	50	100	7	Yes	10	–	–	3	–	–
5	8[†,‡]	24	75	10	No	7	1	6	8	6.8	Very much improved
6	9	120	100	7	No	7	6	1	0	0	No change
7	10[*,†,‡]	36	100	15	No	6	0	6	3	3.4	Very much Improved
8	11	96	100	10	Yes	7	–	–	0	–	–
8	12	96	90	10	No	7	7	0	0	0	No change
9	13	60	100	Lost	–	7	–	–	6	–	–
10	14	60	70	6	Yes	5	10	−5	6	0	Worse
10	15	60	70	6	Yes	5	10	−5	6	0	Worse
11	16	120	100	10	No	6	5	1	6	0	No change
11	17	120	100	10	No	6	5	1	6	0	No change
12	18[*,†,‡]	36	100	11	No	6	0	6	6	6.8	Improved
12	19[‡]	36	100	11	No	6	1	5	6	6.8	Minimally improved
13	20	72	100	8	No	8	8	0	0	−2.1	Minimally improved
14	21	240	100	8	No	8	7	1	12	6.8	Minimally improved
15	22[†,‡]	12	75	6	No	10	5	5	9	2.8	Improved
15	23[†,‡]	12	75	10	No	10	5	5	9	2.8	Improved
16	24[‡]	48	100	7	No	6	4	2	3	0	Minimally improved
16	25[‡]	48	100	7	No	6	4	2	3	0	Minimally improved
17	26	60	100	Lost	–	6	–	–	7	–	–
18	27	72	100	7	No	8	7	1	7	0	No change
19	28[*,†,‡]	36	100	8	No	8	0	8	3	2.8	Very much improved
19	29[*,†,‡]	36	100	8	No	8	0	8	3	2.8	Very much improved
20	30[†,‡]	60	50	10	No	8	1	7	3	−2.5	Improved
20	31	60	100	10	No	8	7	1	3	0	No change

(continued)

Table 2 Continued

Patient	Knee	Symptom Duration, mo	Relief (%) from Diagnostic Block	Time to Follow-Up, mo	TKA	NRS Scores			MQSIII Value		PGIC Score
						Preprocedure Baseline	Postprocedure Follow-Up (Minimum 6 mo)	Difference (Follow-Up Minus Baseline)	Baseline	Difference (Follow-Up Minus Baseline)	
21	32*,†,‡	108	100	14	No	6	0	6	18	5.3	Very much improved
22	33*,†,‡	8	100	10	No	6	0	6	3	0	Very much improved
23	34‡	135	100	10	No	8	6	2	8	7.6	Minimally improved
23	35	135	50	10	No	8	8	0	8	7.6	Minimally improved
24	36	12	100	9	No	10	10	0	6	0	No change
24	37	12	70	9	No	10	10	0	6	0	No change
25	38*,†,‡	15	90	6	No	7	0	7	8	7.6	Very much improved
25	39*,†,‡	15	90	6	No	7	0	7	8	7.6	Very much improved
26	40	240	50	7	No	7	6	1	22	6.4	Minimally improved
26	41	240	50	7	No	6	6	0	22	6.4	Minimally improved
27	42‡	30	100	6	No	9	5	4	5	3.4	Minimally improved
27	43*,†,‡	30	100	6	No	9	0	9	5	3.4	Improved
28	44‡	84	80	6	No	8	5	3	15	0	Minimally improved
28	45	84	50	6	Yes	8	–	–	15	–	–
29	46	120	100	6	Yes	7	–	–	11	–	–
30	47	9	99	Lost	–	7	–	–	14	–	–
31	48*,†,‡	24	100	6	No	8	0	8	6	2.3	Very much improved
32	49	72	100	6	No	6	5	1	7	3.8	No change
32	50	72	100	6	No	6	5	1	7	3.8	No change
33	51‡	60	100	6	No	9	6	3	3	3	Minimally improved
33	52‡	60	100	6	No	9	6	3	3	3	Minimally improved

Lost = lost to follow-up; MQSIII = Medication Quantification Scale III; NRS = numeric rating scale; PGIC = Patient Global Impression of Change; TKA = total knee arthroplasty.
*Treatment success based on definition of complete relief of pain AND PGIC of "very much improved or improved" AND did not undergo TKA.
†Treatment success based on definition of ≥50% reduction in NRS score AND PGIC of "very much improved or improved" AND did not undergo TKA.
‡Treatment success based on definition of a reduction of two or more points from baseline NRS value.

TABLE 10.

Title: **Analgesic Effect and Functional Improvement Caused by Radiofrequency Treatment of Genicular Nerves in Patients with Advanced Osteoarthritis of the Knee Until 1 Year Following Treatment**

Citation: Santana Pineda MM, Vanlinthout LE, Moreno Martín A, van Zundert J, Rodriguez Huertas F, Novalbos Ruiz JP. Reg Anesth Pain Med 2017;42:62-68.

Study Design	Type of RFA	Number of Subjects	Indication	Median Age In Years (range)	Median Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain in Months	Results*	Adverse Events
Prospective, observational, noncontrolled, longitudinal	Standard	25	Eligible patients suffered from chronic pain (during >6months) of moderate to severe intensity (scoring ≥5 on VAS) due to advanced OA of the knee (grades 3-4 according to the Kellgren-Lawrence classification). The pain proved to be resistant to conservative treatments including physiotherapy, oral analgesics, and intraarticular injection with hyaluronic acids or steroids. Genicular nerve ablation was applied as an alternative analgesic approach for those who refused knee arthroplasty; were judged by their surgeons as being inappropriate for surgical treatment, for example, because of cardiovascular or other comorbidities; or who had to be managed for persistent pain and stiffness after TKA. One patient (1/25) continued suffering from pain for more than 6 months after TKR. Before SRFA, patients were unsuccessfully treated with paracetamol (23/25), tramadol (9/25), opioids (3/25), NSAIDs (9/25), and other conservative therapies (5/25) including physiotherapy, articular injection with hyaluronic acids or steroids, or a combination of these.	75 (52-88)	29 (23-38)	>6	Radiofrequency neurotomy of genicular nerves significantly reduced perceived pain (VAS) and disability (WOMAC) in the majority of participants, without untoward events. The proportion of participants with improvement of 50% or greater in pre-treatment VAS scores at 1, 6, and 12 months following intervention was 22/25 (88%), 16/25 (64%) and 8/25 (32%), respectively. The beneficial effect of treatment started to decline after 6 months, but even one year after the intervention, 32% of patients reported 50% improvement or greater in pre-treatment VAS scores.	Although several patients experienced temporary touch pain from the RF cannula during the procedure, the pain was tolerable and required no medication. There were no other participant-reported adverse events during the 12 months following treatment.

From Santana Pineda et al.:

TABLE 3. Results of the Statistical Analysis

Parameter	Score Before Treatment	Score at 1 mo Following Treatment	Score at 6 mo Following Treatment	Score at 12 mo Following Treatment
VAS	8.5 (8.2–8.8)*	2.5 (1.8–3.3)†	3.9 (3.1–4.9)‡	5.8 (3.7–7.8)
WOMAC A	14.0 (13.2–14.8)*	5.2 (3.9–6.6)†	6.4 (4.8–8.1)‡	8.4 (6.4–10.4)
WOMAC B	3.8 (3.1–4.3)	3.2 (2.8–3.7)	3.3 (2.8–3.8)	3.5 (2.9–4.0)
WOMAC C	47.3 (44.9–49.8)*	31.4 (27.0–35.9)†	32.8 (27.8–37.8)	36.3 (31.8–40.8)
WOMAC Total	65.2 (61.8–68.5)*	39.5 (33.5–45.6)†	40.7 (32.6–48.9)‡	49.2 (38.5–60.0)

Results of the repeated-measures analysis of variance of the investigated categories, that is, VAS and WOMAC A, B, C, and total. Post hoc pairwise comparison of different levels of the investigated categories was done using the Holm-Šídák approach to multiple comparisons Values are mean (95% confidence interval).

*Significantly different from the scores at 1, 6, and 12 months following treatment ($P < 0.001$).

†Significantly different from the score at 12 months following treatment ($P < 0.01$).

‡Significantly different from the score at 12 months following treatment ($P < 0.01$).

Comparator Studies

Non-Randomized Controlled Trials

TABLE 11.

Title: Percutaneous Radiofrequency Treatment for Refractory Anteromedial Pain of Osteoarthritic Knees

Citation: Ikeuchi M, Ushida T, Izumi M, Tani T. Pain Med 2011;12:546-551.

Study Design	Type of RFA	Number of Subjects		Clinical Background	Mean Age (SD)		Mean Body Mass Index in kg/m^2 (SD)		Pre-Procedure Mean Duration of Pain in Years (SD)		Results	Adverse Events
		SRFA	NB		SRFA	NB	SRFA	NB	SRFA	NB		
Open-label, nonrandomized, controlled	Standard	18	17	Age older than 65 years, previous conservative treatments longer than three months, and radiological OA grade 3 and 4 according to the Kellgren–Lawrence grading system. Comparator treatment in this study was nerve block.	77 (7)	77 (8)	Not indicated.	Not indicated.	10 (8)	9 (5)	Radiofrequency treatment significantly decreased knee pain as measured by VAS for 12 weeks compared with the control group. In terms of responders (defined as a 50% or greater decrease in the pain VAS or the WOMAC pain subscale), more patients in the SRFA group responded to the treatment than in the control group. The differences were significant at 4 weeks, 8 weeks, and 12 weeks in pain. Eight patients (44%) treated with SRFA rated the global assessment of her/his condition as "excellent" or "good", but three	There were no SAEs, but some minor effects during the current study were noted. Subcutaneous bleeding at the site of needle insertion was the most frequent side effect, which was observed in 67% of the patients (12/18) in the SRFA group and 82 % (14/17) in the control group. There was no hematoma formation. Prolonged hypoesthesia at the IPBSN region was observed only in patients of the SRFA group (14/18), which lasted for 2-6 weeks after the initial treatment. The size of hypoesthesia area gradually shrank and disappeared. All of the patients who

											(18%) in the control group rated treatment as "good", although the difference was not significant.	responded to SRFA treatment showed prolonged hypoesthesia.

From Ikeuchi et al.:

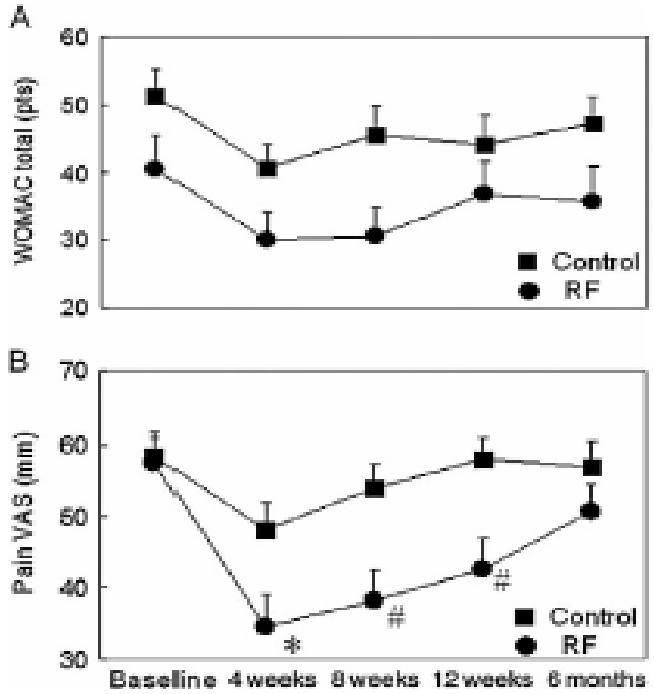

Figure 2 Comparison of treatment results between the RF and control groups in (A) WOMAC total score and (B) pain visual analog scale. Error bar represents standard error of the mean (SEM). pts = points. #$P < 0.01$; *$P < 0.05$ vs control group.

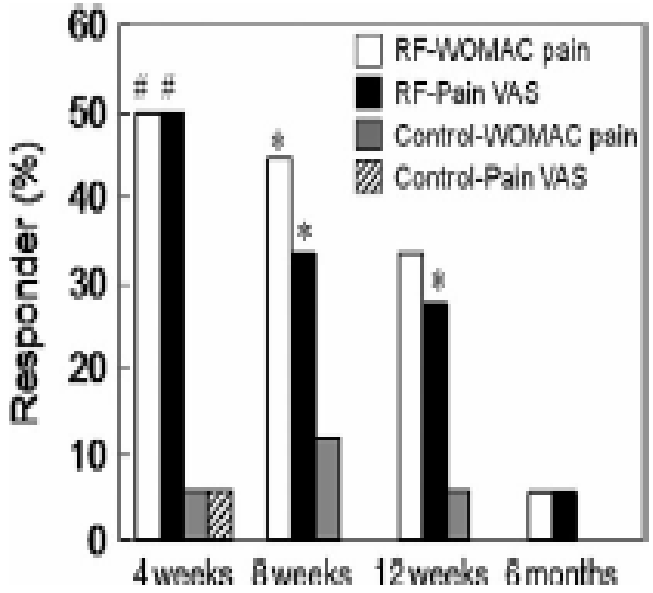

Figure 3 Percentage of patients who responded to treatment (defined as a >50% decrease in Western Ontario McMaster Universities osteoarthritis index pain subscale or pain visual analog scale). #$P < 0.01$; *$P < 0.05$ vs control group.

TABLE 12.

Title: **Which One is More Effective for the Clinical Treatment of Chronic Pain in Knee Osteoarthritis: Radiofrequency Neurotomy of the Genicular Nerves or Intra-Articular Injection?**

Citation: Sarı S, Aydın ON, Turan Y, Özlülerden P, Efe U, Kurt Ömürlü İ. Int J Rheum Dis 2016 Aug 12. [Epub ahead of print].

Study Design	**Type of RFA**	**Number of Subjects**		**Clinical Background**	**Mean Age (SD)**		**Mean Body Mass Index in kg/m^2 (SD)**		**Pre-Procedure Median Duration of Pain in Months (25-75 percentile)**		**Results (significant difference = $p < 0.05$)**	**Adverse Events**
		SRFA	IAS		SRFA	IAS	SRFA	IAS	SRFA	IAS		
Prospective, controlled	Standard	37	36	Patients with stage 2 or higher OA-related radiological changes based on the Kellgren-Lawrence rating scale were included in the study. Additional clinical criteria for inclusion in the study were pain at least moderate in severity or pain on a daily basis for more than three months, and patients had to be clinically unresponsive to conservative treatment modalities (physical therapy and rehabilitation practices, orally administered analgesics and anti-inflammatory agents) and unable to have arthroplasty.	64 (8)	64 (10)	23.51 (4.06)	22.89 (3.67)	5 (3-8)	5 (3-8)	In both groups, significant intragroup differences were found between the measurements of VAS pain, WOMAC total, and WOMAC subgroups at the baseline and the measurements at the first month and third month ($p < 0.001$). No statistically significant difference was found between the two groups in baseline VAS pain. In the SRFA group, a significant reduction was observed in VAS pain at the first month ($p < 0.001$) and at the third month ($p < 0.001$) in comparison to the IAS group. Also, in the SRFA group, a significant reduction was observed in WOMAC total scores at 1 month ($p < 0.001$) in comparison to the IAS group. Compared to group IAS, the only significant healing in WOMAC stiffness scores was observed at the third month, ($p = 0.007$) in the SRFA group, while a significant improvement in the WOMAC physical function was observed at the first month ($p = 0.003$).	None reported.

TABLE 13.

Title: **Radiofrequency Thermocoagulation in Relieving Refractory Pain of Knee Osteoarthritis**

Citation: Shen WS, Xu XQ, Zhai NN, Zhou ZS, Shao J, Yu YH. Am J Ther 2017;24:E693-E700.

Study Design	Type of RFA	Number of Subjects		Clinical Background	Mean Age (SD)		Mean Body Mass Index in kg/m^2		Pre-Procedure Mean Duration of Pain in Years (SD)		Results (significant difference = $p < 0.05$)	Adverse Events
		SRFA	CON		SRFA	CON	SRFA	CON	SRFA	CON		
Prospective, controlled	Standard	27	27	Patients with unilateral or bilateral knee pain; patients with a disease course of more than three months; patients with scores of 6-9 (VAS) (mean score of 7.13±1.04); patients with poor response or high resistance to NSAIDs; patients with no coagulation abnormality or infection to peripheral tissues of knee; and patients with no history of intraarticular steroid injection in the last three months. The control (CON) group was treated with injection of platelet-rich plasma and sodium hyaluronate.	62.24 (10.35)	62.35 (9.7)	Not indicated.	Not indicated.	5.01 (3.29)	4.96 (3.4)	At the termination of treatments and 3-month follow-ups, SRFA patients gained significantly increased scores in vitality, bodily pain, general health perceptions, physical functioning, and social role functioning by SF-36 scaling and in pain, range of motion, stability, walking, and stair climbing by AKSS (all $p < 0.05$). Controls received higher scores by AKSS in pain at the termination of treatments and in pain, range of motion, and walking at the termination of 3-month follow-ups (all $p < 0.05$). Both SRFA and control cohorts presented significant difference between VAS scores before treatments and those at the termination of 3-month follow-ups (both $p < 0.05$). All patients felt less pain after treatments, with the SRFA cohort presenting better improvement ($p < 0.05$). Pain was stronger in females compared with males and in a positive correlation with age, while had no obvious relation to disease course. In conclusion, SRFA may have better efficacy in relieving refractory pain and promoting function recovery in patients with knee OA than regular treatment.	None reported.

TABLE 14.

Title: **Radiofrequency Treatment Relieves Chronic Knee Osteoarthritis Pain: A Double-Blind Randomized Controlled Trial**

Citation: Choi WJ, Hwang SJ, Song JG, Leem JG, Kang YU, Park PH, Shin JW. Pain 2011;152:481-487.

Study Design	Type of RFA	Number of Subjects		Clinical Background	Mean Age (SD)		Mean Body Mass Index in kg/m^2 (SD)		Pre-Procedure Mean Duration of Pain in Years (SD)		Results (significant difference = $p < 0.05$)	Adverse Events
		RFA	PBO		RFA	PBO	RFA	PBO	RFA	PBO		
RCT	Standard	17	18	Patients 50-80 years of age and with knee pain were examined to ascertain their eligibility. After clinical and radiologic assessment, the study subjects comprised elderly patients with chronic knee pain (i.e., knee pain of moderate intensity or greater on most or all days for ≥3 months) and radiologic tibiofemoral OA (Kellgren-Lawrence grade 2-4, evaluated by a radiologist). These patients' conditions did not respond to other treatments including	67.9 (7.1)	66.5 (4.8)	26.2 (3.3)	26.5 (2.1)	6.3 (3.9)	7.4 (4.0)	VAS scores showed that the SRFA group had less knee joint pain at 4 ($p < 0.001$) and 12 ($p < 0.001$) weeks compared with the control group. OKS showed similar findings ($p < 0.001$). In the SRFA group, 10/17 (59%), 11/17 (65%), and 10/17 (59%) achieved at least 50% knee pain relief at 1, 4, and 12 weeks, respectively. SRFA of genicular nerves lead to significant pain reduction and functional improvement in a subset of elderly chronic knee OA pain, and thus may be an effective treatment in such cases.	Although several participants experienced temporary periosteum touch pain from the RF cannula during the procedure, the pain was tolerable and required no medication. Otherwise, no participant reported a post-procedure adverse event during the follow-up period, and there were no withdrawals from the study owing to an adverse event. Most of patients had rescue analgesics for breakthrough pain in previously prescribed medications. If their medication was not enough to relieve pain, patients were requested to call or visit to our investigator, physician. In this study, no participant needed the changes to their analgesic medications during the follow-up period.

				physiotherapy, oral analgesics, and intraarticular injection with hyaluronic acids or steroids.								

TABLE 15.

Title: **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**

Citation: McCormick ZL, Reddy R, Korn M, Dayanim D, Syed RH, Bhave M, Zhukalin M, Choxi S, Ebrahimi A, Kendall MC, McCarthy RJ, Khan D, Nagpal G, Bouffard K, Walega DR. Pain Med 2017 Dec 28. [Epub ahead of print]

Study Design	Type of RFA	Number of Subjects		Clinical Background	Median Age (IQR)		Median Body Mass Index in kg/m^2 (IQR)		Pre-Procedure Median Duration of Pain in Months (IQR)		Results (significant difference = $p < 0.05$)	Adverse Events
		-PB	+PB		-PB	+PB	-PB	+PB	-PB	+PB		
RCT	Cooled	25	29	Lack of pain relief from conventional therapy, including NSAIDs, opioids, muscle relaxants, oral steroids, physical therapy, and intra-articular injection therapy. Kellgren-Lawrence knee OA grade of 2 or greater.	65 (55-76)	69 (57-76)	35.2 (26.8-47.8)	30 (26.6-39.1)	60 (24-120)	36 (14-60)	Twenty-nine participants (36 knees) had CRFA following a PB, and 25 patients (35 knees) had CRFA without a block. Seventeen participants (58.6%) in the PB group and 16 (64%) in the no block group had ≥50% pain relief (NRS) at six months ($p = 0.34$). A 15-point decrease in the WOMAC at six months was present in 17 of 29 (55.2%) in the PB group and 15 of 25 (60%) in the no block group ($p = 0.36$).	None reported.

TABLE 16.

Title: **Prospective, Multicenter, Randomized, Crossover Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation with Corticosteroid Injection in the Management of Knee Pain from Osteoarthritis**

Citation: Davis T, Loudermilk E, DePalma M, Hunter C, Lindley D, Patel N, Choi D, Soloman M, Gupta A, Desai M, Buvanendran A, Kapural L. Reg Anesth Pain Med 2018;43:84-91.

Study Design	Type of RFA	Number of Subjects		Indication	Mean Age (SD)		Mean Body Mass Index in kg/m^2 (SD)		Pre-Procedure Mean Duration of Pain in Months (SD)		Results (significant difference = $p < 0.05$ or $p < 0.0083$ (OKS))	Adverse Events
		CRFA	IAS		CRFA	IAS	CRFA	IAS	CRFA	IAS		
RCT	Cooled	76	75	Subjects with bilateral knee OA were not excluded; only one knee was screened and enrolled as the "index knee" for treatment. Inclusion criteria included (1) knee pain for 6 months or more that was unresponsive to conservative treatments (physical therapy, oral analgesics, intra-articular injections with steroids, and/or viscosupplementation); (2) Numeric Rating Scale (NRS) pain score of 6 or greater for the index knee; (3) radiological confirmation of OA grades 2 to 4 noted within 12 months of enrollment; (4) OKS of 35 or less; (5) positive diagnostic genicular nerve block (defined as a decrease of ≥50% in NRS score); and (6) if the patient was taking an opioid or other	63 (12)	66 (13)	30.6 (5.5)	30.4 (6.3)	127.9 (138.9)	102.9 (108.7)	At 6 months, the CRFA group had more favorable outcomes in NRS: pain reduction 50% or greater: 74.1% versus 16.2%, $p < 0.0001$ (25.9% and 83.8% of these study cohorts, respectively, were non-responders – a patient who did not report an NRS score decrease from baseline of 50% or greater. Mean NRS score reduction was CRFA 4.9±2.4 versus IAS 1.3±2.2, $p < 0.0001$; mean OKS was CRFA 35.7±8.8 vs IAS 22.4±8.5, $p < 0.0001$; mean improved Global Perceived Effect was CRFA 91.4% vs IAS 23.9%, $p < 0.0001$; and mean reduction in non-opioid medication use was CRFA > IAS ($p = 0.02$).	There were 61 and 65 AEs reported among 34 and 30 subjects in the CRFA and IAS cohorts, respectively, with the majority of them in each group having an "unrelated" or "unlikely" relationship to study intervention (CRFA, 77% (47 events/61 total events)); IAS, 97% (63/65)). Three subjects in the CRFA group experienced 4 SAEs, whereas 7 subjects in the IAS group experienced 8 SAEs. Three (75%) of the 4 SAEs in the CRFA cohort involved the respiratory system: (1) exacerbation of asthma, (2) severe acute asthma, and (3) acute respiratory failure), and 1 (25%) involved urogenital function (pyelonephritis). The majority (50% (4/8)) of the 8 SAEs in the IAS group involved

				morphine-equivalent medication, the dose must have been clinically stable (<10% change in dosage for ≥2 months prior to the screening visit).								gastrointestinal function: (1) nausea and vomiting, (2) worsening of hiatal hernia, (3) gastric volvulus, and (4) abdominal pain secondary to small bowel obstruction, whereas 2 (25%) pertained to the cardiovascular system (heart attacks, 2 subjects), and 2 (25%) were categorized as "other": (1) opioid overdose and (2) death. None of the SAEs were related to the study treatments.

TABLE 17.

Title: **Fluoroscopic Guided Radiofrequency of Genicular Nerves for Pain Alleviation in Chronic Knee Osteoarthritis: A Single-Blind Randomized Controlled Trial**

Citation: El-Hakeim EH, Elawamy A, Kamel EZ, Goma SH, Gamal RM, Ghandour AM, Osman AM, Morsy KM. Pain Physician 2018;21:169-177.

Study Design	Type of RFA	Number of Subjects		Clinical Background	Mean Age (SD)		Mean Body Mass Index in kg/m^2 (SD)		Pre-Procedure Mean Duration of Pain in Months (SD)		Results	Adverse Events
		SRFA	ALGC		SRFA	ALGC	SRFA	ALGC	SRFA	ALGC		
RCT	Standard	30	30	The patients included in this study were diagnosed with knee OA according to the American College of Rheumatology criteria, and were confirmed radiologically to be in stage 3 or 4 of the Kellgren-Lawrence classification.	62 (7.37)	56.87 (6.53)	32.02 (6.26)	30.21 (3.69)	7.6 (3.14)	5.7 (5.1)	VAS values were significantly lower in SRFA group during the whole follow-up period. Follow-up VAS scales showed significant decreases compared to their corresponding basal value in each group. The total WOMAC index showed significant differences between the two groups by the 6th month only; however, specific WOMAC domains (pain and stiffness) showed significant differences in the 3rd, and 6th months, with lower values in the RF cohort. Overall, the WOMAC index and its domains showed significant improvement compared to baseline conditions in each group. There was an improvement in the quality of life for all participants. Patient`s satisfaction showed significantly higher values in the SRFA group compared to the analgesics group in the 3rd and 6th months. Follow-up showed significant increases in patient satisfaction in physical condition compared to baseline values in each group. A high percentage of the patients (63.3%) in the analgesics group received physiotherapy during the follow-up period. The participants in the SRFA group did not record a need for supplementary analgesia related to the treated joint during the whole follow-up period.	None reported.

From El-Hakeim et al.:

Table 2. *Follow-up of study scales in both groups.*

Variables	Group A (n=30)	Group C (n=30)	*P* value
VAS			
Pre-intervention	7.07±0.2	6.9±0.2	0.622
2nd week	2.47±0.3¥	3.63±0.27¥	0.004*
3rd month	2.83±0.5¥	4.93±0.2¥	<0.001*
6th month	3.13±0.3¥	5.72±0.26¥	<0.001*
WOMAC			
Pain			
Pre-intervention	10.7±0.4	11.27±0.6	0.78
2nd week	3.67±0.5¥	3.83±0.4¥	0.1
3rd month	4.63±0.51¥	4.5±0.3¥	0.01*
6th month	6.57±0.5¥	7.9±0.52¥	< 0.001*
Stiffness			
Pre-intervention	7.87±0.25	4.63±0.3	0.07
2nd week	3.6±0.31¥	3±0.25¥	0.5
3rd month	3.7±0.37¥	3.13±0.19¥	0.004*
6th month	3.63±0.38¥	3.2±0.2¥	< 0.001*
Difficulties			
Pre-intervention	65.97±1.4	37.5±2.2	0.15
2nd week	14.4±3.2¥	24.07±1.8¥	0.36
3rd month	15.9±3.2¥	29.43±1.6¥	0.16
6th month	22.93±3¥	32.4±1.5¥	0.007*
Total WOMAC score			
Pre-intervention	93.53±1.9	54.07±3	0.09
2nd week	21.67±4.4¥	30.93±2.5¥	0.17
3rd month	24.23±4.3¥	37.1±1.5¥	0.1
6th month	33.13±4.1¥	43.5±2¥	< 0.001*

Data are expressed as mean± SE. VAS visual analog scale, WOMAC Western Ontario McMaster Universities OA Index. Group A; the radiofrequency treated patients. Group C; the conventional medically treated participants. Post-intervention values in the 2nd week, 3rd month, 6th month. (*) Statistically significant difference between the two groups. (¥) statistically significant change in comparison to the pre-intervention value within the same group. $P < 0.05$ is considered statistically significant.

Investigations of Radiofrequency Ablation to Treat Chronic Pain Emanating from the Hip

Question 1. *What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*

Radiofrequency ablation of sensory nerves of the hip to reduce chronic pain derived from this joint has been examined in various study formats.

Five of the six case reports concerning RFA of hip sensory nerves involved SRFA. In one case, a patient experienced dramatic hip pain relief upon rest and activity. The use of NSAIDS was abolished, with pain recurring 6 months post-intervention. With the assistance of NSAIDs again, severe pain at two years following SRFA was in remission (Table 18). Another patient indicated as much as 80% pain relief after one hip was treated for pain, with sustained analgesia in both hips up to 3 months after having the other hip treated as well (Table 19). Each of two SRFA interventions produced at least 20% hip pain relief, but was followed by continued need for pain medicine prior to joint replacement (Table 20). Other patients treated by SRFA for hip pain indicated pain relief from 9/10 to 1-2/10 on the VAS, and satisfactory analgesia and function up to 6 months (Table 21) or had a VAS reduction from 9/10 to 4/10, but continued to use an opioid and NSAID upon hospital discharge (Table 23).

The single case report regarding CRFA to treat chronic hip pain involved a patient who reported >90% pain relief and a drastic improvement in functionality and daily life activities. At 4 weeks, her NRS score had decreased from 10/10 to 1-2/10, and she reported that no pain was present the majority of the time. At 6 months, her NRS was 0/10, and she reported pain only with extensive activity with a maximum NRS score of 1/10. At 24 months, her NRS was 0-1/10 at rest and 1-2/10 with extensive activity. She described improvements particularly with walking, climbing stairs, bending, and standing from a sitting position (Table 22).

In case series described herein, SRFA was used in all instances. Hip pain loss (Table 24), sometimes as high as 50% up to 11 months (Table 25), and greater flexibility (Table 24), were evident after SRFA. Another case series involving four patients revealed significant hip pain relief (e.g., 60% reduction (8/10-2/10) on VAS at 4-week follow-up, and at 2 and 3 months, VAS was 4/10 without pain medications) and functional improvements. Satisfactory analgesia was not accompanied by functional improvements in two patients (Table 26). Another patient said that hip pain was still at least 50% better 2 months post-intervention than prior to SRFA. He could walk for 9 hours after SRFA (only 4 hours prior to SRFA), and had no need for a cane for ambulation (whereas the patient used a cane to alleviate his pain and assist his walking prior to SRFA) (Table 27). After SRFA, another patient reported that her anterior thigh and groin area pain level dropped from 8/10 to 0/10 on VAS. The patient could resume her physical therapy on day three after SRFA; she was able to tolerate the range of motion and strengthening exercises of the lower extremities along with gait training. On 3-month follow-up, there was no reported pain at rest or with sitting. She could walk continuously with a cane for 10 to 15 minutes; with intermittent breaks, she was able to walk for several blocks (Table 27).

In a retrospective study, CRFA decreased verbal pain scores significantly (relieved hip pain), from a mean of 7.61±1.2 before CRFA to 2.25±1.4 after CRFA. The time interval of pain relief extended from 30 to 320 days for the first ablation, and 42 to 300 days for the second ablation. Patients were very satisfied with pain relief, and most claimed improved mobilization. There were two patients who underwent successful nerve blocks, but had no improvement after CRFA. Opioid use did not decrease significantly (Table 29).

Prospective examinations of RFA effects on chronic hip pain included those that were non-randomized, non-controlled and non-randomized, controlled. In the former, before CRFA and at 6-month follow-up, mean VAS scores were 9.52 (range, 7-10; SD, 0.79) and 6.35 (range, 3-10; SD, 2.17), respectively; mean Harris Hip Scores were 28.64 (range, 19-41; SD, 6.98) and 43.88 (range, 23-71; SD, 16.38), respectively; and mean WOMAC scores were 75.70 (range, 92-59; SD, 9.70) and 63.70 (range, 78-44; SD, 11.37), respectively. The score changes indicated significant decrease in pain, reduced disability, and enhanced function. Eight patients reported >50% pain relief at the 6-month follow-up (Table 28). In the controlled prospective study, at 1 week, 4 weeks, and 12 weeks following SRFA, improvements in VAS were significantly greater with SRFA compared to a combination of exercise programs and medications (control), including paracetamol, NSAIDs, and/or narcotic drugs. Improvements in OHS were significantly greater in the SRFA group at 1 week, 4 weeks, and 12 weeks. Patients in the SRFA group also used less pain medications. Eight participants in the control group switched to SRFA after 12 weeks. Six (75%) of them had an improvement of >50% with pain, whereas two patients (25%) had no improvement (Table 30).

Question 2. *What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?*

Three of thirteen (23%) studies included in this report that focus on RFA to treat chronic hip pain reported AEs. As for RFA use to address chronic knee pain, the RFA/hip-associated AEs were mostly minor, with little or no medical attention required for their resolution. Among 17 patients that received CRFA, three hematomas in the inguinal and internal groin zones were observed one day post-operatively (Table 28), and elsewhere, one case of neuritis (severe burning in the groin area) was observed, which resolved within one-week post-denervation (Table 29). No major complications associated with SRFA of the hip were noted, except for one subcutaneous hematoma related to RF needle puncture, which presented for one week (Table 30).

Question 3. *Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:*

a. Indication

b. Patient characteristics

There are very few AEs reported in studies that have examined use of RFA as a therapy for chronic hip pain. Consequently, it is difficult to definitively associate an indication or patient characteristic(s) with the likelihood of a particular AE to occur with RFA of the hip. Thus, no indication or patient characteristic(s) was identified as being predictive of eliciting an AE upon SRFA or CRFA for chronic pain originating from the hip.

No objective evidence of a specific indication for RFA of sensory nerves of the knee was provided in the studies included in this report. However, as for patients suffering from chronic knee pain, some patients with hip pain were reportedly unable to undergo surgery for their ailment due to co-morbidities (chronic obstructive pulmonary disease, coronary artery disease lymphedema, HIV/AIDS) and/or the risks (e.g., infection) such clinical issue could present in the context of such an invasive intervention. Moreover, conservative treatments had failed for various patients who experienced chronic hip pain, and even THA was unsuccessful. Analgesic drug use was either contraindicated, for example in the case of NSAIDs for a patient who had a prior gastric bypass, or were denied due to anxiety associated with their (i.e., opioids) use. The patient pool that received RFA for chronic hip pain in the studies of this report is comprised of a heterogeneous population with respect to clinical backgrounds. Hence, these citations presented no evident patient characteristics or disease conditions to predict the extent of RFA success for treating chronic hip pain.

Non-Comparator Studies

Case Reports

TABLE 18.

Title: Successful Relief of Hip Joint Pain by Percutaneous Radiofrequency Nerve Thermocoagulation in a Patient with Contraindications for Hip Arthroplasty

Citation: Fukui S, Nosaka S. J Anesth 2001;15:173-175.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	A woman with a history of severe left coxalgia and lymphedema of her left lower extremity presented to the pain clinic. It was suggested that the severe lymphedema was a complication of radiation therapy for uterine cancer. Her left lower extremity had been infected several times, rapidly developing to destructive coxopathy in her hip joint. She had been complaining of constant and severe pain in her thigh, back, and groin for years. She experienced gradually worsening pain in the inguinal, thigh, and hip area to the level that she could not walk, sit, take care of herself at home, and sleep well. She was only able to ambulate with a wheelchair. The pain was constant, severe, sharp, and deep in her thigh, groin, and hip. It radiated to the left anterior knee at times. Past conservative drug therapy had failed. Hip arthroplasty was contraindicated because of the presence of severe lymphedema and the high risk of infection. The hip x-ray indicated severe bilateral hip joint destruction. MRI of the pelvis also indicated severe bilateral hip joint degeneration and destruction.	59	Not indicated.	Not indicated.	Post-SRFA, the patient had dramatic relief of pain. Rest pain disappeared and motion pain decreased from 9-10 to 1-2 on the VAS. The patient had immediate analgesia and improved ability to ambulate with a cane for 6 months. The patient could return to her usual activity at home and sleep well without use of NSAIDs. Satisfactory pain relief was noted, which lasted for more than four months. There were no complications related to the procedure. The patient reported a gradual recurrence of pain six months following the treatment, and needed NSAIDs for recurrent pain. However, two years after SRFA, severe pain was still in remission, and the patient was able to ambulate with a cane and take care of herself at home and sleep well with NSAIDs.	None reported.

TABLE 19.

Title: **Use of Ultrasound and Fluoroscopy Guidance in Percutaneous Radiofrequency Lesioning of the Sensory Branches of the Femoral and Obturator Nerves**

Citation: Chaiban G, Paradis T, Atallah J. Pain Pract 2014;14:343-345.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	The patient had a history of intractable hip pain after open reduction and internal fixation of the hip due to hip fracture. His pain responded to joint capsule injections and bursa injections, but with only brief periods of relief. Additionally, the patient had multiple comorbidities, including severe chronic obstructive pulmonary disease and severe coronary artery disease. He was taking daily clopidogrel for anticoagulation and is on home oxygen, making him a poor candidate for surgery. In an effort to achieve longer periods of pain relief, the authors discussed with him RFA of the sensory branches of the obturator and femoral nerves. The author's did not stop the patient's home clopidogrel dose.	80	Not indicated	Not indicated	The patient tolerated the procedure well, and there were no observed complications. In follow-up, the patient reported > 80% improvement in his pain. One month after the original procedure, the authors performed the same procedure on the opposite hip with similar results. Three months after the procedures, the patient was still experiencing pain relief in both hips.	None reported.

TABLE 20.

Title: **Radiofrequency Denervation of the Hip Joint for Pain Management: Case Report and Literature Review**

Citation: Gupta G, Radhakrishna M, Etheridge P, Besemann M, Finlayson RJ. US Army Med Dep J 2014;Apr-Jun:41-51.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	The patient presented with severe pain and functional limitations as a result of left groin pain attributed to OA. Past medical history included hypertension, dyslipidemia, sleep apnea, type 2 diabetes mellitus, depression, and opioid addiction. Medications included atenolol, hydrochlorothiazide, amlodipine, trazodone, duloxetine, amitriptyline, quetiapine, and pregabalin. Physical examination revealed an antalgic gait, painful range of motion for the left hip, mild pain to palpation in the left groin, and a glove and stocking decrease for pinprick in the lower limbs. X-ray imaging revealed mild superior-lateral hip osteoarthritic changes. Magnetic resonance arthrogram revealed a small, undisplaced, anterior labral tear. He failed multiple treatments including physical therapy, medications, and various injections. Arthroscopic debridement of the labral tear did not result in clinical improvement, but significant osteoarthritic changes were noted superior-laterally. Because the waitlist for a hip arthroplasty was in excess of one year, thermal RF lesioning of the articular branches was offered in the interim.	55	Not indicated.	Not indicated.	The first SRFA treatment provided almost 90% relief, a return to almost all baseline function except playing hockey, and discontinuation of pain medication for a period of 6 months. The second treatment provided between 20% to 50% relief, with moderate ongoing functional limitations, and the necessity for adjunctive pain medication until joint replacement 4 months later.	None reported.

TABLE 21.

Title: **Percutaneous Radio Frequency Ablation for Relief of Pain in a Patient of Hip Joint Avascular Necrosis**

Citation: Kasliwal P, Iyer V, Kasliwal S. Ind J Pain 2014;28:121-123.

Study Design	Type of RFA	Number of Subjects	Indication	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain in Months	Results	Adverse Events
CR	Standard	1	The patient complained of bilateral constant and severe pain in his thigh and groin for 6 months, right hip more than the left. The patient initially responded well to conservative drug therapy, but he experienced gradually worsening pain in the right groin and hip area to the level that he could not walk, sit, take care of himself at home, and sleep well (VAS 9-10). He was unable to move without support. The pain was constant, severe, sharp, and deep in his groin and hip. It radiated to the right knee. The patient was also suffering from pulmonary tuberculosis and was on Akt. Hip arthroplasty was contraindicated because of the high risk of infection and anticoagulants. The hip MRI of the pelvis also indicated bilateral hip joint degeneration and destruction. So, SRFA of the right hip joint articular nerve branches was planned.	25	Not indicated.	6	Post-SRFA, the patient noted a decrease in pain (VAS 9-10 to 1-2), and motion pain also decreased. The patient had an improved ability to ambulate for 6 months. Now the patient can carry out his daily routine activites at home without much pain and can sleep comfortably. Until 6 months follow-up, the patient had good pain relief in the right hip joint. For the left hip joint pain, he requires analgesics (Tramadol 50 mg) intermittently.	None reported.

TABLE 22.

Title: **Ultrasound-guided Radiofrequency Lesioning of the Articular Branches of the Femoral Nerve for the Treatment of Chronic Post-arthroplasty Hip Pain**

Citation: Kim DJ, Shen S, Hanna GM. Pain Physician 2017;20:E323-E327.

Study Design	Type of RFA	Number of Subjects	Indication	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain in Months	Results	Adverse Events
CR	Cooled	1	Following THA revision, the patient's hip pain gradually returned over the course of 6 months despite physical therapy, acupuncture, and medical pharmacotherapy, including hydrocodone/acetaminophen 5 mg/325 mg (3-5 tablets daily), cyclobenzaprine 10 mg nightly, topical diclofenac daily and duloxetine 30 mg twice daily. She was not on systemic NSAIDs, due to a prior gastric bypass procedure. Initially, the patient was prescribed a long-acting opioid (morphine sulfate controlled-release 15 mg twice daily) to help with pain and aid in physical therapy. Upon follow-up, the patient denied improvement of pain and reported an increase in the dosage frequency of her pain medication.	59	Not indicated.	7	During follow-up at two weeks, the patient reported >90% pain relief of hip pain and a drastic improvement in functionality and daily life activities. At 4 weeks, her NRS score had decreased from 10/10 to 1-2/10, and she reported that no pain was present the majority of the time. At 6 months, her NRS was 0/10, and she reported pain only with extensive activity with a maximal score of 1/10. At 24 months, her NRS was 0-1/10 at rest and 1-2/10 with extensive activity. She described improvements particularly with walking, climbing stairs, bending, and standing from a sitting position. There were no side effects or complications following the procedure including motor weakness, sensory loss, and neuralgias.	None reported.

TABLE 23.

Title: **Combined Ultrasound and Fluoroscopic Guidance for Radiofrequency Ablation of the Obturator Nerve for Intractable Cancer-Associated Hip Pain**

Citation: Stone J, Matchett G. Pain Physician 2014;17:E83-E87.

Study Design	Type of RFA	Number of Subjects	Clinical History	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CR	Standard	1	The female patient had a history of stage IV non-small cell lung cancer, with bone metastasis to the right femoral head and acetabulum, and was admitted to the oncology service with worsening right hip pain over the preceding two weeks, causing her to be unable to walk. Prior to admission the patient had a history of a right femoral metastatic lesion. Symptomatic treatment of this prior to admission included five fractions of radiation therapy, receiving 2000 centigrays in total. Repeat MRI imaging shortly before admission demonstrated progressive neoplastic disease in the femoral head and acetabulum. Physical examination was noteworthy for substantial pain with movement of the hip joint and a complete inability to ambulate. After oral systemic opioid and co-analgesic medication optimization, the patient still had 10/10 (VAS) pain with movement while taking sustained-release oxycodone 10 mg daily and hydrocodone/acetaminophen 10/325 every 6 hours. Further upward titration of opioid medications was not feasible because of sedation. The pain service was consulted for evaluation of nerve block therapy.	79	Not indicated.	Not indicated.	Following SRFA, the patient's pain remained controlled to the extent that she could walk again with assistance. Pre-SRFA, the daily average worst VAS was 9+1.2, and post-SRFA, the average daily worst VAS score was 4.1+3.0. She was ultimately discharged to hospice eight days after the procedure. At the time of discharge, she was taking a combination of sustained release oxycodone 10 mg twice daily and hydrocodone/acetaminophen 10/325 every 6 hours as needed for pain. Also at discharge, she was able to flex her hip to 90 degrees, and was able to ambulate with assistance.	None reported.

Case Series

TABLE 24.

Title: **Percutaneous Radiofrequency Destruction of the Obturator Nerve for Treatment of Pain Caused by Coxarthrosis**

Citation: Akatov OV, Dreval ON. Stereotact Funct Neurosurg 1997;69:278-280.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CS	Standard	13	Not indicated.	Range: 47-79	Not indicated.	Not indicated.	The post-SRFA period lasted up to 3 years. Pain loss was noted in all cases, except in one man with a brachymorphic constitution with a nervus obturatorius accessories. An increased range of motion in the hip joint was noted in nine cases. Three patients had myofascial nodes in musculus iliopsoas caused by their chronic severe pain syndrome, which necessitated application of additional treatment, including blocks and post-isometric relaxation, which was successful. Roentgenographic examinations performed during the late post-operative period did not reveal any negative changes.	None reported.

TABLE 25.

Title: **Percutaneous Radiofrequency Lesioning of Sensory Branches of the Obturator and Femoral Nerves for the Treatment of Hip Joint Pain**

Citation: Kawaguchi M, Hashizume K, Iwata T, Furuya H. Reg Anesth Pain Med 2001;26:576-81.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age Range (years)	Body Mass Index Range (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CS	Standard	14	Eight patients had OA of the hip, four patients had prolonged hip pain after surgical treatments, and two patients had coxalgia associated with metastasis to the hip. Of eight patients with OA of the hip, six patients rejected hip arthroplasty, and two patients were at increased perioperative risk with aortic aneurysm and heart disease. In two patients with metastasis, operation was not indicated because of the advanced stages of the disease. All patients complained of groin, thigh, and/or trochanteric (lateral) pain. In all cases, intra-articular hip blocks with local anesthetics and/or articular branch blocks of obturator nerve relieved the pain, suggesting that the pain was from the hip joint. However, the efficacy of these local anesthetic blocks was only transient.	See Table below.	Not indicated.	Not indicated.	Mean VAS scores before and after SRFA were 6.8±0.9 (SD) and 2.7±1.3, respectively. Twelve patients (86%) reported at least 50% relief of pain for 1 to 11 months (mean, 4.2 months).	None reported.

From Kawaguchi et al.:

Table 1. Percutaneous Radiofrequency Lesioning of Sensory Branches of Obturator and Femoral Nerves for the Hip Joint Pain

Cases	Age/ Sex	Disease	Pain	Treatments	VAS Scores		Outcome	Duration of Effectiveness (mo)	Operation
					Before	After			
1	62/F	Osteoarthritis	rt-groin	O	6.5	1.8	Effective	6	Rejected
2	74/F	Osteoarthritis	rt-groin	O	6.2	2.2	Effective	3	Rejected
			rt-trochanteric	F	6.2	2.5	Effective	3	
3	71/F	Osteoarthritis	bil-groin	O	7.2	3.5	Effective	2	Rejected
4	85/F	Osteoarthritis	bil-groin	O	6.5	4.5	Ineffective		Rejected
5	74/M	Osteoarthritis	lt-groin	O	6.5	1.5	Effective	6	High risk (AAA)
6	77/F	Osteoarthritis	lt-groin	O	7.2	1.5	Effective	3	Rejected
			lt-trochanteric	F	7.6	2	Effective	3	
7	64/F	Osteoarthritis	rt-groin	O	7.5	3.1	Effective	5	Rejected
8	55/F	Osteoarthritis	rt-groin	O	7.2	3.5	Effective	1	High risk (heart disease)
9	42/F	Congenital dislocation	rt-groin, thigh	O	7.2	0.5	Effective	11	Postoperative
10	26/M	Dislocation and fracture	lt-groin	O	8.2	1.3	Effective	8	Postoperative
11	26/F	Congenital dislocation	lt-groin	O	6.5	3.8	Ineffective		Postoperative
			lt-trochanteric	F	4.5	4	Ineffective		
12	87/F	Osteoarthritis	rt-groin	O	6.5	3.2	Effective	4	Postoperative
			rt-trochanteric	F	5.7	2.3	Effective	6	
13	57/F	Metastasis	lt-groin	O	7.8	2.5	Effective	1	Not indicated
			lt-trochanteric	F	7.8	2.5	Effective	1	
14	70/M	Metastasis	lt-groin	O	7.1	6	Ineffective		Not indicated

Abbreviations: O, percutaneous radiofrequency lesioning of sensory branches of obturator nerve at 75-80°C for 90 seconds; F, percutaneous radiofrequency lesioning of sensory branches of femoral nerve at 75-80°C for 90 seconds; AAA, abdominal aortic aneurysm; rt, right; lt, left; bil, bilateral.

TABLE 26.

Title: **Percutaneous Radiofrequency Lesioning of Sensory Branches of the Obturator and Femoral Nerves for the Treatment of Non-Operable Hip Pain**

Citation: Malik A, Simopolous T, Elkersh M, Aner M, Bajwa ZH. Pain Physician 2003;6:499-502.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age (years)	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain in Years/Months	Results	Adverse Events
CS	Standard	4	Patients who demonstrated hip pain in the anterior and medial distribution. The patients were chosen after orthopedic consultation determined that these patients were not good candidates for joint replacement surgery based on their co-morbidities.	Cases 1: 70 2: 49 3: 70 4: 52	Not indicated.	Cases 1: 5 years 2: Not indicated 3: 1 month 4: Not indicated	**Case 1:** At 4 weeks after SRFA, the patient reported little to no pain. At 8 and 12 weeks, her pain was 2/10 and 4/10 (VAS), respectively. Since the procedure, she could ambulate for longer distances outside her home, and is no longer using a cane except at community distances. She now only uses tramadol on as needed basis, usually 1 or 2 tablets a day. **Case 2:** The patient had a history of liver transplant rejection and severe liver failure from blood transfusion-acquired hepatitis C after a gunshot wound. Immediately post-SRFA, he had no pain and could move the left leg, but was not able to walk due to significant deconditioning. He was discharged to rehabilitation unit two days later. In therapy, he could participate, and was eventually able to walk 200 feet with a rolling walker. He had a telephone follow-up at one month and was having significant pain relief and stated his pain ranged from 3-5/10 verbal scale versus VAS of 9-10/10 reported prior to the procedure. He reported no side effects from the procedure. He continued to use the same amount of opioids, since he had other pains. Unfortunately. he passed away soon after the telephone follow-up. **Case 3:** After SRFA, the patient had excellent relief at 4-week follow-up (60% reduction of pain on VAS, from 8/10-2/10). Follow-up at 2 and 3 months revealed VAS 4/10 without pain medications. She did have numbness on the lateral surface of the hip area, but this did not cause any problems for her. She reported no increased activities of daily and no increased physical activity, and she remained wheelchair bound. She did come off the cox-2 inhibitors that she was given initially, but continued with the oxycodone which helped with residual pain. **Case 4:** At a 1, 2 and 3-month follow-up her pain in the right hip ranged from 2-4/10 on VAS. She did not have significant improvement in function, but believed that her quality of life was better since the procedure. She had no complications	None reported.

							from this procedure. She increased dosage of the methadone, but this was for cancer-related pains.	

TABLE 27.

Title: **Pulsed Radiofrequency Treatment of Articular Branches of the Obturator and Femoral Nerves for Management of Hip Joint Pain**

Citation: Wu H, Groner J. Pain Pract 2007;7:341-344.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age	Body Mass Index (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
CS	Standard	2	**Case 1:** The patient was a 48-year-old man with a history of chronic left hip pain secondary to HIV/AIDS and trauma-induced stage III avascular necrosis of the left femoral head unresponsive to medical treatment. Hip joint injection with corticosteroid and local anesthetic provided transient pain relief. The patient was not a surgical candidate, because of concerns regarding the high probability of post-operative infection and the potential for poor wound healing. On presentation, the patient complained of constant, achy hip pain, located in the left groin and anterior thigh region. The pain was aggravated with movement of his left hip and walking, and relieved when recumbent. The pain level was rated as 8-10/10 on the VAS. **Case 2:** The patient was a 74-year-old woman with history of osteoporosis who presented with a 5-year history of left medial groin and anterior/lateral thigh pain. She had a history of bilateral hip arthroplasty (THA) via the posterior-lateral approach, and revision of left THA twice as the result of the superior migration of the replaced femoral head relating to the progression of her thoraco-lumbar scoliosis. However, the	See "Clinical Background."	Not indicated.	Not indicated.	**Case 1:** At 1-month follow-up, the pain level was reported as 2-3/10 on VAS. At 2 months, the hip pain was still at least 50% better than prior to SRFA (4-5/10 on VAS). He could walk for 9 hours after SRFA (only 4 hours prior to SRFA), and had no need for a cane for ambulation (whereas the patient was using a cane to alleviate his pain and assist his walking prior to SRFA). At 4 months, the hip pain was 4-5/10 on VAS with walking. The patient described his hip pain as tolerable and could work as a housekeeper for 8 hours per day. The patient was lost to follow-up after the fourth month clinical visit. **Case 2:** After SRFA, the patient reported that her anterior thigh and groin area pain level dropped from 8/10 to 0/10 on VAS. Her lateral thigh pain also decreased from 8/10 to 1-2/10 on VAS. There was no detectable sensory loss in the groin and thigh region after the SRFA procedure. The patient could resume her physical therapy on day three after SRFA; she was able to tolerate the range of motion and strengthening exercises of the lower extremities along with gait training. On 3-month follow-up, there was no reported pain at rest or with sitting. Her average pain level with activity, at the anterior and lateral thigh areas, was 2-3/10 on VAS. There was no pain at the inner groin region. She could walk continuously with a cane for 10 to 15 minutes; with intermittent breaks, she is able to walk for several blocks.	None reported.

			patient reported no significant improvement in pain after the hip surgery. Laboratory work-up, plain radiograph, and bone scan were all negative for aseptic loosening or inflammatory arthritis. The left anterior/lateral thigh and groin pain was described as an intermittent sharp pain with average intensity of 8/10, and at worst a level of 10/10 on VAS. The pain was exacerbated with walking and standing. The patient was not able to tolerate physical therapy and walking because of the severe hip pain, and she deferred the option of oral medication for pain management because of the fear of adverse effects.					

Prospective Study

TABLE 28.

Title: **Percutaneous Radiofrequency Denervation in Patients with Contraindications for Total Hip Arthroplasty**

Citation: Rivera F, Mariconda C, Annaratone G. Orthopedics 2012;35:E302-E305.

Study Design	Type of RFA	Number of Subjects	Indication/ Clinical Background	Age	Body Mass Index Range (kg/m^2)	Pre-Procedure Duration of Pain	Results	Adverse Events
Prospective, non-randomized, non-controlled	Cooled	17	Inclusion criteria were contraindications for THA, radiographic Tönnis grades I and II, and groin, thigh, and trochanteric pain. An articular branch block test using 3 ml of ropivacaine hydrochloride 10 mg/ml was performed in all 18 patients under fluoroscopic control using the same technique of denervation described below. Intra-articular hip blocks were not performed. Pain disappeared immediately in 17 of 18 patients. One patient (prolonged hip pain in THA) was excluded from the study. The efficacy of anesthetic block in the remaining 17 patients was transient (1-3 days). After a variable period from 5 to 16 days, percutaneous RF lesioning of the sensory branches of the obturator and femur was performed.	Not indicated.	Not indicated	Not indicated.	Before CRFA and at 6-month follow-up, mean VAS scores were 9.52 (range, 7-10; SD, 0.79) and 6.35 (range, 3-10; SD, 2.17), respectively; mean Harris Hip Scores were 28.64 (range, 19-41; SD, 6.98) and 43.88 (range, 23-71; SD, 16.38), respectively; and mean WOMAC scores were 75.70 (range, 92-59; SD, 9.70) and 63.70 (range, 78-44; SD, 11.37), respectively. All values were statistically significant. Eight patients reported >50% pain relief at 6-month follow-up.	Three hematomas in the inguinal and internal groin zones were observed one day post-operatively.

Retrospective Study

TABLE 29.

Title: **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**

Citation: Kapural L, Jolly S, Mantoan J, Badhey H, Ptacek T. Pain Physician 2018;21:279-284.

Study Design	Type of RFA	Number of Subjects	Clinical Background	Age Range (years)	Body Mass Index Range (kg/m^2)	Pre-Procedure Duration of Pain	Results (significant difference = $p < 0.05$)	Adverse Events
Retrospective chart review of consecutive cases	Cooled	23	All except two patients were on opioids ranging from 10 to 450 mg of daily oral morphine equivalents. All were also given various membrane stabilizers and antidepressants for pain. All patients except three carried secondary chronic pain diagnoses, with the most frequent being lumbosacral spondylosis, lumbar spinal stenosis, and chronic knee pain. In general, all treated patients were either not candidates for or previously had an arthroplasty (two patients) with ongoing severe, intractable chronic hip pain after surgery. Most patients carried a hip related diagnosis of degenerative joint disease of the hip (18 patients), avascular necrosis of the hip (two patients), Ehlers-Danlos Syndrome (one patient), and neuropathic pain after arthroplasty (two patients).	27-73	18-50	Not indicated.	Expectedly, the needle approach to the lateral articular branches of the femoral nerve was easily achieved with more than a 1 cm passage distance from the femoral nerve in all 52 RF cases (median 2.5 range 1-3.5 cm). Placement of the second trocar to the incisura acetabuli was more challenging; in 21 CRFA cases the passing distance was less than 1 cm (range 0.5 to 1.9 cm, median 0.8). Motor stimulation (2 Hertz) at less than 1 volt was positive for the obturator nerve in 26 cases, which resulted in electrode repositioning more laterally (2-5 mm). Change in the pain scores indicated reduced pain, as the baseline was 7.61±1.2 before CRFA and 2.25±1.4 after CRFA ($p < 0.01$). The time interval of pain relief was much longer for CRFA. Opioid use did not decrease significantly.	There were no reported adverse events during the procedure, immediately after, or at 3 months after procedure except one case of neuritis (severe burning in the groin area), that resolved within one-week post-denervation.

From Kapural et al.:

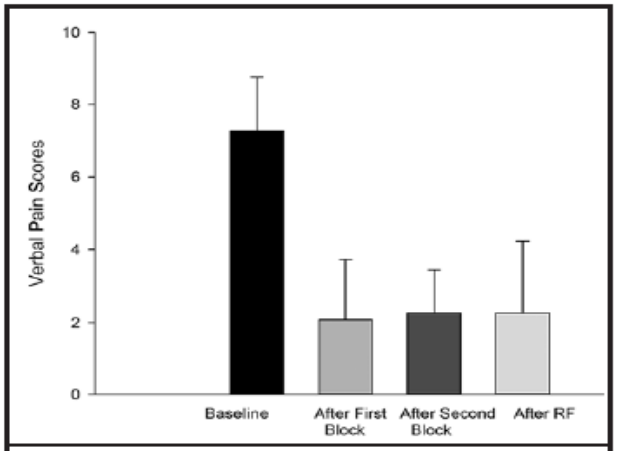

Fig. 3. Improvements in the pain scores were compared for all 23 patients. Comparable improvements in the pain scores were achieved after either blocks or RF ablations.

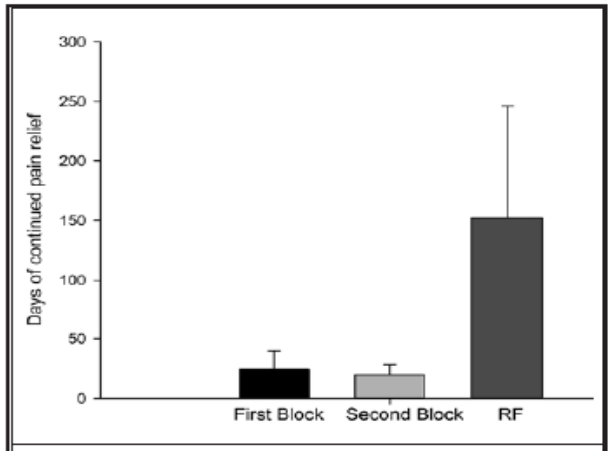

Fig. 4. *Time interval of pain relief was much longer for RF ablation ranging from 30 to 320 days for the first ablation and 42 to 300 days for second RF ablation.*

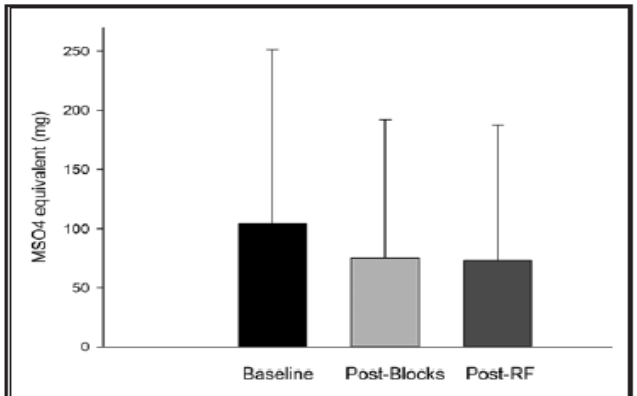

Fig. 5. *An average opioid daily use in patients who underwent diagnostic blocks and then RF hip denervation.*

Comparator Study

TABLE 30.

Title: **Pulsed Radiofrequency Treatment of Articular Branches of Femoral and Obturator Nerves for Chronic Hip Pain**

Citation: Chye CL, Liang CL, Lu K, Chen YW, Liliang PC. Clin Interv Aging 2015;10:569-574.

Study Design	Type of RFA	Number of Subjects		Clinical Background	Mean Age (SD)		Mean Body Mass Index in kg/m^2 (SD)		Pre-Procedure Mean Duration of Pain in Months (SD)		Results	Adverse Events
		SRFA	CON		SRFA	CON	SRFA	CON	SRFA	CON		
Prospective, non-randomized, controlled	Standard	15	14	This comparative study was approved by the local institutional review board. Patients suffering from chronic hip pain for >3 months with radiographic OA of the hip (Tönnis grades I and II) were approached for this study. Patients presented with pain on a range of motions, groin and thigh pain, and limitation of range of motion, especially internal rotation. Fifteen patients were offered SRFA. Fourteen patients who declined SRFA because of the possibility of SRFA complications were managed conservatively. These patients	65.53 (11.7)	67.71 (11.8)	Not indicated.	Not indicated.	Not indicated.	Not indicated.	At 1 week, 4 weeks, and 12 weeks after treatment initiation, improvements in VAS were significantly greater with SRFA. Improvements in OHS were significantly greater in the SRFA group at 1 week, 4 weeks, and 12 weeks. Patients in the SRFA group also used less pain medications. Eight participants in the control group switched to the SRFA group after 12 weeks. Six (75%) of them had an improvement of >50% with pain, whereas two patients (25%)	No major complications related with PRF were observed, except for one subcutaneous hematoma related to RF needle puncture, which presented for 1 week.

				received exercise programs and medications, including paracetamol, NSAIDs, and/or narcotic drugs for chronic hip pain. Patients who declined SRFA were evaluated longitudinally and served as controls. In the SRFA group, patients received the SRFA procedure and exercise programs. Pain medications were allowed if SRFA procedures did not decrease chronic hip pain. Patients who received conservative treatment but who still had severe pain could receive SRFA procedure after 12 weeks' treatment if they wanted to cross over.							had no improvement.	

In summary, of this comprehensive clinical summary of evidence for both conventional/standard radiofrequency and cooled thermal radiofrequency we respectfully ask that the Washington State Health Care Authority technology assessment committee consider this body of evidence.

Please contact Diane Weaver, Sr. Manager Health Policy at Avanos for further information. My cell phone number is: (858) 776-7682 and my email address is: diane.weaver@hyh.com

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Dear Sir/Madam who might concerns,

My name is Jiang Wu M.D. I am an assistant professor, anesthesiologist & chronic pain physician who works at the University of Washington Medical Center – Center for Pain Relief. Our Center for Pain Relief is a tertiary pain referral center. We have more than 10 pain specialists from different medical backgrounds including internal medicine, PM&R, neurology, anesthesiology, social worker, psychology, psychiatry, and dentistry. We are collaborating closely in a multidisciplinary fashion and providing a comprehensive approach to take care of the most challenging pain patients within Washington state and also from multiple states around WA.

Since the US Food and Drug Administration (FDA) clearance of marketing the COOLIEF Cooled Radiofrequency (RF) thermal treatment device for knee osteoarthritis (OA) in April 2017, our center has been one of the first institutes providing this treatment to highly selected patients, who have refractory/debilitating chronic knee pain, indicated for Total Knee Replacement, but declined by surgeon due to too high of surgical risk from co-existing severe systemic comorbidities. We offer the RF treatment of knee to such patient population to improve their quality of life and to promote their physical rehabilitation and functional restoration.

So that I would like to attest to this treatment based on my personal clinic experiences:
1), the treatment goal of the RF of knee OA is to provide partial (> 60%) but longer-lasting pain relief, which is consistent with current literature:

1.1 *"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 fewer than five years are associated with high accuracy in predicting treatment success." Published in Pain Med. 2017 Sep 1;18(9):1631-1641. doi: 10.1093/pm/pnx069. Titled of "Cooled Radiofrequency Ablation of the Genicular Nerves for Chronic Pain due to Knee Osteoarthritis: Six-Month Outcomes." Authored by McCormick ZL1, Korn M2, Reddy R3, Marcolina A4, Dayanim D5, Mattie R6, Cushman D7, Bhave M2, McCarthy RJ2, Khan D2, Nagpal G2, Waleg*

1.2 *"Based on patient interviews and data collection, RFA of genicular nerves can supply on average greater than 60% pain relief in our patient population for as long as 6 months", published in Pain Physician. 2017 Mar;20(3):E437-E444. - A Review of Long-Term Pain Relief after Genicular Nerve Radiofrequency Ablation in Chronic Knee Osteoarthritis. Authored by Iannaccone F1, Dixon S2, Kaufman A3.*

2), the diagnostic genicular nerve block is essential in our protocol in selecting/screening the appropriate RF candidate who might benefit from it the most; > 80% pain reduction from the diagnostic genicular nerve block is the therapeutic threshold to consider further RF treatment per our protocol.

3), after our strict screening process as above, the outcome of RF of the knee is overall very satisfactory to my patients.

There are many patients elected to move on the RF treatment on the other side of the knee after they completed the treatment on one side, which truly demonstrated their treatment satisfaction and attested to the longer-term efficacy of this treatment.

4), for more and more aging population with debilitating and refractory chronic knee pain from severe knee OA, but with co-existing severe systemic co-morbidities, deemed not a surgical candidate for total knee replacement and in the context of current opioids epidemics, the RF treatment of chronic knee pain is a very promising interventional option with acceptable risks and great outcomes from my personal experience.

I suggest, when evaluating the efficacy of this RF treatment in knee pain, please take few facts into your consideration: 1) it is still young (only 1 year after FDA clearance); 2) with satisfactory clinic experiences; 3) promising results in highly selected patient population; 4) limited treatments other than TKA for refractory knee pain; 5) under current more strict opioids guideline in the context of opioids epidemics.

I urge you to decide the fate of this RF treatment in WA with an extremely careful approach and being open-minded, as it is one of very promising and effective interventional advancement in modern chronic pain management. It will be unfair to deny those appropriate patient candidates in need of their access to this RF treatment based on no evidence of failure.

Thank you for your attention and please contact me if you have further questions or concerns.

Regards.

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9 August, 2018

Washington Health Technology Assessment

Re: Peripheral nerve ablation for the treatment of limb pain

I am writing regarding the pending assessment/review of radiofrequency nerve ablation for control of limb pain, specifically for painful knee and hip pain that have failed more conservative treatments and impacts quality of life. I am the Medical Director of the University of Washington's outpatient chronic pain clinic, the Center for Pain Relief. We provide comprehensive interdisciplinary care which at times incorporates interventional pain management techniques including radiofrequency ablation (RFA) of peripheral nerves to treat limb/joint pain.

Radiofrequency ablation (RFA) is a safe, effective treatment option for selected patients. One of my colleagues, Dr. Michele Curatolo, has published on the anatomy that helped lay the groundwork for this technique, (1) and subsequent clinical trials establish that RFA of peripheral sensory nerves can provide meaningful reduction in pain, particularly of the knee (2-5). In comparison to the modest effects of NSAIDS (6), topical analgesics (7), acetaminophen (8), or other medication approaches the outcomes of RFA appear favorable. Interventional options such as injected corticosteroids (9) and visco-supplementation (10) only have modest data at best to support their use. While the benefits of exercise, physical therapy, and developing better coping strategies are undeniable, the data to support sustained pain reduction for chronic knee pain with these approaches is not overwhelming (11).

In conclusion, for patients who have failed more conservative treatment, have persistent and localized joint/limb pain, and have an impact on their function/quality of life RFA is an appropriate option and should be encouraged as a pain management approach.

Sincerely,

Brett R. Stacey

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From: Weaver, Diane
To: HCA ST Health Tech Assessment Prog
Subject: WA HTA - Peripheral Nerve Ablation for the Treatment of Limb Pain
Date: Thursday, August 9, 2018 8:38:43 AM

To whom it may concern:

I am writing this letter in support of peripheral nerve ablation for the treatment of limb pain. I work as a physician dealing with chronic pain and will encounter patients who have end stage arthritis of peripheral joints including the knee. Fortunately many of these patients are able to undergo total knee arthroplasty (or other surgical procedures) with orthopedic surgery and able to resume a functional life. However there are situations where the patient may not be a good surgical candidate due to medical or other co-morbidities.

Radiofrequency ablation of the genicular nerves for the knee has been a useful option for some of these patients. The decision of loss of mobility/ambulation vs. pursuing genicular nerve radiofrequency is a question that we occasionally face. The challenge is limited published evidence for this procedure, but over time we have seen more data coming out in favor of this procedure. The benefit can be significant pain reduction and improved functional mobility, and the risks are very low for this procedure.

I hope that Washington State and the HTCC will carefully consider this option in a select/specific group of patients that would otherwise have no other options.

Thank you for your consideration,
Daniel Kwon, MD