Policy	MM-093
Effective Date	**09/01/2024**
Reviewed/Revised Date	05/11/2026
Next Review Date	05/11/2027
Origination Date	6/27/2024
Originated Department	Clinical Operations

Ablation of Peripheral Nerves to Treat Pain

Audience

Medical Management

Purpose

Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions and must reference the member-specific benefit plan document. The terms of the member-specific Policy document may differ from the standard benefit plan on which this medical policy is based. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the member-specific policy document supersedes this medical policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time

Definition

N/A

Policy/Procedure

Policy Statement and Criteria

1. Commercial Plans

Mountain health Co-Op considers radiofrequency ablation of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered investigational**.**

Cryneurolysis is peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered investigational.

Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered investigational.

Ablation of peripheral nerves to treat pain is considered investigational in all other conditions, with the exception of facet joint pain (see evidence review 7.01.616).

Section 1862(a)(1)(A) of the Social Security Act is the basis for denying payment for types of care, specific items, services, or procedures, not excluded by any other statutory clause, meeting all technical requirements for coverage, but are determined to be any of the following:

- Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used,
- Not proven to be safe and effective based on peer review or scientific literature
- Experimental
- Not medically necessary in the particular case
- Furnished at a level, duration or frequency that is not medically appropriate
- Not furnished in accordance with accepted standards of medical practice, or
- Not furnished in a setting appropriate to the patient's medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

- Consistent with the symptoms or diagnosis of the illness or injury under treatment; and
- Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental or investigational);and
- Not furnished primarily for the convenience of the patient, the provider or supplier; and
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Mountain Health Co-Op payments, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.

Background

Nerve Radiofrequency Ablation

Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue and a small sphere of tissue is coagulated around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled RFA is a variation of nerve RFA using a water-cooled probe that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve (see Table 1). The goal of ablating the nerve is the same.

RFA is also distinguished from pulsed radiofrequency (RF) treatment, which has been investigated for different types of pain. The mechanism of action of pulsed RF treatment is uncertain but it is thought not to destroy the nerve.[1] It does produce some degree of nerve destruction but is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

For the indications assessed in this evidence review, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some individuals have been treated for plantar fasciitis with a fasciotomy procedure using an RF device. This procedure does not ablate a specific nerve.

Table 1. Types of Radiofrequency Ablation

Type	Procedure	Tissue Temperature	Key Differences
Standard RFA	Electrode tip provides thermal energy for 90 – 130 seconds	70 – 90° C	Longer term pain relief but with more adjacent thermal tissue injury and limitation in size and shape of lesion.
Pulsed RFA	Non-ablative - provides 20 ms pulses every 30 seconds	42° C	Limits tissue damage but results in shorter duration of pain relief.
Cooled RFA	Water circulates through RF electrode to cool the tip	60° C	Larger lesion with limited thermal injury to tissue. Longer term pain relief.

RF: radiofrequency; RFA: radiofrequency ablation
Adapted from Oladeji et al (2019)[2]

Cryoneurolysis

Cryoneurolysis is being investigated to alleviate pain. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about 3 to 5 months. The iovera° cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

Regulatory Status

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in Table 2.

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). One of the indications is specifically for "creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 24) and a positive response (> 50% reduction in pain) to a diagnostic genicular nerve block."

Table 2. Radiofrequency and Cryoneurolysis Devices

Device	Manufacturer	Clearance	Date	FDA Product Code
SInergy®/Bayless Pain Management Probe	Kimberly-Clark/Baylis	K053082	2005	GXD
NeuroTherm® NT 2000	NeuroTherm	K111576	2011	GXD
iovera°	Pacira (formerly Myoscience)	K133453	2014	GXH
COOLIEF® Cooled Radiofrequency Kit	Avanos (formerly Halyard Health)	K163236	2016	GXI
COOLIEF® Cooled RF Probe	Avanos (formerly Halyard Health)	K163461	2017	GXI
Rulo(TM) Radiofrequency Lesion Probe	Epimed International	K190256	2019	GXI
Intracept Intraosseous Nerve Ablation System	Relievant Medsystems, Inc	K222281	2022	GXI
Apex 6 Radiofrequency Lesion Generator	RF Innovations, Inc	K220122	2023	GXD

Rationale

This evidence review was created in January 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 27, 2023.

This review includes indications for heel pain due to plantar fasciitis and knee pain due to osteoarthritis (OA). This review also evaluates the evidence for radiofrequency ablation (RFA) of a occipital neuralgia and cervicogenic headache. RFA and cryoneurolysis of other peripheral nerves are not addressed in this review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition

has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Radiofrequency Ablation for Knee Osteoarthritis

Clinical Context and Therapy Purpose

The purpose of RFA in individuals with knee OA who have severe refractory pain is to provide a treatment option that is an alternative to intra-articular injections or total joint replacement. Pain in OA can be transmitted via the genicular sensory nerves, which are branches of the femoral, tibial, peroneal, saphenous, and obturator nerves around the knee.[2,] The genicular nerve branches can be divided into a 4 quadrant system —superomedial, superolateral, inferomedial, and inferolateral. Nerves in the superomedial, superolateral, and inferomedial quadrants are located near the periosteum, but the inferolateral branch is close to the peroneal nerve and is usually avoided. The exact neuroanatomy around the knee is variable and can also be affected by chronic OA. Although the location of the target nerves is aided by palpating the bony landmarks and fluoroscopy, variability may prevent the exact localization. Diagnostic nerve blocks have been evaluated to confirm the location of the genicular nerves and predict efficacy. In addition to the genicular nerves, studies have reported RFA of the saphenous nerve, the sciatic nerve, the femoral, tibial, saphenous nerves, and peripatellar plexus in combination, and the intra-articular joint space.[3,]

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with knee OA.

Knee osteoarthritis (OA) is common, and often the cause of substantial disability. Prevalence increases with age, from about 24% among those 60 to 64 years of age to as high as 40% in those 70 to 74 years of age.[4] Knee osteoarthritis is characterized by pain upon initiation of movement or walking. As osteoarthritis progresses, the pain becomes continuous and joint functionality is severely impaired.

Interventions

The therapy being considered is RFA of the superomedial, inferomedial, and superolateral genicular nerves. Due to the variable location of the genicular nerves, it is thought that the increased area of denervation associated with cooled-RFA may be more effective than standard or pulsed RFA

Comparators

The following therapy is currently being used to treat OA: conservative management, which may include analgesics, physical therapy, or intra-articular injections.

Treatment for OA of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of OA and are not considered curative. Nonsurgical modalities used include: exercise; weight loss; various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (e.g., ibuprofen); nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from nonsteroidal anti-inflammatory drugs is insufficient, or the patient is at risk of gastrointestinal adverse events. If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Total knee arthroplasty is an operative treatment for symptomatic OA of the knee.

Outcomes

The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a 10 cm visual analog scale (VAS) or 11-point numeric rating scale (NRS). The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome. Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey.

The Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) is also frequently used to evaluate pain and function due to OA. The WOMAC includes 3 subscales: pain, stiffness, and physical functioning. Scores range from 0 to 96, with higher scores indicating greater disability.

The Lysolm Knee Score (LKS) has 8 domains to assess limitations in function, including limp, use of supports, locking, instability, pain, swelling, stair-climbing, and squatting. Scores range from 0 to 100, with lower scores indicating greater disability.

Because of the variable natural history of OA and the subjective nature of the outcome measures, RCTs are needed to determine whether outcomes are improved with interventions for pain. Trials should include a homogenous population of individuals with a defined clinical

condition, use standardized outcome measures when possible, and define a priori the clinically significant magnitude of response.

The effect of RFA is likely to be transient, so the period for follow-up is within a month to determine procedural success and adverse effects and at least 1 year to evaluate durability. Longer follow-up would be needed to evaluate whether denervation of sensory nerves of the knee could have adverse long-term effects on knee anatomy in individuals with OA.

Study Selection Criteria

We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months of outcomes, and systematic reviews of RCTs. It is preferred to have double-blinded sham interventions to control for placebo effects.
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Review of Evidence

Systematic Reviews

Characteristics of systematic reviews are described in Tables 3 and 4.

Chen et al (2021) conducted a systematic review of RFA for the treatment of knee OA.[5] The authors (including several affiliated with the American Academy of Orthopaedic Surgeons) identified 7 randomized controlled trials (RCTs) published through 2019 that met inclusion criteria. Quality of the studies was assessed based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology for risk of bias of randomization, allocation concealment, blinding, incomplete data, selective reporting, and other bias. Five of the trials were rated as high quality[6,7,8,9,10] despite lack of blinding in most and moderate risk of bias for allocation concealment and other biases. Two [11,12] were rated as moderate quality. A majority of the studies were conducted outside of the U.S., with a number of participants ranging from 24 to 151. Techniques included radiofrequency ablation (RFA) and cooled RFA (C-RFA). RFA was compared to non-treated controls or sham procedures, intraarticular corticosteroids, or hyaluronic acid. There was high heterogeneity due to the variability in comparators and outcome measures that limited meta-analysis, but analysis of the mean differences for the individual studies showed general agreement that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6 month followup.

Liu et al (2022) performed a systematic review of RFA, pulsed RF, C-RFA, and RF thermocoagulation to either the genicular nerve or intra-articular nerves in patients with knee OA.[13] The authors identified 15 RCTs which met their inclusion criteria. This assessment

concluded that all studies had a low risk of bias for random sequence generation, 12 (80%) had a low risk of bias for allocation concealment, 6 (40%) had a low risk of bias for blinding of participants, and personnel as well as blinding of outcome assessment. A low risk of selective reporting was identified in 12 (80%) studies, and all studies were reported as having a low risk of other biases. No overall assessment of study quality was provided. The authors reported a mean pain score difference in favor of the radiofrequency group over the control group at 1 to 2 weeks (-1.72; 95% confidence interval [CI], -2.14 to -1.30), 4 weeks (-1.49; 95% CI, -1.76 to 1.21), 12 weeks (-1.83; 95% CI, -2.39 to -1.26), and 24 weeks (-1.96; 95% CI, -2.89 to -1.04); however, all these estimates had significant heterogeneity ranging from 66% to 97% (p<.00001). A subgroup analysis limiting the site of radiotherapy to the genicular nerve included 5 trials and found a weighted mean difference between RF and control of -1.64 (95% CI, -2.19 to -1.09; p<.001) with a high level of heterogeneity (I_2, 84%; p<.001) at 1 to 2 weeks posttreatment. The mean difference in Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores also favored the radiofrequency group over control groups at 4 weeks (-10.64; 95% CI, -13.11 to -8.17), 12 weeks (-6.12; 95% CI, -7.67 to -4.57), and 24 weeks (-10.89; 95% CI, -12.28 to -9.51). No significant heterogeneity was observed in the 4 and 12 week WOMAC score pooled estimates, but the evidence was limited to being pooled from 4 trials. The rate of adverse events appeared equivalent between groups when observed when pooling data from 13 RCTs (risk difference, 0.03; 95% CI, -0.01 to 0.06; p=.14) with no significant heterogeneity.

Wu et al (2022) conducted a systematic review and network meta-analysis of multiple RFA modalities versus other treatments for osteoarthritis (OA) with a focus on short-term clinical outcomes through 6 months post-treatment.[14] Twenty-one RCTs were identified that were eligible for inclusion. The evidence base consisted of 1818 individuals with a range of 24 to 260 participants across the included RCTs. Outcomes of interest included VAS Pain and WOMAC function scores as well as adverse events. The authors found that C-RFA has better efficacy for pain and function than conventional or pulsed modalities and that conventional RFA outperforms pulsed RFA. Visual analog scale (VAS) pain scores were reported in 16 studies at 3 months follow-up (n=1401). All interventions, with the exception of exercise, had significant improvement compared with placebo. In a ranked surface under the cumulative ranking curve (SUCRA) analysis, monopolar C-RFA of the genicular nerve ranked first in analgesia performance, followed by conventional monopolar RFA of the genicular nerve, intraarticular platelet-rich plasma injection (IAPRP), pulsed monopolar RFA of the genicular nerve, intraarticular anesthesia injection (IAA), intraarticular dextrose injection (IAD), intraarticular sodium hyaluronate injection (IAHA), pulsed monopolar RFA of the saphenous nerve, intraarticular corticosteroid injection, nonsteroidal anti-inflammatory drugs (NSAIDs). At 6 months, 10 trials reported on 1,021 individuals for VAS pain outcomes. All treatments, save NSAIDs, had a significantly decreased VAS score compared with exercise at 6 months follow-up. A SUCRA analysis showed that the best-performing intervention was conventional bipolar RFA of the genicular nerves (MD, -5.5; 95% CI, -4.3 to -6.7) followed by conventional monopolar RFA of the genicular nerves, pulsed monopolar intraarticular RFA, pulsed monopolar RFA of the genicular nerve, IACS, IAHA, IAPRP, and NSAIDs. WOMAC scores were reported in 14 studies (n=1091) at 3 months and by 9 studies (n=821) at 6 months follow-up. At 3 months, except for exercise, NSAIDs, and pulsed monopolar IPRFA, all treatments had a significant reduction in WOMAC scores compared to placebo. SUCRA analysis suggested the first rank intervention for improved knee performance at 3 months follow-up was cooled monopolar RFA of the genicular nerve followed by conventional bipolar

RFA of the genicular nerve, pulsed monopolar intraarticular RFA, conventional monopolar RFA of the genicular nerve, pulsed monopolar intraarticular RFA plus IAPRP, IAA, pulsed monopolar RFA of the genicular nerves, pulsed monopolar IPRFA, IAS, and IAHHA. All interventions had a significant improvement in WOMAC scores at 6 months compared to exercise. SUCRA analysis showed the best performance for cooled monopolar RFA of the genicular nerve followed by conventional bipolar RFA of the genicular nerve, conventional monopolar RFA of the genicular nerve, pulsed monopolar RFA of the genicular nerve, IACS, IAHA, NSAIDs and exercise. The authors also reported that adverse events were recorded in 6 RCTs (n=836) and found 43 (8.3%) in the RFA groups, which were likely attributable to RFA; major adverse events included: pain (n=5), post-procedural pain (n=7), fall (n=5), stiffness (n=1) and swelling (n=2).

The trials by Davis et al (2018), El-Hakeim et al (2018), Xiao et al (2018), and Chen et al (2020), along with later RCTs that are not included in the systematic reviews, are described in greater detail below.

Table 3. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Chen et al (2021)[5,]	1966 - 2019	7	Individuals with OA of the knee who were treated with RFA or C-RFA	NR (24 to 151)	RCT	up to 12 months
Liu et al (2022)[13,]	Database inception - 2021	15	Individuals with OA of the knee who were treated with RFA, C-RFA, pulsed radiofrequency, or RF thermocoagulation	1009 (16 to 177)	RCT	up to 24 months
Wu et al (2022)[14,]	Database inception - 2021	21	Individuals with OA of the knee who were treated with RFA, C-RFA, pulsed radiofrequency, bi-polar RFA, IAA, IAD, IAPRP, IAHA, intra-articular erythropoietin, IACS, NSAIDs, or exercise	1818 (24 to 260)	RCT	6 months

C-RFA: cooled radiofrequency ablation; IAA: intra-articular anesthesia; IACS: intra-articular corticosteroid; IAD: intra-articular dextrose; IAHA: intra-articular sodium hyaluronate; IAPRP: intra-articular platelet rich plasma; NR: not reported; NSAIDs: non-steroidal anti-inflammatory drugs; OA: osteoarthritis; RCT: randomized controlled trial; RF: radiofrequency; RFA: radiofrequency ablation.

Table 4. Comparison of Trials/Studies Included in SR & M-A

Study	Trial Size	Nerve Target	Prognostic Block	RF Method	Comparator	Follow-up	Chen et al (2021)	Liu et al (2022)	Wu et al (2022)
Choi et al (2011)	38	GN	Yes	RFA	Sham	3 months	•	•	•
Yi et al (2012)	36	GN	No	RFA	IA Hyaluronic Acid	3 months		•	
Rahimzadeh et al (2014)	50	IA	No	PRF	IA Sham	3 months		•	•
Hashemi et al (2016)	72	IA+GN	NR	PRF	IA Steroid	3 months			•
Yang et al (2015)	62	GN	No	RFA	IA Hyaluronic Acid	3 months		•	
Hu et al (2016)	92	IA	No	PRF	NSAIDs	6 months		•	
Sari et al (2016)	50	GN	NR	RFA	Ultrasound	3 months			•
Yuan (2016)	24	IA	Yes	PRF	IA Steroid	6 months		•	•
Gulec et al (2017)	100	IA	NR	PRF	Monopolar RFA	3 months			•
Shen et al (2017)	54	IA	No	RFA	Standard Treatments	3 months	•	•	
Sari et al (2018)	73	GN	No	RFA	IA Steroid	3 months	•	•	•
Davis et al (2018)	151	GN	Yes	C-RFA	IA Steroid	6 months	•	•	
El-Hakeim et al (2018)	60	GN	No	RFA	Acetaminophen and NSAIDs	6 months	•	•	•
Jadon et al (2018)	30	GN	NR	RFA	Monopolar RFA	6 months			•
Ray et al (2018)	24	GN	Yes	RFA	IA Hyaluronic Acid	3 months	•		•
Xiao et al (2018)	96	GN	No	RFA	IA Hyaluronic Acid	6 months	•	•	•
Davis et al (2019)	151	GN	NR	C-RFA	IACS	12 months			•
Monerris et al (2019)	28	GN	NR	PRF	Placebo	6 months			•
Kumaran et al (2019)	30	IA	No	RFA	Sham	3 months		•	
Chen et al (2020)	177	GN	Yes	C-RFA	IA Hyaluronic Acid	6 months		•	•
Han et al (2020)	62	GN	NR	C-RFA	Exercise	6 months			•
Hong et al (2020)	53	GN	No	RF thermocoagulation	IA Steroid	6 months		•	
Santana et al (2022)	216	GN	NR	PRF	IA Hyaluronic Acid	12 months			•
Carpenedo (2021)	16	IA	Yes	PRF	Sham PRF	6 months		•	
Abdelraheem et al (2021)	200	GN	NR	PRF	IA-PRP	12 months			•
Sameh et al (2021)	60	GN	NR	PRF	IARFA+IAPRP	12 months			•

Roberta et al (2021)	20	SN	NR	PRF	Placebo	6 months			•
Ahmed et al (2021)	58	GN	NR	RFA	IACS	6 months			•

C-RFA: cooled radiofrequency ablation; IA: intra-articular; NSAIDS: nonsteroidal anti-inflammatory drug; PRF: pulsed radiofrequency; RCT: randomized controlled trial; RFA: radiofrequency ablation; SN: saphenous nerve.

Randomized Controlled Trials

Characteristics and results of RCTs are described in Tables 5 and 6.

El-Hakeim et al (2018) reported a single-center RCT that compared RFA of the genicular nerves to conventional analgesics in 60 individuals with Kellgren-Lawrence stage III or IV knee OA.[10] The investigators did not use a positive response to nerve blocks to determine who to treat but did assess the accuracy of the target by sensory and motor responses to stimulation. The best approach to identify the genicular nerves is uncertain.[15] The VAS pain scores decreased from baseline in both groups and were significantly lower in the RFA group from 2 weeks to 6 months after treatment. The WOMAC scores, which were assessed by a clinician who was blinded to treatment, were significantly better only at the 6 months time point.

Davis et al (2018) reported on a multicenter randomized trial comparing cooled RFA to corticosteroid injection in 151 individuals who had chronic (>6 months) knee pain unresponsive to conservative therapy.[9] At 1 month after treatment, both groups showed a reduction in pain, with a 0.9-point difference on an 11-point NRS. By 3 months after treatment, pain scores had increased in the steroid group, while pain scores in the RFA group remained low throughout the 6 month follow-up. At the 6-month follow-up, 74.1% of individuals in the RFA group were considered responders (≥50% decrease in the NRS), compared with 16.2% of individuals treated with steroid injections (p<.001). Twelve-month follow-up was reported in 2018.[16] Out of the 76 individuals randomized to RFA, 52 (68%) individuals were available for follow-up at 12 months. Out of those 52, 34 (65%) reported at least a 50% decrease in pain on an NRS. Limitations of this observational portion of the study include the 32% loss to follow-up and the lack of blinding for this subjective measure. All but 4 of the individuals in the intra-articular steroid arm had crossed over to cooled RFA by the 12-month follow-up.

Twelve to 24-month follow-up of a subset of individuals treated with RFA in the RCT by Davis et al (2018) was reported by Hunter et al (2020) and is shown in Table 7.[9,17] There were 42 individuals randomized to RFA and 41 randomized to the control group who crossed over to RFA at 6 months and qualified for follow-up at participating sites. Of the 83 potential participants, 15 had additional procedures (e.g. steroid injection, total knee arthroplasty, hyaluronic injection, repeat RFA) and were not included in the analysis, 35 (42.2%) could not be reached or declined to participate, and 33 (40%) consented for the study. Although 44% of individuals who participated in follow-up maintained their improvement in pain scores, this was a small percentage of the individuals who received treatment. Interpretation of this study is limited due to the small number of individuals and the potential for bias in this non-blinded study.

Another manufacturer-sponsored trial on cooled RFA for knee osteoarthritis was reported by Chen et al (2020).[18] The investigators randomized 177 individuals to RFA or a single injection of

hyaluronic acid (Synvisc ONE). Although widely used, the efficacy of hyaluronic acid has not been supported by evidence.[19] Therefore, it might be considered a placebo treatment. Crossovers to RFA (n=68, 82.9%) were allowed at 6 months. A major limitation of this publication is that results were reported only for the 83% of controls who crossed over; the authors noted that the remainder of the individuals reported long-term pain relief from hyaluronic acid. Lyman et al (2022) published an extension study to assess long-term outcomes through 24 months for participants in this trial who received RFA.[20] Of the initial 66 RFA patients who had 12 months follow-up, 36 signed the informed consent to participate in the extension study. Thirty-two of these participants completed 18 month follow-up and 27 completed 24 month follow-up; the primary reason for loss to follow-up was receiving another knee procedure (Table 7). At baseline, the participants had a mean NRS of 6.8±0.8 which was reduced to 2.4 ± 2.5 (64% reduction) at 18 months and 3.4 ± 3.2 (51% reduction) at 24 months; a ≥ 50% improvement in NRS pain scores was experienced by 22 (69%) of patients at 18 and 17 (63%) at 24 months. Mean WOMAC scores at baseline for these participants were 64.4 ± 14.7, which were reduced by a mean of 34.7±27.5 (54%; p<0.0001 versus BL) and 24.8±32.8 (35%; p<0.0007) at 18 and 24 months respectively. No serious or non-serious adverse events related to cooled RFA were reported by the authors at 18 or 24 months post-treatment.

An independent study by Elawamy et al (2021) compared pulsed radiofrequency to a single injection of platelet-rich plasma in 200 individuals with OA (NCT03886142).[21] VAS scores showed an improvement of 50% (from a score of 6 to 3) in both groups at 3 months, with values returning to a score of 5 by the sixth month. Scores on the Index of Severity for OA of the Knee were reduced from 7 at baseline to 4 at the third month, increasing to 5 at the sixth month. Twelve-month scores were not reported. Platelet-rich plasma is not considered a standard of care treatment for OA and there were a number of additional limitations in conduct and reporting of this study. Limitations of these studies, which include potential for bias due to lack of blinding of study participants and insufficient number of individuals in follow-up, are described in Tables 8 and 9.

A single-center, double-blind RCT by Malaithong et al (2021) compared bipolar radiofrequency to a sham RFA procedure using low-level sensory stimulation in 64 individuals with OA (Thailand Clinical Trial Registration 20170130003).[22] Both treatment groups received genticular nerve blocks prior to RFA or sham procedure. The bipolar RFA and sham RFA treatment arms experienced significant improvements in pain at 12 months from baseline, but no differences between groups were observed (Table 6). Similar findings were observed for WOMAC scores through 12 months follow-up as well as the Patient Global Improvement Index. Interpretation of this study is limited due to the small number of individuals enrolled.

Overall, the available studies have methodological limitations and the number of individuals studied for this common condition is low.

Table 5. Summary of Key RCT Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	Comparator
Davis et al (2018)[9]	U.S.	11	151 individuals with	Cooled RFA of the	Intra-

			chronic (>6 mo) knee pain unresponsive to conservative therapy[a]; pain score ≥6; OA grades 2-4; Oxford Knee Score of ≤35; a positive diagnostic genicular nerve block[a,b]	genicular nerves under fluoroscopic guidance (n=76)	articular steroid (n=75)
El-Hakeim et al (2018)[10,]	Egypt	1	60 individuals with stage III or IV knee OA	RFA of the genicular nerves under fluoroscopic guidance (n=30)	Conventional analgesics (n=30)
Xiao et al (2018)[12,]	China	1	96 individuals with OA with VAS >6 and LKS <60 who had abandoned other therapeutic measures	RFA of the genicular nerves guided by a plexus nerve stimulator (n=49)	Single intra-articular hyaluronic acid injection (n=47)
Chen et al (2020)[18,]	U.S.	Multicenter	177 individuals with knee OA	Cooled RFA of the genicular nerves under fluoroscopic guidance (n=89)	Single hyaluronic acid injection (Synvisc- One, n=88)
Elawamy et al (2021)[21,]	Egypt	2	200 individuals with knee OA grade III or IV refractory to conservative management	Pulsed RFA with identification of the genicular nerves based on proximity to the arteries by ultrasound and sensory stimulation (n=100)	Single intra-articular platelet rich plasma (n=100)
Malaithong et al (2022)[22,]	Thailand	1	64 individuals with chronic OA grade III or IV refractory to conservative management with a positive diagnostic genicular nerve block[b]	Bipolar RFA of the genicular nerves under fluoroscopic guidance (n=32)	Sham RFA with a genicular nerve block (n=32)

LKS: Lysolm Knee Score; OA: osteoarthritis; RCT: randomized controlled trial; RFA: radiofrequency ablation; VAS: visual analog score. aConservative treatment included physical therapy, oral analgesics: ≤60 mg morphine equivalence, stable for 2 months; intra-articular injections with steroids and/or viscosupplementation, body mass index (BMI) <40, and reporting ≥50% response to blocks as bAt least 50% reduction in numeric rating scale for pain with anesthetic injection to the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve.

Table 6. Summary of Key RCT Results

Study	Mean Pain Scores (SD)		Function	

	1 Month	3 Months	6 Months	Responders at 6 Months, %[a]	Mean Oxford Knee Score at 6 Months (SD)	Global Perceived Effect at 6 Months, %
Davis et al (2018)[9,]	NRS					
N	136	132	126	126	125	126
RFA	3.0 (2.3)	2.8 (2.2)	2.5 (2.3)	74.1	35.7 (8.8)	91.4
Steroid injection	3.9 (2.2)	5.2 (2.0)	5.9 (2.2)	16.2	22.4 (8.5)	23.9
p-Value	.025	<.001	<.001	<.001	<.001	<.001
El-Hakeim et al (2018)[10,]	VAS			WOMAC		
	2 Weeks	3 Months	6 Months	2 weeks	3 Months	6 Months
N	60	60	60	60	60	
RFA	2.47 (0.3)	2.83 (0.5)	3.13 (0.3)	93.53 (1.9)	21.67 (4.4)	24.23 (4.3)
Analgesics	3.63 (0.27)	4.93 (0.2)	5.73 (0.26)	54.07 (3.0)	30.93 (2.5)	37.1 (1.9)
p-Value	.004	<.001	<.001	.17	.10	<.001
Xiao et al (2018)[12,]	VAS			Lysolm Knee Score		
	3 Days	6 Months	12 Months	3 Days	6 Months	12 Months
N	96	96	96	96	96	96
RFA	3.38 (1.02	2.41 (1.06)	3.12 (1.03)	78.1 (7.5)	68.3 (6.6)	84.6 (4.3)
Hyaluronic Acid	5.11 (1.13)	5.13 (1.12)	7.01 (1.01)	61.1 (5.3)	54.1 (6.2)	43.2 (6.1)
p-Value	<.05	<.05	<.05	<.05	<.05	<.05
Chen et al (2020)[18,]	NRS				WOMAC	
	1 Month	6 Months	12 Months	Responders at 6 Months, %[a]	6 Months	12 Months
N	153	144	128	144	144	128
RFA (95% CI)	3.0 (2.5 to 3.5)	2.7 (2.2 to 3.2)	2.8 (2.2 to 3.4)	71.1%	33.6 (28.4 to 38.9)	33.2 (27.5 to 38.9)
Hyaluronic Acid	NR	NR	NR	NR	NR	NR
Subgroup of control individuals who crossed over to RFA at 6 mo	4.2 (3.6 to 4.8)	5.0 (4.4 to 5.6)	3.0 (2.4 to 3.6)	29.4%	58.1 (53.4 to 62.8)	38.4 (32.7 to 44.1)
p-Value	.002	<.001	.618	<.001	<.001	.1996
Elawamy et al (2021)[21,]	VAS			ISK		
	1 Week	6 Months	12 Months	1 Week	6 Months	12 Months
N	200	NR	NR	200	NR	NR
RFA	3	5	5	5	4	NR
Platelet-rich Plasma	3	5	6	6	6	NR
p-Value	NR	NR	NR	NR	NR	

Malaithong et al (2022)[22,]	VAS			WOMAC		
	1 Month	6 Months	12 Months	1 Month	6 Months	12 Months
N	64	59	53	64	59	53
RFA	3.0 (2.3)	3.3 (2.7)	3.2 (2.6)	63.6 (51.8)	74.6 (50.3)	67.1 (51.9)
Sham RF	3.1 (1.9)	3.1 (2.3)	2.6 (2.4)	66.8 (42.4)	66.2 (43.5)	24.6 (38.5)
p-Value	.15	.29	.73	.78	.81	.70

CI: confidence interval; ISK: Index of Severity for Osteoarthritis of the Knee; NR: not reported; NRS: numeric rating scale; RCT: randomized controlled trial; RFA: radiofrequency ablation; SD: standard deviation; VAS: visual analog score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Greater than 50% reduction in the NRS.

Table 7. Extended Follow-up of Individuals Treated with RFA

Study	**Mean Pain Scores (SD)**				**Function**	
	At 12 Months	**At 18 Months**	**At 24 Months**	**Responders at 18 Months, %[a]**	**Oxford Knee Score at 18 Months (SD)**	**Oxford Knee Score at 24 Months (SD)**
Davis et al (2018), Hunter et al (2020)[9,][17,]	NRS					
N (randomized and crossover)	30	25	18	25	25	18
RFA	3.0 (2.5)	3.1 (2.7)	3.6 (2.8)	44.0	47.2 (8.1)	46.8 (10.3)
	At 12 Months	At 18 Months	At 24 Months	Responders at 24 Months, %[a]	WOMAC Score at 18 Months (SD)	WOMAC Score at 24 Months (SD)
Chen et al (2020), Lyman et al (2022)[18,20,]	NRS					
N (randomized and crossover)	32	32	27	27	32	27
RFA	1.9 (1.9)	2.4 (2.5)	3.4 (3.2)	63.0	34.7 (27.5)	24.8 (32.8)

NRS: numeric rating scale; RFA: radiofrequency ablation; SD: standard deviation; [a] Greater than 50% reduction in the NRS.

Table 8. Study Relevance Limitations

Study	**Population[a]**	**Intervention[b]**	**Comparator[c]**	**Outcomes[d]**	**Duration of Follow-Up[e]**
Davis et al (2018)[9,]					1. Follow-up >6 mo is needed to evaluate durability of the procedure. Extended follow-up is in progress (see Table 18).

El-Hakeim et al (2018)[10],	4. Study population was not selected by a positive response to a nerve block		2. Controls received only analgesics and physical therapy if needed		1. Follow-up >6 mo is needed to evaluate durability of the procedure
Xiao et al (2018)[12],	4. Study population was not selected by a positive response to a nerve block		2. Efficacy of a single injection of hyaluronic acid as an active comparator is not supported by evidence		
Chen et al (2020)[18],			2.. Efficacy of a single injection of hyaluronic acid as an active comparator is not supported by evidence		
Elawamy et al (2021)[21],	4. Study population was not selected by a Positive response to a nerve block	1. Both groups received analgesics and physical therapy, but these were not recorded	2. Efficacy of a single injection of platelet-rich plasma as an active comparator is not supported by evidence		
Malaithong et al (2022) [22],		1. Both groups received analgesic therapy, but these were not recorded			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest. [c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively. [d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported. [e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Davis et al (2018)[9],		1. Study population was not blinded to treatment assignment, which		1. Unequal loss to follow-up 3. Crossovers to RFA were allowed at 6 mo		2. The study used Wilcoxon signed-rank sum test rather than a repeated-

		might have affected subjective scores				measures test
El-Hakeim et al (2018)[10],	2. Allocation concealment not described	1. Study population was not blinded to treatment assignment, which might have affected subjective scores				2. The study did not use a repeated-measures test for the different time points.
Xiao et al (2018)[12],	2. Allocation concealment not described	1. Study population was not blinded to treatment assignment, which might have affected subjective scores			1. Power calculations were not reported	2. The study did not use a repeated-measures test for the different time points.
Chen et al (2020)[18],		1. Study population was not blinded to treatment assignment, which might have affected subjective scores	2. Results were reported only for controls who failed treatment and crossed over			2. The study did not use a repeated-measures test for the different time points.

Elawamy et al (2021)[21]		1. Study population was not blinded to treatment assignment, which might have affected subjective scores		6. It is unclear how many individuals completed the 12 month follow-up		2, 4. The study did not use a repeated-measures test and there was no comparison between groups.
Malaithong et al (2022) [22]	2. Allocation concealmen t not described				4. Power calculations may have underestimated the number of patients needed to recruit; effect size based on older study	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. RFA: radiofrequency ablation.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias. [b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4.Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Kapural et al (2022) reported a retrospective assessment of pain relief in 340 consecutive patients with chronic knee pain at a single center who were treated with either C-RFA (n=170) or conventional RFA (n=170) (Table 10).[23] The mean age at treatment was 63 years in the C-RFA group and 61 years in the conventional RFA group; both treatment groups had similar levels of baseline VAS pain reported prior to nerve block (8.4 in the C-RFA group and 8.3 in the traditional RFA group). Included patients had at least one year of follow-up after treatment and were evaluated on short-term and long-term pain outcomes on the VAS and opioid use (Table 11). The authors reported that at the first follow-up, approximately 4 to 6 weeks posttreatment, individuals in the C-RFA group had superior pain reduction on the VAS when compared to traditional RFA as well as significantly longer durability of pain relief. This reduction in pain, however, did not translate into a reduction in the usage of opioids from baseline which showed no significant differences in either treatment arm.

Wu and colleagues (2022) published a retrospective cohort study of C-RFA versus traditional RFA of the genicular nerves in patients who had chronic knee pain despite attempts at conservative management.[24] The mean age of treatment was 72 years of age in the C-RFA group and 69.6 after matching; both groups reported similar levels of baseline NRS pain prior to treatment and

similar Kellgren-Lawrence grade for classification of OA. Patients were followed for one year after administration of RFA and were evaluated for treatment success (defined as a reduction of 2 or more on the NRS), duration of pain relief, and the probability of having total knee arthroplasty (TKA) within 1 year post-RFA. In this cohort, patients treated with traditional

RFA were significantly more likely to report treatment success at 1, 3 and 6 months follow-up (p<.01); the mean duration of relief was 175 days in the c-RFA group and 156 days in the traditional RFA group and did not vary significantly (p=.69). The traditional RFA group had a significantly greater reduction in NRS pain scores at 1 month post-RFA (-3.59 versus 4.71; p=.02), but this was not sustained at 3, 6, 9 and 12 months follow-up. A higher probability of having TKA was observed in the C-RFA group (14%) compared to traditional RFA (7.7%), but this difference did not reach statistical significance (p=.18).

Table 10. Summary of Key Nonrandomized Trials OR Observational Comparative Study Characteristics

Study	Study Type	Country	Dates	Participants	C-RFA	Traditional RFA	Follow-Up
Kapural et al (2022)[23],	Retrospective	U.S.	2013-2019	340 consecutive individuals with chronic knee pain who had either C-RFA or conventional RFA at a single center. Median VAS pain prior to treatment was 8 prior to nerve block.	C-RFA of the genicular nerves under fluoroscopic guidance following geniculate block (n=170)	Conventional RFA of the genicular nerves under fluoroscopic guidance following geniculate block (n=170)	1 year
Wu et al (2022) [24],	Retrospective	U.S.	NR	208 patients with chronic knee pain who were unresponsive to conservative treatments and had either C-RFA or conventional RFA at a single center. Mean BL NRS pain scores were 7 prior to treatment and the mean Kellgren-Lawrence grade was 3.6.	C-RFA of the genicular nerves (n=104)	Conventional RFA of the genicular nerves (n=104)	1 year

BL: baseline; C-RFA: cooled radiofrequency ablation; NR: not reported; NRS: numeric rating scale; RFA: radiofrequency ablation; VAS: visual analogue scale

Table 11. Summary of Key Nonrandomized Trials OR Observational Comparative Study Results

Study	VAS Pain Score Baseline +SD	VAS Pain Score at 4-6 Wks f/u + SD	Mean Duration of pain Relief (>50% VAS pain decrease)	>50% VAS Pain Decrease at 6 Mos, n (%)	>50% VAS Pain Decrease at 12mos, n (%)	Opiod Usage
Kapural et al (2022)[23],	340	340	340	340	340	340
C-RFA (n=170)	8.4 ± 1.5	4.26 ± 3.2; p=.001	11.1 mos	107 (63%)	78 (46%)	Mean 53 mg at BL; 53.2 ± 32 mg OME at 12 mos f/u; p=.954
RFA (n=170)	8.3 ± 1.4	5.07 ± 2.8; p=.001	2.6 mos	35 (20.6%)	15 (8.8%)	Mean 48.6mg at BL; 41.5 ± 20 mg OME at 12 mos f/u; p=.054
Diff; p-value	NA	p=.010	8.5 mos; p=0.001	42.6%; NR	37.2%; NR	No between-group comparison
	Treatment Success, % (95% CI) at 1 mo	Treatment Success, % (95% CI) at 3 mo	Treatment Success, % (95% CI) at 6 mo	Mean Change in NRS Pain Score (95% CI) at 3 mo	Mean Change in NRS Pain Score (95% CI) at 6 mo	Mean Change in NRS Pain Score (95% CI) at 12 mo
Wu et al (2022) [24],	104	104	104	104	104	104
C-RFA (n=104)	43 (34 to 53)	55 (45 to 64)	59 (49 to 68)	-1.14 (-2.2 to -0.1)	-0.83 (- 2.1 to 0.4)	1 (-2 to 4)
RFA (n=104)	62 (51 to 71)	59 (49 to 68)	79 (70 to 86)	-2.05 (-2.9 to -1.2)	-1.18 (-2.4 to 0.03)	-0.83 (-2.4 to 0.7)
Diff; p-value	.01	<.001	<0.01	.18	.68	.22

BL: baseline; C-RFA: cooled radiofrequency ablation; CI: confidence interval; Diff: difference; f/u: follow-up; mos: months; NR: not reported; NRS: numeric rating scale; OME: oral morphine equivalent; RFA: radiofrequency ablation; SD: standard deviation; VAS: visual analagoue scale; wks: weeks.

Safety

In 2021, the Spine Intervention Society's Patient Safety Committee published an article on the safety of genicular nerve RFA.[25], The committee reviewed case reports of septic arthritis, pes anserine tendon injury, third-degree skin burn, and clinically significant hematoma and/or hemarthrosis with RFA of the genicular nerves, concluding that larger cohort studies are needed to determine the incidence of these complications for this emerging technology.

Section Summary: Radiofrequency Ablation for Knee Osteoarthritis

Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. To date, the evidence on RFA for knee pain includes systematic reviews and metaanalyses of RCTs, RCTs with 24 to 200 individuals , and prospective observational studies with up to 24 months of follow-up. The systematic reviews generally found that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6-

month follow-up; however, most estimates were determined to have moderate to high heterogenity. The network meta-analysis compared between multiple RFA modalities and found that cooled RFA had significant efficacy for pain and function through 6 months follow-up than traditional or pulsed RFA. Trials have compared RFA to sham procedures, intra-articular steroid injection, intra-articular hyaluronic acid injection, and platelet-rich plasma injection.

Although intra-articular steroid injection is an established treatment for OA pain, it has limited durability. The efficacy of hyaluronic acid has been challenged and that of platelet-rich plasma is uncertain so it is unclear whether these would be considered active or placebo controls. Few of the studies were blinded, which may have biased the subjective outcome measures. Additional limitations in design and conduct include suboptimal statistical analyses and reporting of loss to follow-up. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate above 70% at 6 months which was significantly greater than the control conditions. Given that OA of the knee is a common condition, studies with a larger number of individuals, preferably in blinded studies with active and sham controls and follow-up of at least 12 months, are needed to determine the benefits and potential harms of this treatment.

Cryoneurolysis for Knee Osteoarthritis or Total Knee Arthroplasty

Clinical Context and Therapy Purpose

The purpose of cryoneurolysis in individuals who have OA or TKA is to provide a treatment option that is an alternative to standard therapies. Pain control in individuals with knee OA can delay TKA, while pain control following TKA is essential for individuals to participate in physical therapy and promote recovery.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with OA or who have undergone TKA.

Interventions

The therapy being considered is percutaneous cryoneurolysis of the anterior femoral cutaneous nerve and/or the infrapatellar branch of the saphenous nerve.

Comparators

The following therapies are currently being used to treat OA or pain with TKA: conservative management, which may include corticosteroid injection or oral medications, for OA, and opioid or peripheral nerve blocks with anesthetics, for TKA.

Outcomes

The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or NRS. The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome.

Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey. The WOMAC score is also frequently used to evaluate function due to OA. The time for follow-up is within days to determine procedural success and at least 6 months to a year to evaluate durability.

Study Selection Criteria

We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months outcomes, and systematic reviews of RCTs.
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Randomized Controlled Trials

Radnovich et al (2017) reported a double-blind multicenter RCT of cryoneurolysis for individuals with mild-to-moderate OA (Table 12).[26] Compared with sham-treated individuals, cryoneurolysis resulted in a greater decrease in WOMAC pain score, WOMAC total score, and VAS score at 30 days (Table 13). The cryoneurolysis group also had better WOMAC total scores at 90 days but not at 60 days. Improvements in VAS scores did not differ significantly between active and sham treatment groups at 60 and 90 days.

Mihalko et al (2021) reported a non-blinded single-center RCT of cryoneurolysis for individuals with OA planning to undergo TKA.[27] Patients were randomized 1:1 to either cryoneurolysis targeting the superficial genicular nerves or standard of care treatment prior to receiving TKA (Table 12). A significant reduction in the primary outcome of opioid consumption was not reported in the intention to treat (ITT) analysis, but PP analysis found that patients in the cryoneurolysis group had significantly lower opioid consumption 72 hours, 6 weeks, and 12 weeks post-discharge ($p<.05$) (Table 13). A significant reduction in pain from baseline was reported at 12 weeks post-discharge but not for earlier evaluated time points when analyzing the PP population. Improvements in the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR) were noted from 72 hours to 12 weeks follow-up in the PP analysis ($p<.0001$). The authors noted an adverse event rate of 17% in the cryoneurolysis group and 35% in the standard of care comparator.

Table 12. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Radnovich et al (2017)[26]	U.S.	17	2013-2016	180 individuals with mild-to-moderate (grade II-III) knee	n=121 percutaneous cryoneurolysis targeting the IBSN with anatomic landmarks (visual	n=59 sham cryoneurolysis with a sham

				OA with knee pain ≥40 mm/100-mm VAS and ≥50% reduction in pain on diagnostic block	and palpation)	tip and local anesthetic
Mihalko et al (2021)[27,]	U.S.	1	2017-2019	124 individuals with severe knee OA who were scheduled to under TKA	n=62 cryoneurolysis targeting the superficial genicular nerves (ISN and AFCN) 3 to 7 days prior to TKA	n=62 standard of care prior to TKA

AFCN: anterior femoral cutaneous nerve; IIBSN: infrapatellar branch of the saphenous nerve; OA: osteoarthritis; RCT: randomized controlled trial; TKA, total knee arthroplasty; VAS: visual analog score.

Table 13. Summary of Key RCT Results

Study	Change in WOMAC Score (SEM)				VAS Score (SEM)		
	Pain at 30 Days	**Total at 30 Days**	**At 60 Days**	**At 90 Days**	**At 30 Days**	**At 60 Days**	**At 90 Days**
Radnovich et al (2017)[26,]							
N	180	180	180	180	180	180	180
Cryoneurolysis	-16.65 (1.26)	-78.78 (5.81)	-75.75 (5.87)	-80.31 (5.89)	-40.09 (2.87)	-38.53 (2.91)	-37.90 (3.01)
Sham	-9.54 (1.63)	-48.26 (7.51)	-56.28 (7.58)	-56.51 (7.60)	-27.83 (3.68)	-32.44 (3.73)	-31.58 (3.86)
Diff (95% CI)	-7.12 (-11.01 to -3.22)	-30.52(-48.52 to -12.53)	-19.47(-37.64 to -1.30)	-23.80(-42.02 to -5.57)	-12.25(-21.16 to -3.35)	-6.09(-15.11 to 2.94)	-6.32(-15.66 to 3.01)
p	.004	.001	.036[a]	.011			.183
Mihalko et al (2021)[27,]	Opioid consumption in TDME (SEM) at 6 weeks post discharge, PP	Opioid consumption in TDME (SEM) at 12 weeks post discharge, PP	Individuals not opioid free, n (%) from discharge to 6 weeks, PP	Mean change in NRS (SD) from BL to 6 Weeks, PP	Mean changein NRS (SD) from BL to 12 Weeks, PP	Mean change in AUC for KOOS JR from BL to 6 weeks, PP	Mean change in AUC for KOOS JR from BL to 12 weeks, PP
N	48	48	48	48	48	48	48
Cryoneurolysis	4.2 (0.5)	2.4 (0.3)	7 (15%)	2.2 (2.2)	3.2 (2.3)	9.7	16
Standard of care	5.9 (0.6)	3.4 (0.4)	19 (40%)	1.6 (2.0)	2.3 (2)	7.7	14.1
Diff (95% CI)	1.6 (0.1 to 3.2)	1 (0 to 2)	25%	0.6 (-0.2 to 1.5)	0.9 (0 to 1.7)	2	1.9
p	.0186	.0234	.006	.068	.0256	<.0001	<.0001

AUC: are under the curve; BL: baseline; CI: confidence interval; Diff: difference; KOOS JR: Knee Injury and Osteoarthritis Outcome Score for Joint Replacement; NRS: numeric rating scale; PP: per protocol; RCT: randomized controlled trial; SEM: standard error of mean; TDME: total daily mean morphone equivalents; VAS: visual analog score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index. [a] Statistical significance was set at a 1-sided level of 0.025.

Tables 14 and 15 display notable limitations identified in the studies evaluated.

Table 14. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Radnovich et al (2017)[26,]	4. A more relevant population would be individuals with moderate-to-severe knee osteoarthritis				
Mihalko et al (2021)[27,]	3.Baseline level of pain for individuals prior to TKA unclear				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. [a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use. [b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest. [c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively. [d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported. [e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 15. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Radnovich et al (2017)[26,]						2. Unclear whether data were modeled for each time point independently or longitudinally
Mihalko et al (2021)[27,]				1,2: Almost 25% missing data 6. Per protocol analysis for many outcomes	4. Per protocol analysis below the required number of participants per group in the power calculation	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Lung et al (2022) reported a retrospective study of pain relief in 57 individuals with OA and chronic knee pain planning to undergo TKA at a single center who were treated with either cryoneurolysis of the anterior femoral cutaneous nerve (AFCN) or infrapatellar branch of the

saphenous nerve (ISN) or conventional TKA without cryoneurolysis.[28] Included patients had at least 1 year of follow-up after treatment and were assessed for the primary outcome of total opioid morphine milligram equivalents (MME) at 6 weeks post-treatment as well as VAS pain, knee injury and osteoarthritis scores (KOOS JR), and short form survey (SF12) outcome measures (Tables 16 and 17). No significant between group differences were found for the outcome of mean total MME during the inpatient stay or follow-up visits at 4 and 6 weeks posttreatment (p>.05). KOOS scores at 12 months follow-up (p=.007) favored the cryoneurolysis group over standard TKA controls, as did SF-12 mental scores (p=.01). However, between-group comparisons on these outcomes at other time points as well as SF12 physician scores and VAS pain at all time points reported, failed to reach significance. Complications were rare and appeared equivalent between groups.

Table 16. Summary of Key Nonrandomized Trials OR Observational Comparative Study Characteristics

Study	Study Type	Country	Dates	Participants	Cryoneurolysis	Control	Follow-Up
Lung et al (2022)[28]	Retrospective	U.S.	2013-2019	57 individuals with OA planning to undergo TKA who had pre-TKA cryoneurolysis of ISN or AFCN nerves compared matched individuals with OA from the same center who received TKA.	Cryoneurolysis delivered by Iovera handheld device of the ISN or AFCN nerves (n=29)	Conventional TKA without cryoneurolysis (n=28)	1 year

AFCN: anterior femoral cutaneous nerve; ISN: infrapatellar branch of the saphenous nerve; OA: osteoarthritis; TKA: total knee arthroplasty

Table 17. Summary of Key Nonrandomized Trials OR Observational Comparative Study Results

Study	KOOS Score MD BL to 3 mos (SD)	KOOS Score MD BL to 12 mos (SD)	SF12 Physical Score MD BL to 3 mos (SD)	SF12 Physial Score MD BL to 12 mos (SD)	SF12 Mental Score MD BL to 3 mos (SD)	SF12 Mental Score MD BL to 12 mos (SD)
Lung et al (2022)[28]	57	57	57	57	57	57
Cryoneurolysis (n=29)	27.5 (10)	38.8 (11.2)	8.8 (4.3)	12.9 (11.4)	-0.6 (7.8)	3.6 (9.7)
Standard TKA (n=28)	25.7 (22.1)	11.1 (9.6)	2.5 (18.2)	4 (7.8)	3.5 (6.8)	-3.8 (6.2)
Diff; p-value	.4	.007	.1	.2	.2	.2

BL: baseline; Diff: difference; KOOS, Knee Injury and Osteoarthritis Outcome Score; MD, mean difference; mos: months; NR: not reported; SD: standard deviation; SF: short form; TKA: total knee arthroplasty

Technical Issues

As noted in a review by Gabriel and Ilfeld (2018), several technical issues have yet to be resolved, including the optimal number of applications for each nerve, the duration of treatment, and the

duration of thawing before moving the cannula.[29] The most effective method for determining the location of the probe (e.g., ultrasound or using anatomic landmarks) also needs to be established.

Section Summary: Cryoneurolysis for Knee Osteoarthritis

Two RCTs and one comparative, retrospective cohort study were identified. One RCT with 180 individuals compared cryoneurolysis with sham treatment in individuals who had knee OA. Cryoneurolysis resulted in a greater decrease in WOMAC pain, WOMAC total, and VAS score at 30 days compared with sham-treated controls. Subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or in VAS scores at 60 or 90 days. Another RCT with 124 individuals compared cryoneurolysis to standard of care treatment for patients with knee OA who were planning to undergo TKA. Cryoneurolysis had a significantly lower rate of opioid consumption, reduction in NRS pain, and KOOS JR performance at 12 weeks from discharge compared to standard of care. A retrospective cohort study reported superiority of cryoneurolysis on the KOOS JR and SF-12 mental score at 1 year follow-up; no significant differences were observed on the SF-12 physical score at 1 year follow-up or on any outcome for 3 month follow-up. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula, have yet to be resolved.

Radiofrequency Ablation for Plantar Fasciitis

Clinical Context and Therapy Purpose

The purpose of RFA in individuals who have plantar fasciitis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with plantar fasciitis.

Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some individuals the pain persists and can impede activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although a repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Interventions

The therapy being considered is RFA.

Comparators

The following therapy is currently being used to make decisions about treating plantar fasciitis: conservative management, which may include corticosteroid injection.

Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

Outcomes

The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and post-treatment measures. Pain is most commonly measured using a VAS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score. The AOFAS ankle-hindfoot scores range from 0 to 100, with up to 40 points for pain, 50 points for functional aspects, and 10 points for alignment. A high score indicates a better outcome. The time for follow-up is within days to determine procedural success and at least 6 months to a year to evaluate durability.

Study Selection Criteria

Because of the variable natural history of plantar fasciitis and the subjective nature of the outcome measures, RCTs are needed to determine whether outcomes are improved with interventions for pain. Trials should include a homogenous population of individuals with a defined clinical condition, use standardized outcome measures when possible, and define a priori the clinically significant magnitude of response.

Review of Evidence

Systematic Reviews

A meta-analysis published by Guimaraes et al (2022) reviewed multiple therapeutic interventions to relieve pain from plantar fasciitis.[30] A total of 8 studies of RFA were identified, but only 2 RCTs were included in the pooled analysis of RFA compared to a control group (n=117). The authors performed a dual assessment of the risk of bias of the included studies using the Cochrane Risk of Bias tool and found a low quality of evidence for RFA to relieve pain from plantar fasciitis. The pooled mean difference between groups for pain outcomes was -1.19 (95% CI, -3.54 to 1.15; p=.32), favoring the RFA group, but this estimate did not achieve statistical significance and had a high level of heterogeneity (I_2, 84%).

Randomized Controlled Trials

Two double-blind sham-controlled randomized trials have assessed RFA for the treatment of chronic heel pain (Table 18). Wu et al (2017) randomized 36 individuals to ultrasound-guided pulsed radiofrequency of the posterior tibial nerve.[31] First step pain, average pain, and the AOFAS ankle-hindfoot score were assessed at baseline and at 1, 4, 8, and 12 weeks. Scores at 12 weeks are shown in Table 19. Changes in VAS score in the sham group were modest (<1 on a 10-point VAS) and of short duration (statistically significant at weeks 1 and 4 but not weeks 8

and 12). The AOFAS ankle-hindfoot score was 60.55 at baseline and 60.05 at 12 weeks in the sham group. In the RFA group, VAS scores at weeks 1, 4, 8, and 12 were all significantly lower than baseline (p<.001), and the AOFAS ankle-hindfoot score increased from 55.5 to 87.6 (p<.001). The improvements in pain and function were greater in the RFA group than in the control group (p<.001 for all measures).

Landsman et al (2013) reported on a double-blind randomized crossover trial (N=17) of RFA applied along the medial aspect of the heel.32, Crossover to the alternate treatment was allowed at 4 weeks. Outcomes assessed weekly were a pain VAS score reported at the first step in the morning, average pain level, and peak pain level (Table 19). In a graphic presentation of results, patient pain levels for all 3 outcomes decreased after RFA but showed minimal change after sham. Following crossover from sham to RFA, there was a steep drop in all pain outcomes. The maximum follow-up assessment was at 16 weeks and appeared to show similar pain levels throughout the follow-up period.

Table 18. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Wu et al (2017)[31,]	Taiwan	1	2014-2016	36 individuals (40 feet) with recalcitrant plantar fasciitis	Ultrasound-guided pulsed RF stimulation of the posterior tibial nerve	Sham with ultrasound-guided lidocaine injection
Landsman et al (2013)[32,]	U.S.	Multicenter	NR	17 individuals failed at least 3 prior types of treatments, pain for >3 mo, and VAS score ≥5	RFA procedure, including stimulation of sensory nerves in an awake patient	Sham with all aspects of the RFA procedure, except delivery of RF energy at the final step

NR: not reported; RCT: randomized controlled trial; RF: radiofrequency; RFA: radiofrequency ablation; VAS: visual analog scale.

Table 19. Summary of Key RCT Results

Study	First Step Pain on VAS Score	Average VAS Pain Score		AOFAS Ankle-Hindfoot Score
	At 12 Weeks	At 12 Weeks		
Wu et al (2017)[31,]				
N	36	36		36
RFA (SD)	1.79 (1.62)	1.54 (1.26)		87.60 (9.12)
Sham (SD)	6.13 (1.75)	6.09 (1.70)		60.05 (11.38)
	Change At 4 Weeks	Change Score	Change in Peak Pain	
Landsman et al (2013)[32,]				
N	17	17	17	
RFA	5.0	4.06	5.33	

Sham	1.33	0.8	1.80	
p	.30	.047	.048	

AOFAS: American Orthopedic Foot and Ankle Society; RCT: randomized controlled trial; RFA: radiofrequency ablation; SD: standard deviation; VAS: 10-cm visual analog score.

Tables 20 and 21 display notable limitations identified in each study.

Table 20. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Wu et al (2017)[31]	3. Study did not report a minimum VAS for inclusion criteria				
Landsman et al (2013)[32]		1. Targeted nerve not clearly defined			1. Crossover allowed at 4 wk

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. VAS: visual analog score. [a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use. [b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest. [c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively. [d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported. [e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 21. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Wu et al (2017)[31]						
Landsman et al (2013)[32]	3. Crossovers at 4 wk prevented longer-term		1. Power calculations not reported			3. Confidence intervals not reported assessments

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. [a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias. [b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. [c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication. [d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials). [e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference. [f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Case Series

Kurtoglu et al (2022) reported the largest case series of standard RFA for plantar fasciitis.[33] The retrospective study, conducted in Turkey, included 261 individuals with plantar heel pain for at least 6 months and at least 2 failed conservative treatments. Mean VAS (scale 0-10) was 8 (range 8-9) at baseline and 0 (range 0-7) at the final mean follow-up of 15 months (p<.001). At follow-up, 16 (6.1%) individuals felt the RFA procedure was unsuccessful.

Cozzarelli et al (2010) reported the case series with the longest follow-up.[34] This study reported on a 12-year follow-up of 82 individuals who had undergone RFA for heel pain. Study participants had undergone RFA between 1994 and 1995 and had been interviewed at 5, 10, and 12 years postprocedure. Baseline pain levels before the procedure were recalled retrospectively at the follow-up interviews. Of 99 individuals potentially eligible to be interviewed, the study evaluated 82 individuals. The results were presented without statistical testing. It appears that 73 of 82 individuals reported being pain-free at 12 years. On a 0-to-10 pain VAS, the pain-free study participants rated their preprocedure pain at a mean of 7.1 and at 0 postprocedure.

Section Summary: Plantar Fasciitis

A meta-analysis found that a pooled assessment of 2 randomized controlled trials (RCTs) investigating radiofrequency ablation (RFA) for pain alleviation in plantar fasciitis did not demonstrate a significant improvement compared to the control group. The analysis revealed significant heterogeneity and the overall quality of evidence was graded as low. Two randomized, double-blind trials (total N for both trials=53) and 2 case series found consistent reductions in pain after RFA for individuals with heel pain due to plantar fasciitis. In one trial, improvements in pain and function were greater in the RFA group than in the control group at 12 weeks. In the second trial, the randomized comparison only evaluated outcomes to 4 weeks. No conclusions about RFA effectiveness can be drawn from the 2 retrospective case series with methodological limitations. To be more confident in the efficacy of this treatment, studies with larger samples and longer follow-up would be necessary. The safety of the procedure cannot be fully evaluated in the small samples studied so far.

Radiofrequency Ablation or Cryoneurolysis for Occipital Neuralgia and Cervicogenic Headache

Clinical Context and Therapy Purpose

The purpose of RFA in individuals who have occipital neuralgia or a cervicogenic headache is to provide a treatment option that is an alternative to or an improvement on existing therapies. The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with occipital neuralgia or a cervicogenic headache.

Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation.

Cervicogenic headache is a headache that is secondary to a disorder of the cervical spine. The pain may be referred from facet joints, intervertebral discs, or soft tissue. The pain is constant rather than throbbing, and may be aggravated by movements of the neck or pressure to certain

areas on the neck. The first 3 cervical spinal nerves can refer pain to the head. The C1 suboccipital nerve innervates the atlanto-occipital joint; the C2 spinal nerve and the C3 dorsal ramus have close proximity to and innervate the C2-C3 facet joint. The C2-3 facet joint is the most frequent source of a cervicogenic headache. A diagnosis of a cervicogenic headache may be confirmed by an anesthetic block of the lateral atlanto-axial joint, the C2-3 facet joint, or the C3-4 facet joint.

Interventions

The therapy being considered is RFA or cryoneurolysis. These treatments involve the percutaneous insertion of a catheter that is directed toward the nerve of interest, and are used to ablate the nerve by thermal lesioning.

Comparators

Treatment for occipital neuralgia may include massage and rest, muscle relaxants, nerve blocks, and injection of steroids directly into the affected area.

Treatment for cervicogenic headache may include nerve blocks, physical therapy, and exercise.

Outcomes

The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or RNS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey. The time for follow-up is within days to determine the procedural success and months to years to evaluate durability.

Study Selection Criteria

We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months outcomes, and systematic reviews of RCTs.
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Review of Evidence

Systematic Reviews

Grandhi et al (2018) conducted a systematic review of RFA for the treatment of a cervicogenic headache.[35] Ten studies met selection criteria, including 3 RCTs, 3 prospective studies, and 4 retrospective studies. There were no high-quality RCTs. Two of the RCTs evaluated RFA of the facet joints and failed to find a benefit of RFA. The third RCT compared RFA with steroid injection of the greater occipital nerve, finding no difference between the groups in the short term, but a longer duration of pain control in the RFA group.

A systematic review by Ducic et al (2014) did not identify any RCTs assessing RFA for chronic occipital neuralgia.[36] Reviewers identified 3 case series (total N=131) on pulsed RF treatment. Success rates in these series ranged from 51% to 100%, with an overall success rate of 55%. Follow-up ranged from 3 to 10 months.

Randomized Controlled Trials

A double-blinded RCT of 52 individuals with cervicogenic headache who were treated with cryoneurolysis or injection of corticosteroid and local anesthetic in a tertiary pain clinic was reported by Kvarstein et al (2019).[37] The investigators noted a temporary benefit of both treatments for cervicogenic headache, but there was no additional benefit for the more invasive procedure. A possibility of adverse effects of repeated occipital cryoneurolysis were noted to include scar and neuroma formation and a risk of neuropathic pain.

Section Summary: Radiofrequency Ablation or Cryoneurolysis for Occipital Neuralgia and Cervicogenic Headache

No RCTs of RFA for chronic occipital neuralgia have been identified. A systematic review identified 3 RCTS of RFA for a cervicogenic headache, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to a placebo effect. Trials with sham or active controls are needed to evaluate the efficacy of this treatment. One RCT of individuals with cervicogenec headache that compared cryoneurolysis with injection of corticosteroid and local anesthetic found no significant improvement with the more invasive treatment.

Summary of Evidence

For individuals who have knee osteoarthritis (OA) who receive radiofrequency ablation (RFA) of peripheral nerves, the evidence includes systematic reviews of randomized controlled trials (RCTs), RCTs with 24 to 200 individuals , and non-randomized comparative studies with up to 12 months of follow-up. Relevant outcomes include symptoms, functional outcomes, and quality of life (QOL). Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. At this time, there is high heterogeneity in methods and comparators. The systematic reviews generally found that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6-month follow-up; however, most estimates were determined to have moderate to high heterogeneity. The network meta-analysis compared multiple RFA modalities and found that cooled RFA had significantly improved efficacy for pain and function through 6 months follow-up than traditional or pulsed RFA. The 2 multicenter trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate of approximately 70% at 6 months, which was significantly greater than the control conditions. A small, doubleblind RCT of bipolar RFA with genicular nerve block compared to genicular nerve block and sham RFA found no differences between groups for visual analog score (VAS) pain or the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores through 12 months follow-up. Given that OA of the knee is a common condition; study in a larger number of individuals, preferably blinded with active and sham controls and follow-up of at least 12 months, is needed to determine the benefits and potential

harms of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have knee OA or total knee arthroplasty (TKA) who receive cryoneurolysis of peripheral nerves, the evidence includes 2 RCTs with a total of 304 participants and a comparative, retrospective cohort study of 57 participants. Relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in individuals with knee OA resulted in a greater decrease in WOMAC pain score, WOMAC total score, and VAS score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or VAS scores at 60 or 90 days. Another RCT investigated cryoneurolysis compared to standard of care for patients with knee OA who were planning to undergo TKA. Cryoneurolysis resulted in a lower rate of opioid consumption, a reduction in numeric rating scale (NRS) pain scores, and Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR) functional performance at 12 weeks post discharge. The retrospective cohort study reported superiority of cryoneurolysis on the KOOS JR and Short Form-12 item (SF-12) mental score at 1 year follow-up; no significant differences were observed on the SF-12 physical score at 1 year follow-up or for any outcome at earlier 3 month assessment. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The most effective method for determining probe insertion location (e.g., ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes 2 RCTs and a meta-analysis. Relevant outcomes include symptoms, functional outcomes, and QOL. The meta-analysis pooled evidence from 2 RCTs and did not demonstrate a significant improvement in pain outcomes compared to the control group. The analysis revealed significant heterogeneity, and the overall quality of evidence was graded as low. One of the randomized trials only evaluated 17 individuals, and assessment of randomized outcomes was limited to 4 weeks post-treatment. A second RCT evaluated 36 individuals out to 12 weeks. Both trials found RFA associated with pain reduction, but to be more confident in the efficacy of this treatment, controlled trials with larger samples and longer follow-up would be necessary. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA or cryoneurolysis of peripheral nerves, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. No RCTs of RFA for chronic occipital neuralgia have been identified. Three RCTs of RFA for a cervicogenic headache have been published, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to a placebo effect. Randomized trials with sham or active controls are needed to evaluate the efficacy of this treatment. One controlled trial found a temporary benefit of cryoneurolysis for cervicogenic headache, but the effect was not significantly better than injection of corticosteroid and local anesthetic. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons et al

In 2021, the American Academy of Orthopaedic Surgeons published a clinical practice guideline, endorsed by the American Association of Hip and Knee Surgeons and the American Physical Therapy Association, on management of osteoarthritis (OA) of the knee.[19] The guideline did not specifically address RFA or cryoneurolysis but did include a guideline statement on denervation therapy that included various ablation techniques (e.g., RFA, cryoneurolysis, thermal ablation and chemical ablation). The guideline stated, "denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee" (strength of recommendation: limited).

American College of Rheumatology and Arthritis Foundation
The 2019 Guidelines from the American College of Rheumatology and the Arthritis Foundation gave a conditional recommendation for radiofrequency ablation for the treatment of knee OA.[38] The recommendation was based on evidence of a potential analgesic benefit, but the studies used heterogeneous techniques and there was a lack of long-term safety data.

American College of Foot and Ankle Surgeons
The American College of Foot and Ankle Surgeons (2018) issued consensus guidelines on the diagnosis and treatment of acquired infracalcaneal heel pain.[39] The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

American Society of Pain and Neuroscience
The American Society of Pain and Neuroscience (2021) issued consensus guidelines using U.S. Preventive Services Task Force (USPSTF) grading criteria on the use of RFA to treat various pain conditions.[40] The guidelines stated that genicular RFA may be used for the treatment of osteoarthritis-related and post-surgical knee joint pain (Grade B), and may be selectively offered for the treatment of occipital neuralgia pain when greater or lesser nerves have been identified as the etiology of pain via diagnostic blocks (Grade C).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 22.

Table 22. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05286996	Cryoneurolysis for TKA - a Pilot Study	20	Oct 2023
NCT05591768	Monopolar Versus Biopolar Radiofrequency in OA Knee Pain	70	Mar 2024
NCT05700253	Comparing Pain Outcomes of Treatment Strategies for Osteoarthritis Knee Patients	76	Sep 2024
NCT05920382	Radiofrequency Ablation for the Treatment of Post-knee Arthroplasty Chronic Pain	86	Dec 2027
Unpublished			
NCT02294864	A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis	50	Apr 2017 (unknown)
NCT02260869	Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain	78	Jun 2019 (terminated due to finances)
NCT02925442[a]	Comparison Between Cooled (C-RFA) and Standard (t-RFA) Radiofrequency Ablation, and Control for Pain Management Following Unilateral Knee Arthroplasty: A Double-Blinded, Parallel-Grouped, Placebo-Controlled Randomized Clinical Trial	150	Feb 2020
NCT03818022	Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty	100	Dec 2020 (unknown)
NCT04145011[a]	A Prospective, Multi-center, Randomized, Single Blind Clinical Trial Comparing COOLIEF* Cooled Radiofrequency to Conventional Radiofrequency Ablation of the Genicular Nerves in the Management of Knee Pain in an Osteoarthritic Patient Population	153	Aug 2022
NCT02915120	Ultrasound-Guided Pulsed Radiofrequency Of The Genicular Nerves In The Treatment Of Patients With Osteoarthritis Knee Pain: Randomized, Double-Blind, Placebo-Controlled Trial	142	Jul 2022

NCT: national clinical trial. [a] Industry sponsored or partially sponsored.

Essential Health Benefits

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits ("EHBs"), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers,

whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntarily offer them.

The ACA requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

Applicable Coding

The following codes and coding guidance are provided for general reference purposes only and may not be all-inclusive. The inclusion of a code does not guarantee or imply any right to member coverage or provider reimbursement, nor does its exclusion represent or imply that coverage or reimbursement is unavailable. All benefit coverage determinations are subject to the member-specific benefit plan documentation as well as additional terms and conditions, including but not limited to the written coverage position set forth in this medical policy, legal requirements, and other policies and guidelines, as applicable.

CPT	**64624**	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
ICD–10-CM		Investigational for plantar fasciitis and knee osteoarthritis
	M17.0-M17.9	Knee osteoarthritis code range
	M72.2	Plantar fascial fibromatosis (includes plantar fasciitis)
ICD-10-PCS		ICD-10-PCS codes are only used for inpatient services. There is no specific ICD-10-PCS code for this procedure.
	015D3ZZ, 015F3ZZ, 015G3ZZ, 015H3ZZ	Peripheral nervous system, destruction, percutaneous. Codes for various nerves of the lower extremity.
Type of Service	**Surgery**	
Place of Service	**Outpatient /Inpatient**	

Vendors

- **MedCom**
- **Health Plan Services (HPS)**

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Vendors
• Health Plan Services (HPS) • MedComm

Review/Revision/Approval History	
Date	Description
9/1/2024	**New Policy**
4/27/2026	**Reviewed and Approved by Policy Committee**

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