
Medical Policy



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Title: Coblation[®], Radiofrequency Ablation for Musculoskeletal Conditions

Description/Background

Radiofrequency (RF) coblation is being evaluated for the treatment of plantar fasciitis, lateral epicondylitis, and various musculoskeletal tendinopathies.

Radiofrequency Coblation

Radiofrequency (RF) coblation uses bipolar low-frequency energy in an electrically conductive fluid (e.g., saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology and orthopedics. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue. Radiofrequency ablation was also found to exhibit several properties that may make it an attractive option for addressing the underlying pathophysiology of chronic tendinopathies, namely increased angiogenesis, reduction of inflammatory responses, and increased expression of growth factors.(1) Radiofrequency coblation surgical wands are utilized by orthopedic surgeons in minimally invasive arthroscopic procedures to facilitate soft tissue debridement, subacromial decompression, meniscal removal and sculpting, or tendon debridement.

Tendinopathy

Tendinopathy is a clinical pain syndrome characterized by tendon thickening due to proliferation and chronic irritation of neovascular repair tissue with a history of repetitive tendon loading. This condition commonly results from overuse and has a high incidence rate in athletes and laborers. Clinical history should clarify predisposing training or activity and assess the level of functioning. Biomechanical abnormalities during activity should be identified and corrected. Standard treatment may, therefore, consist of biomechanical modification, activity modification, physical therapy (e.g., heavy load resistance training), and nonsteroidal anti-inflammatory medication. For chronic tendinopathies, glucocorticoids should only be used in select cases

(e.g., rotator cuff tendinopathy). Surgical consultation following 6 months of a well-designed physical therapy program with adjunct medical treatments can be considered if there is no improvement in pain or function.(2) Validated and reliable functional assessment scores should be utilized by the clinician to grade symptoms and assess patient function. Examples of suitable scales include the Victoria Institute of Sport Assessment for Achilles tendinopathy.(3) Surgical approaches may involve incisions to the paratendon and removal of adhesions and degenerate tissue. Longitudinal incisions may be made in the tendon to promote a repair response. This latter strategy has also been delivered via minimally invasive arthroscopic approaches.(4,5) These approaches may also address the debridement of the neovascular supply to the tendon surface. Collectively, a prolonged recovery duration to accommodate tendon healing May be required with these interventions.

Plantar Fasciitis

Plantar fasciitis is a musculoskeletal condition characterized by pain in the plantar region of the foot that worsens upon initiation of walking and with local point tenderness elicited during a clinical examination. Radiographic and ultrasonographic studies are not typically indicated for primary diagnosis but may be useful in ruling out alternative causes and visualizing the thickening of the plantar fascia. Initial standard therapy may consist of stretching exercises, orthotics, activity and lifestyle modification, nonsteroidal anti-inflammatory drugs, splints or casts, and glucocorticoid injections. The vast majority of patients improve without surgery. Surgery is generally considered a last line of therapy and is reserved for individuals who do not respond to at least 6 to 12 months of initial, nonsurgical therapy. Surgical approaches include variations of open or endoscopic, partial or complete, plantar fascia release, which may or may not include calcaneal spur resection, excision of abnormal tissue, and nerve decompression. The use of RF microtenotomy during open or percutaneous surgery has been explored alone or in combination with plantar fasciotomy.(6)

Plantar fasciitis is one of the most common causes of foot and heel pain in adults. It is estimated to be responsible for approximately 1 million patient medical visits per year in the U.S.(7) The peak incidence of the condition in the general population occurs between ages 40 and 60. There is a higher incidence rate among runners with a younger age of onset. The etiology of plantar fasciitis is poorly understood and may be multifactorial in nature. Contributing risk factors may include obesity, prolonged standing or activity, flat feet, and reduced ankle dorsiflexion.(8,9) Plantar fasciitis has been reported in association with fluoride use for the treatment of osteoporosis.(10) Differential sources of foot and heel pain may include Achilles tendinopathy, stress fractures due to osteoporosis, rheumatoid arthritis, peripheral neuropathies associated with diabetes, extrinsic factors (e.g., inappropriate footwear), aging, and structural disorders.

Lateral Epicondylitis

Lateral epicondylitis, also known as tennis elbow, represents chronic tendinosis of the myotendinous group of the lateral epicondyle characterized by pain and disability. The incidence in the general population may approach 1 to 3%.(11) Risk factors include smoking, obesity, forceful activity, and repetitive activity for at least 2 hours daily. Lateral epicondylitis is characterized by injury to the extensor carpi radialis brevis or extensor digitorum communis muscles. The condition is diagnosed through findings of localized tenderness and pain with clinical examination. Initial conservative management includes modification of activity and biomechanics, counterforce bracing or splinting, nonsteroidal anti-inflammatory drugs, and physical therapy.(12) Surgical referral is typically reserved for patients with severe symptoms

that do not improve despite compliance with an appropriately designed physical therapy program for at least 6 months.

Cold radiofrequency energy can be delivered by a variety of wands, hand devices and stylette tips, depending on the targeted anatomic site.

The Topaz™ Microdebrider is a Coblation wand marketed as a soft tissue debrider for the tendons in the knee, shoulder, elbow and ankle during minimally invasive arthroscopic procedures. Other similar devices include Super Turbo Vac® or UltraVac® Coblation Wands, Paragon T2 Wand, Super Multi Vac, and Topaz.

Acute and musculoskeletal conditions including tendonitis, neck/shoulder pain, and plantar fasciitis are common disorders which cause disability. Standard of care includes any, or a combination of the following: rest, massage, physical therapy, surgery and/or oral/injectable medication. Coblation has been proposed as an additional method of therapy.

Regulatory Status

In 2014, the TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch, an electrosurgical cutting and coagulation device (ArthroCare Corporation, K140521), was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, on the basis of an earlier predicate device (ArthroCare Topaz Wand, K080282, 2008). The surgical wands are indicated for debridement, resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures, including fasciotomy, synovectomy, tenotomy, and capsulotomy of the foot and tenotomy of the knee, wrist, elbow, ankle, shoulder, and rotator cuff.

In 2016, the Paragon T2 Wand with Integrated Cable (ArthroCare Corporation, K153675) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process on the basis of being similar to a predicate device (ArthroCare Arthro Wands (Paragon T2 Wand with Integrated Cable, K033584). The Paragon T2 Wand with Integrated Cable is specifically intended for resection, ablation and coagulation of soft tissue, homeostasis of blood vessels in arthroscopic and orthopedic procedures of the knee.

In 2018, the Super Multivac 50 wand with Integrated finger Switches (Ambient; K180848) 510(k) premarket notification of intent to market was reviewed by the FDA. It has been determined that the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act that do not require approval of a premarket approval application. The AMBIENT™ Super MULTIVAC™ 50 Wand with Integrated Finger Switches is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures: All joints (hip, knee, shoulder, wrist, ankle, elbow).

FDA product code: GEI.

Medical Policy Statement

Coblation, or cold radiofrequency ablation for musculoskeletal conditions are experimental/investigational. There is insufficient scientific evidence in the current medical literature to determine whether the technology improves health outcomes.

Examples include, but are not limited to: plantar fasciitis, lateral epicondylitis, wrist tendinopathy, shoulder or rotator cuff tendinopathy, Achilles tendinopathy, patellar tendinopathy.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

20999

28899

Rationale

For the purpose of this policy, the following PICO was used.

Clinical Context and Therapy Purpose

The purpose of radiofrequency (RF) coblation tenotomy is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with musculoskeletal conditions.

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

Populations

The relevant population of interest are individuals with the diagnoses being reviewed.

Interventions

The therapy being considered is RF coblation tenotomy, also referred to as microtenotomy.

Comparators

The following practice is currently being used to treat:

- Plantar fasciitis: conservative management, including orthotics, activity and lifestyle modification, splinting or casting, and physical therapy. Surgical referral may be appropriate for patients not responding to at least 6 to 12 months of initial, non-operative

therapy. Surgical interventions include variations of open or endoscopic, partial or complete, plantar fasciotomy which may or may not include calcaneal spur resection, excision of abnormal tissue, and nerve decompression.

- Lateral epicondylitis and wrist tendinopathy: conservative management, including activity and lifestyle modification, splinting or casting, and physical therapy. Surgical referral maybe appropriate for patients not responding to at least 6 to 12 months of initial, non-operative therapy. Surgical interventions for lateral epicondylitis include the arthroscopic release of the extensor carpi radialis brevis (ECRB) tendon.
- Achilles tendinopathy - conservative management, including activity and lifestyle modification, splinting or casting, and physical therapy. Surgical referral may be appropriate for patients not responding to at least 6 to 12 months of initial, non-operative therapy. Surgical interventions for midportion Achilles tendinopathy may include open peri- or intratendinous debridement, flexor hallucis longus transfer, longitudinal tenotomy, gastrocnemius lengthening or recession, minimally invasive paratendon debridement, and surgical decompression.(4,23)
- Shoulder and Rotator Cuff Tendinopathy - conservative management, including activity and lifestyle modification, and physical therapy. Surgical referral may be appropriate for patients not responding to at least 6 to 12 months of initial, non-operative therapy. Surgical interventions may include subacromial decompression.(27)
- Patellar Tendinopathy - conservative management, including activity and lifestyle modification, and physical therapy. Surgical referral may be appropriate for patients not responding to at least 6 to 12 months of initial, non-operative therapy. Surgical interventions may include mechanical debridement.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Follow-up through at least 1 year is of interest to monitor outcomes.

Pain symptoms are typically reported via the visual analog scale (VAS) or numerical rating scale (NRS). A score reduction of at least 2 points is considered clinically meaningful.(13)

Plantar Fasciitis - Functional outcomes for plantar fasciitis are typically assessed via the American Orthopedic Foot & Ankle Society (AOFAS) hindfoot score, with a score of 100 reflecting an asymptomatic patient. Patient-reported functional and QOL outcomes are typically assessed by the Short-Form 36-Item Health Survey (SF-36), with sub scores available for various physical or mental functional domains. A score of 100 indicates an asymptomatic patient.(14)

Lateral epicondylitis and wrist tendinopathy - Functional and QOL outcomes relating to disability for lateral epicondylitis are typically assessed with the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, with score reductions of at least 10.2 points meeting the threshold for a clinically meaningful difference and 12.2 points meeting the threshold for a minimal detectable change.(13) Functional outcomes are frequently assessed with the Mayo Elbow Performance Score, with a score of 100 reflecting an asymptomatic patient.(21)

Achilles Tendinopathy - The Victoria Institute of Sport Assessment (VISA) questionnaire for Achilles tendinopathy (VISA-A) is typically utilized to assess functional, pain, and activity

domains, where 100 represents a perfect score.(3) Successful recovery is typically defined with scores >80.(24)

Shoulder and Rotator Cuff Tendinopathy - Functional outcomes may include Constant-Murley scores and range of motion.

Patellar Tendinopathy - Functional outcomes may include the Fulkerson-Shea Patellofemoral Joint Evaluation Score.(29)

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies not identifying the marketed version of the technology were excluded.

PLANTAR FASCIITIS

Systematic Reviews

Nayar et al (2023) completed a systematic review of surgical treatment options for plantar fasciitis including open plantar fasciotomy, endoscopic plantar fasciotomy, gastrocnemius release, RF microtenotomy, and dry needling.(15) A total of 17 studies (8 RCTs, 3 prospective cohort, and 6 retrospective cohort) with 865 patients were selected for inclusion.

Radiofrequency microtenotomy was investigated in 4 studies (n=215), all of which were retrospective cohort studies (see Comparative Cohort Studies summaries below). Two studies compared RF microtenotomy to open plantar fasciotomy, 1 to endoscopic plantar fasciotomy, and 1 to proximal medial gastrocnemius release. The 2 studies comparing RF microtenotomy and plantar fasciotomy found no difference between groups in VAS and AOFAS outcomes. Similarly, the other studies found no difference in pain or function between groups. In network meta-analysis, RF microtenotomy significantly improved VAS compared with nonoperative management (weighted mean difference, -2.72; 95% CI, -4.84 to -0.060). No other significant difference between RF microtenotomy and other surgical interventions was found (mean differences not reported). The analysis is limited by the lack of high-quality studies. Studies included were largely observational, and at some risk of bias.

Comparative Cohort Studies

Yuan et al (2020) retrospectively compared open plantar fasciotomy to RF microtenotomy in 31 patients with plantar fasciitis.(16) Although operative time (19.93 minutes vs. 36.78 minutes) and recovery time (13.27 days vs. 25.94 days) were shorter with RF microtenotomy, there were no differences in VAS scores or AOFAS score between the treatments.

Huang et al (2018) reviewed all patients with plantar fasciitis (N=34) who underwent RF microtenotomy (TOPAZ device) with or without a gastrocnemius recession from 2007 to 2014 at a single institution.(17) The AOFAS hindfoot score scale (total score [HINDTOT], VAS pain score [HINDVAS]) and the patient-reported SF-36 were administered pre-operatively and at 3, 6, and 12 months post-operatively. There were no significant differences in HINDTOT or HINDVAS between groups at any of the measured timepoints. Components of SF-36 scores

were also similar between individual treatments, but some components were improved with combination treatment compared with either RF microtenotomy or gastrocnemius recession alone.

Wang et al (2017) published the results of a retrospective, cohort study evaluating subjective outcomes with endoscopic plantar fasciotomy (n=12) compared to RF microtenotomy (n=22) for recalcitrant plantar fasciitis at a single center from 2007 to 2015.(14) Prospectively collected data from 34/58 patients undergoing either procedure were included in this study as they had a complete data set with 1 year of follow-up. Patients were required to fail a conservative treatment program of at least 6 months in duration. The American Orthopaedic Foot & Ankle Society hindfoot score scale (total score [HINDTOT], visual analog scale pain score [HINDVAS]) and the patient-reported SF-36 were administered pre-operatively and at 3, 6, and 12 months postoperatively. There was no difference in baseline outcome measures. At 3 months, patients receiving endoscopic plantar fasciotomy had better results compared to patients receiving open RF microtenotomy, with statistically significant improvement in visual analog pain scores (HINDVAS; 0.9 vs 3.3; p=0.027) patient-reported social-functioning (92.5 vs 71.3; p=0.030) and role-functioning-emotional (93.3 vs 80.4; p=0.030). At 6 months and 1-year post-treatment, no significant differences between treatment groups were noted. HINDVAS scores decreased from 7.2 to 1.3 and 7.3 to 0.9 over 1 year in fasciotomy and RF microtenotomy groups, respectively. Complications consisting of reports of persistent postoperative pain, recurrence of pain at 6 months, and recurrence of pain at 1 year were 0% vs 9.1%, 8.3% vs 13.6%, and 16.7% vs 13.6% in fasciotomy and RF microtenotomy groups, respectively.

Chou et al (2016) evaluated outcomes in patients undergoing plantar fasciotomy, RF microtenotomy, or both procedures between 2007 and 2014 at a single institution.(6) Patients were required to fail conservative therapy and contain a full dataset with 1 year of follow-up to be included for analysis. Patients were evaluated preoperatively and at 6 months and 1-year post-treatment with the AOFAS Ankle-Hindfoot Scale and SF-36 Health Survey. A total of 27 feet (n=27 patients) underwent plantar fasciotomy, 55 feet (n=48 patients) underwent RF microtenotomy, and 9 feet (n=9 patients) underwent both procedures. The rate of complications consisting of consistent heel pain at 1 year in each group was 11%, 7.3%, and 33%, respectively. Differences in complications between groups were not found to be statistically significant (p=.069). No significant differences were reported between groups for all outcomes measured at each time point. HINDVAS pain scores (standard deviation [SD]) at baseline and 1 year were 7.407 (1.185) vs. 1.963 (2.653), 7.352 (1.580) vs. 1.585(2.389), and 7.667 (2.000) vs. 0.556 (1.333) for fasciotomy, RF microtenotomy, and combination groups, respectively.

Tay et al (2012) conducted a prospective cohort study comparing percutaneous RF microtenotomy (n=27) and open RF microtenotomy (n=32) in patients with plantar fasciitis.(1) Outcomes were measured with the AOFAS Ankle-Hindfoot scale scores and SF-36 Health Survey at baseline and 3-, 6-, and 12-months post-treatment. At 3 months, there was no significant difference in HINDVAS pain scores and AOFAS HINDTOT between groups. However, the SF-36 reported a statistically significant difference in bodily pain between the open (59.2) and percutaneous (44.2) groups (p=.017). At 6 months, there were no significant differences in HINDVAS pain scores and AOFAS HINDTOT between groups. However, SF-36 component scores for vitality (72.0 vs. 56.5; p=.007), functioning (emotional) (100.0 vs. 75.6; p=.006), and mental health (84.4 vs. 74.9; p=.049) fared significantly better in the percutaneous versus open RF microtenotomy groups. While it is unclear to what extent these

findings correlate with baseline differences in SF-36 mental health findings (84.0 vs.74.25; $p=.028$), no significant differences in SF-36 outcome measures were detected at 12 months between groups. SF-36 scores for role functioning (physical) were pooled for analysis. Scores increased from 25.0 at baseline to 68.8 at 12months ($p=.009$). At 12 months, the open group had a significantly lower pain score of 0.78 versus 3.00 in the percutaneous group ($p=.035$) but the AOFAS hindfoot score was not significantly different (74.9 vs. 87.0; $p=.159$).

Case Series

Several small case series have addressed the use of RF microtenotomy for plantar fasciitis.(18,19,20) Sean et al (2010) conducted a prospective, single-center pilot study in 14 patients with plantar fasciitis and failed conservative treatment of at least 6 months in duration.(20) AOFAS ankle-hindfoot and SF-36 Health Survey scores were assessed at baseline and 3and 6 months post-treatment. Mean AOFAS hindfoot scores improved from 34.47 to 69.27 and 71.33 at 3 and 6 months($p=.00$). There was a significant decrease in SF-36 bodily pain ratings ($p=.01$), and significant increases in physical($p=.01$) and social function ($p=.04$) scores. Twelve out of 14 (85.7%) patients reported good to excellent satisfaction with their results at 6 months and 12 out of 14 (85.7%) had their expectations met at 6 months of follow-up. No peri- or postoperative complications were reported.

Section Summary: Plantar Fasciitis

A systematic review of comparative cohort studies failed to find a difference in pain or function scores between RF coblation microtenotomy and other surgical intervention for plantar fasciitis. Nonrandomized, comparative cohort studies and case series demonstrate that the use of RF coblation microtenotomy for the treatment of plantar fasciitis improves pain and functional scores over 3 to 12 months, with better pain outcomes for open versus percutaneous approaches. No significant differences in these or patient-reported physical outcome measures were reported when compared to surgical fasciotomy. However, open RF coblation microtenotomy was associated with a higher incidence of postoperative persistent pain (9.1%) compared to endoscopic plantar fasciotomy (0%) in 1 study, with a separate study reporting a complication rate of 33% when both interventions were used in combination. A higher number of postoperative pain recurrences at 6 and 12 months were also reported with open RF coblation microtenotomy compared to endoscopic plantar fasciotomy. The durability of this intervention is unknown as no studies have reported long-term outcomes beyond 12 months. Studies are limited by small sample sizes, heterogeneity in surgical technique (open, percutaneous, endoscopic), missing data and/or inappropriate exclusions, lack of randomization, unclear blinding practices for patient outcome assessments, and poor statistical reporting. Due to these limitations and the increased complication rate, the efficacy of RF coblation microtenotomy for improving plantar fasciitis cannot be drawn from the current evidence.

LATERAL EPICONDYLITIS AND WRIST TENDINOPATHY

Lee et al (2018) conducted a RCT comparing the clinical effects of open RF microtenotomy ($n=22$) and arthroscopic release of the ECRB tendon ($n=24$) in patients with refractory lateral epicondylitis that had failed 2 or more corticosteroid injections, extracorporeal shock-wave therapy, and conventional treatment for least 6 consecutive months.(22) Pre-operative magnetic resonance imaging (MRI) of the elbow was performed in all patients to assess for intra-articular or ligamentous lesions. The primary outcome was the Mayo Elbow Performance Score (MEPS) at 24 months post-procedure. Additional outcome measures included the VAS score for pain, flexion-extension arcs and grip strength, and the DASH questionnaire at 3-, 6-,

12-, and 24-months post-surgery. Fifty-five patients were randomized, and 9 patients were lost to follow-up, leaving 46 patients for analysis. One complication consisting of persistent postoperative pain was reported in the arthroscopic release group and 1 complication consisting of postoperative ECRB rupture was reported in the RF microtenotomy group. Both patients recovered following revision surgery. Patients in both groups showed statistically significant functional improvement with regard to grip strength and DASH, VAS, and MEPS scores at 2 years ($p < .05$). Differences between groups were not statistically significant. The mean operation time was significantly shorter for the RF microtenotomy group (mean (SD); 15.6 (3.6) vs. 41.4 (5.2) min; $p < .001$). Three patients (12.5%) in the arthroscopic release group and 2 patients (9.1%) in the RF microtenotomy group reported persistent pain or discomfort with a MEPS score < 90 at 2 years.

Hamlin et al (2018) published the results of a RCT comparing RF microtenotomy ($n=21$) with standard open release surgery ($n=18$) for refractory lateral epicondylitis.(13) The NRS pain scores and DASH scores were evaluated at baseline, 6 weeks, 6 months, and 12 months. Grip strength was assessed at baseline and 6 weeks. The primary outcome measure was the NRS pain score at 12 months. NRS pain scores improved significantly in both groups at all time points. There was a significant difference between RF microtenotomy [mean (SD); -2.285 (0.5174)] and open release surgery [-4.689(0.6012); $p=.0021$] at 6 weeks only. Grip strength improved by 31% in the RF microtenotomy group compared to 38% in the open release surgery group, however, there were no significant differences between initial and 6-week scores nor between groups. Two patients (9.5%) that received RF microtenotomy opted to receive open release surgery after the final assessment of the study due to persistent symptoms. Two patients (11.1%) that received open release surgery also reported persistent symptoms at 1 year. The study investigators indicate that since RF microtenotomy provides no clear treatment or risk-benefit, surgical candidates should be offered open release surgery.

Meknas et al (2013) randomized patients to either open release surgery ($n=11$) or RF microtenotomy ($n=13$) for treatment of refractory lateral epicondylitis following the failure of 1 year of conservative treatment.(21) Outcome measures included- VAS pain scores, grip strength, and MEPS score functional assessment. Select patients were also evaluated via MRI and dynamic infrared thermography. One patient in the open release group died prior to mid-term follow-up. One patient in the RF microtenotomy group was excluded due to revision open release surgery. Mean follow-up for the open release group was 75.5 months (SD, 8.1 months) and 68.4 months (SD, 6.2 months) for the RF microtenotomy group ($p=.02$). NRS scores decreased significantly for both groups with no statistically significant differences between groups at baseline or mid-term follow-up. Grip strength increased in both groups but was not found to be significant or significantly different between groups. Median MEPS scores improved significantly in both groups with no significant differences between treatments. Dynamic infrared thermography revealed 7 hot spots in each group preoperatively. At medium-term follow-up, the number of detected hot spots was reduced to 1 in the open release group ($p=.041$) and 4 in the microtenotomy group($p=.092$). Differences in the total number of hot spots between groups were not significant.

Section Summary: Lateral Epicondylitis

Three small RCTs comparing RF coblation microtenotomy to open or arthroscopic elbow release surgery demonstrate significant reductions in pain scores (>2) at post-operative time points of 1 to 7 years for both approaches, with no significant differences between treatment groups. Similar results are noted for MEPS functional assessments. For DASH disability assessments, open release surgery met the threshold for a clinically meaningful improvement

over RF microtenotomy at 1 year in 1 study, though this mean difference was not statistically significant. Studies were generally underpowered or demonstrated inconsistent delivery and unclear blinding of outcome assessments and inappropriate handling of missing or crossover data.

ACHILLES TENDINOPATHY

Randomized Clinical Trials

Morrison et al (2017) conducted a single-blind RCT evaluating RF coblation microdebridement compared to surgical decompression for patients with non-insertional Achilles tendinopathy who had failed a conservative management program of at least 6 months in duration.(23) The primary outcome measure was the difference in VAS pain score at 6 months. The secondary outcome measure was the VISA-A score. The control group had significantly less severe symptoms as indicated by higher VISA-A scores and lower VAS scores at baseline. Both groups demonstrated statistically significant improvements in scores at 6 months, with no significant differences noted between groups ($p > .05$). The analysis of covariance was adjusted for age, sex, and body mass index (BMI). Not all study subjects demonstrated improvement in their VAS scores. In the control group, 2 patients (12.5%) reported worsening of pain (12.5%) and 1 (6.25%) reported no change. In the RF microdebridement group, 2 patients (10%) reported worsening of pain and 4 (20%) reported no change. Two patients (12.5%) reported a decrease in VISA-A score following decompression surgery compared to 5 patients (25%) in the RF microdebridement group. Complications included 2 cases of superficial wound infection in the decompression group and 1 partial Achilles rupture in the RF microdebridement group. Study investigators concluded there was no added benefit for the use of RF microdebridement and have discontinued its use in their practice.

Al-Ani et al (2021) conducted a single-blind RCT evaluating RF microtenotomy compared to physical therapy for individuals with Achilles tendinopathy of at least 6 months in duration that was impairing daily and sports activities.(25) The primary outcome measure was VAS at 2 years, with a difference of 2 units considered a clinically important difference. The control group had significantly less severe symptoms as indicated by lower VAS scores at baseline. The RF microtenotomy group demonstrated significantly greater improvements in both the VAS and Foot and Ankle Outcome Score (FAOS) Quality of Life measures at 2 years. However, conclusions cannot be drawn based on these findings due to numerous and notable study relevance and design/conduct limitations as detailed below.

Retrospective Studies

Shibuya et al (2012) conducted a retrospective review of institutional patient cases to elucidate the safety and efficacy of percutaneous RF coblation for the treatment of insertional Achilles tendinopathy between 2005 and 2011.(26) Forty-seven patients were identified ranging in age from 23 to 76. The mean BMI was 37.1 (SD, 6.96) with a mean follow-up duration of 8.6 months (range, 1 to 40). Revision surgery was performed in 15% of patients. Twenty-six patients (55%) had at least 3 months of follow-up data available, and revision surgery was performed in 23%. Study authors believe these higher than typical rates of reoperation indicate that a percutaneous approach may not be as effective as an open technique. Furthermore, patients in this study had a high mean BMI, whereas other studies addressing foot and ankle tendinopathies have typically excluded patients with a BMI >35 due to a known correlation with poorer outcomes.

Section Summary: Achilles Tendinopathy

A small, single-blind RCT did not demonstrate an added benefit for RF microdebridement compared to surgical decompression. Pain and functional outcomes improved in both groups but were not statistically different at a 6-month follow-up. The study was limited by a control group that showed significantly less severe symptom scores at baseline that did not fully meet the 2-point threshold for a clinically meaningful difference in pain score reduction. Although another small RCT demonstrated potential benefits in pain and quality of life for RF microtenotomy (ArthroCare) compared with physical therapy at 2 years, conclusions cannot be drawn based on these findings due to numerous notable study limitations. Larger, adequately controlled studies with longer follow-up durations are required to appropriately assess the technology.

SHOULDER AND ROTATOR CUFF TENDINOPATHY

Randomized Clinical Trials

Al-Ani et al (2019) performed a small RCT evaluating arthroscopic subacromial acromioplasty (n=14) compared to RF microtenotomy (n=13) for the treatment of rotator cuff tendinopathy in patients with a minimum symptom duration of 6 months.(28) About half of patients in each arm had previously received 1 to 3 corticosteroid injections at least 6 months prior to inclusion. The main outcome measures included VAS pain scores, functional Constant scores, and strength measures through 2 years. Significant pain reductions were reported at 12 weeks, 6 months, and 2 years, with no significant differences between groups. Treatment harms were not reported.

Lu et al (2013) randomized patients with shoulder impingement syndrome and rotator cuff tendinopathy to receive either arthroscopic subacromial decompression alone (n=40) or in combination with RF microtenotomy (n=40) using the TOPAZ microdebrider (ArthroCare) after failing a conservative management program of at least 5 months in duration.(27) Outcome measures included VAS pain scores at 3 weeks, 6 weeks, 3 months, 6 months, and 1 year. Functional outcomes included a range of motion, American Shoulder & Elbow Surgeon's score, Simple Shoulder Test questionnaire, UCLA score, and Constant-Murley score at 3 months, 6 months, and 1 year. Sixty-five out of 80 patients (81.3%) were available for final follow-up at 1 year. Pain scores decreased significantly at 3 weeks postoperatively for both treatment groups. While there was a significant difference between group pain scores at 3 weeks, the combination group did not meet the threshold for a clinically meaningful reduction in pain at this early time point compared to subacromial decompression only. Scores continued to improve over time with no significant difference between groups. For functional measures (American Shoulder & Elbow Surgeon's score, UCLA, Simple Shoulder Test questionnaire, Constant-Murley, range of motion), scores improved significantly for both groups with no significant differences between groups at any postoperative timepoint. The authors noted that they did not detect any added benefits for the addition of RF microtenotomy to the standard surgical procedure. The study is limited by a high loss to follow-up, the use of an independent observer that was not blinded to treatment assignment, and lack of reporting on harms.

Section Summary: Rotator Cuff Tendinopathy

Small RCTs did not demonstrate an added benefit for RF microdebridement compared to arthroscopic subacromial decompression surgery. Pain and functional outcomes improved in both groups but were not statistically different through 1 to 2 years of follow-up. Neither study prespecified a clinically meaningful difference in outcome measures nor were harms assessed throughout their course. The loss to follow-up in 1 study was 18.7%. Larger studies with appropriate harms reporting are required to appropriately assess the technology.

PATELLAR TENDINOPATHY

Randomized Clinical Trials

Owens et al (2002) randomized patients with symptomatic patellar chondral lesions to RF coblation microdebridement (n=19) or mechanical debridement (n=20).⁽²⁹⁾ All patients had failed a 6-month course of conservative treatment. The primary outcome measure was the Fulkerson-Shea Patellofemoral Joint Evaluation Score, which combines pain, functional, and clinical outcomes into an overall performance score. A score of 100 indicates a perfect score. While RF microdebridement achieved statistically higher scores at 1 and 2 years of follow-up, a clinically meaningful difference was not prespecified and pain outcomes were not directly assessed. Furthermore, the incidence of crepitus in the afflicted knee was 55% for RF microdebridement compared to 32% for mechanical debridement after 2 years. This study was further limited by restricting enrollment to female patients only and not blinding the independent observer to treatment assignments.

Section Summary: Patellar Tendinopathy

A small RCT did not demonstrate an added benefit for RF microdebridement compared to the mechanical debridement of chondral lesions in patients with patellar tendinopathy. The study lacked reporting with validated pain measures over time and reported a higher incidence of crepitus in patients undergoing RF microdebridement. Furthermore, the study only enrolled female participants, limiting the broader applicability of these findings. Larger studies with validated pain and functional outcome measures are required to adequately assess the technology.

Summary of Evidence

For individuals with plantar fasciitis who receive RF coblation tenotomy, the evidence includes nonrandomized, comparative cohort studies, a systematic review of these studies, and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trials reported improved pain and functional scores over 3 to 12 months, with improved outcomes with open versus percutaneous approaches. However, open RF coblation microtenotomy was associated with a higher incidence of postoperative persistent pain (9.1%) compared to endoscopic plantar fasciotomy(0%) in 1 study, with a separate study reporting a complication rate of 33% when both interventions were used in combination. A higher number of postoperative pain recurrences at 6 and 12 months were also reported with open RF coblation microtenotomy compared to endoscopic plantar fasciotomy. The durability of this intervention is unknown as no studies have reported long-term outcomes beyond 12 months. Studies are limited by small sample sizes, heterogeneity in surgical technique (open, percutaneous, endoscopic), missing data and/or inappropriate exclusions, lack of randomization, unclear blinding practices for patient outcome assessments, and poor statistical reporting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with lateral epicondylitis who receive RF coblation tenotomy, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trials compared RF microtenotomy to open or arthroscopic elbow release surgery. Clinically meaningful improvements in pain and functional scores were noted for all treatment arms, with no significant differences between groups through 1 to 7 years of follow-up. For disability assessments in 1 study, open release surgery met the threshold for a clinically meaningful improvement over RF microtenotomy at 1

year, though this mean difference was not statistically significant. Studies were generally underpowered or demonstrated inconsistent delivery and unclear blinding of outcome-assessments and inappropriate handling of missing or crossover data. No studies featuring RF coblation tenotomy for the treatment of wrist tendinopathy were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Achilles tendinopathy who receive RF coblation tenotomy, the evidence includes small, single-blind RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. One trial did not demonstrate an added benefit for RF microdebridement compared to surgical decompression. Pain and functional outcomes improved in both groups but were not statistically different at a 6-month follow-up. The study was limited by a control group that showed significantly less severe symptom scores at baseline that did not fully meet the 2 point threshold for a clinically meaningful difference in pain score reduction. The other small RCT demonstrated potential benefits in pain and quality of life for RF microtenotomy (ArthroCare) compared with physical therapy at 2 years. But, conclusions cannot be drawn based on these findings due to numerous notable study limitations. Larger, adequately controlled studies with longer follow-up durations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with shoulder or rotator cuff tendinopathy who receive RF coblation tenotomy, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Trials did not demonstrate an added benefit for RF microdebridement compared to arthroscopic subacromialde compression surgery. Pain and functional outcomes improved in both groups but were not statistically different through 1 to 2 years of follow-up. Neither study prespecified a clinically meaningful difference in outcome measures nor were harms assessed throughout their course. The loss to follow-up in 1 study was 18.7%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with patellar tendinopathy who receive RF coblation tenotomy, the evidence includes 1 small RCT. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trial did not demonstrate an added benefit for RF microdebridement compared to mechanical debridement in patients with chondral lesions and patellar tendinopathy. The study lacked reporting with validated pain measures over time and reported a higher incidence of crepitus in patients undergoing RF microdebridement. Furthermore, the study only enrolled female participants, limiting the broader applicability of these findings. Larger studies with validated pain and functional outcome measures are required to adequately assess the technology. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

American College of Foot and Ankle Surgeons

In 2017, the American College of Foot and Ankle Surgeons published a clinical consensus statement on the diagnosis and treatment of adult acquired infracalcaneal heel pain based

upon the best available evidence in the literature.(30) The panel determined that the following statement was uncertain – that is – neither appropriate nor inappropriate:

- “Other surgical techniques (e.g., ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) are safe and effective options for chronic, refractory plantar fasciitis.”

American College of Occupational and Environmental Medicine

In 2013, the American College of Occupational and Environmental Medicine updated their treatment guidelines for lateral epicondylitis as a result of a systematic review of the literature.(31) Surgery is recommended for cases inadequately responsive to multiple evidence-based treatments (Level of Evidence: I, insufficient evidence). Microtenotomy is also recommended (Level of Evidence: C, limited evidence base).

Government Regulations

Medicare:

National/Local:

There is no national or local policy regarding radiofrequency coblation tenotomy for the musculoskeletal conditions addressed in this policy.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Cryoablation of Peripheral Nerves (e.g., Iovera^o System)

Facet Joint Denervation

Radiofrequency Ablation of Peripheral Nerves to Treat Pain Including Coolief Cooled RF

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/2/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/10	9/15/10	8/17/10	Joint policy established
5/1/12	2/21/12	2/21/12	Routine maintenance
11/1/13	8/22/13	8/27/13	Routine maintenance
3/1/15	12/12/14	12/29/14	Routine maintenance
5/1/16	2/16/16	2/16/16	<ul style="list-style-type: none"> • Routine maintenance • Added “for Musculoskeletal Conditions” to policy title and policy statement. • Policy retired
9/1/20	6/16/20		<ul style="list-style-type: none"> • Policy unretired • Replacing IMP with same title
9/1/21	6/15/21		<ul style="list-style-type: none"> • Routine maintenance
9/1/22	6/21/22		<ul style="list-style-type: none"> • Routine maintenance • Adopted BCBSA policy • Added 28899 as EI
9/1/23	6/13/23		<ul style="list-style-type: none"> • Routine maintenance (slp) • Vendor Managed: N/A
9/1/24	6/11/24		<ul style="list-style-type: none"> • Routine maintenance (slp) • Vendor Managed: N/A • Aliments in the body of the policy clarified in the MPS

Next Review Date: 2nd Qtr.2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: COBLATION[®], RADIOFREQUENCY ABLATION FOR MUSCULOSKELETAL
CONDITIONS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Medicaid requires manual review.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.