7.01.165	Radiofrequency Coblation Tenotomy for Musculoskeletal Conditions		
Original Policy Date:	March 1, 2024	**Effective Date:**	March 1, 2024
Section:	7.0 Surgery	**Page:**	Page 1 of 33

Policy Statement

I. Radiofrequency coblation tenotomy is considered **investigational** as a treatment for musculoskeletal conditions, including but not limited to, the following conditions:
   A. Plantar fasciitis
   B. Lateral epicondylitis
   C. Wrist tendinopathy
   D. Shoulder or rotator cuff tendinopathy
   E. Achilles tendinopathy
   F. Patellar tendinopathy

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

- N/A

Description

Radiofrequency (RF) coblation is being evaluated for the treatment of plantar fasciitis, lateral epicondylitis, and various musculoskeletal tendinopathies. When utilized for tenotomy, bipolar RF energy is directed into the tendon to generate a controlled, low-temperature field of ionizing particles that break organic bonds, ablating or debriding target tissue with the goal of relieving pain and restoring function.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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. FDA product code: GEI.

Rationale

Background

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 coblation 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.

Literature 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 patients 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. Randomized controlled trials 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.

Plantar Fasciitis

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 individuals with musculoskeletal conditions.

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

Populations

The relevant population of interest is individuals with plantar fasciitis.

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.

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,] Functional outcomes for plantar fasciitis are typically assessed via the American Orthopaedic 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 subscores available for various physical or mental functional domains. A score of 100 indicates an asymptomatic patient.[14,]

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.

Review of Evidence

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 edoscopic plantar fasciotomy, and 1 to proximal medial gastrocnemius release. The 2

studies comparing RF microtenetomy 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 administrated 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 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 AOFAS hindfoot score scale (HINDTOT and HINDVAS) and the patient-reported SF-36 were administrated pre-operatively and at 3, 6, and 12 months post-operatively. 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=.027), patient-reported social-functioning (92.5 vs. 71.3; p=.030), and role-functioning-emotional (93.3 vs. 80.4; p=.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 data set 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 12 months (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).

Study characteristics and results are summarized in Tables 1 and 2. Study relevance, design, and conduct limitations are summarized in Tables 3 and 4.

Table 1. Comparative Study Characteristics: Plantar Fasciitis

Study	Study Type	Country	Dates	Participants	Intervention	Comparator(s)	Follow-Up
Yuan et al (2020)[16,]	Cohort, retrospective	China	2009-2018	Patients with plantar fasciitis who failed a conservative therapy program of at least 6 months in duration.	Percutaneous RF ablation (n=15)	Open plantar fascia release (n=16)	3 days, 12 months, and end of study
Huang et al (2018)[17,]	Cohort, retrospective	Singapore	2007-2014	Patients with plantar fasciitis who failed a conservative therapy program of at least 6 months in duration.	RF microtenotomy (n=28)	Gastrocnemius recession (n=8) or both RF microtenotomy and gastrocnemius recession (n=7)	12 months
Wang et al (2017)[14,]	Cohort, retrospective	Singapore	2007-2015	Patients with plantar fasciitis who failed a conservative therapy program of at least 6 months in duration. Patients with a BMI >35 kg/m2 were excluded.	Open RF coblation microtenotomy via TOPAZ microdebrider device (ArthroCare) (n=22)	Endoscopic plantar fasciotomy or combination treatment (n=12)	12 Months
Chou et al (2016)[6,]	Cohort, retrospective	Singapore	2007-2014	Patients with plantar fasciitis who	Open or percutaneous RF coblation	Plantar fasciotomy with dissection or use	12 Months

Study	Study Type	Country	Dates	Participants	Intervention	Comparator(s)	Follow-Up
				failed conservative therapy with a full set of clinical data.	microtenotomy via TOPAZ microdebrider device (ArthroCare) (n=48)	of an endoscope (n=27) or combination of both treatments (n=9)	
Tay et al (2012)[1,]	Cohort, prospective	Singapore	2007-2009	Patients with plantar fasciitis who failed a conservative therapy program of at least 6 months in duration. Patients with a BMI >35 kg/m2 were excluded.	Open RF coblation microtenotomy via TOPAZ microdebrider device (ArthroCare) (n=32)	Percutaneous RF coblation microtenotomy via TOPAZ microdebrider device (ArthroCare) (n=27)	12 Months

BMI: body mass index; RF: radiofrequency.

Table 2. Comparative Study Results: Plantar Fasciitis

Study	Pain Outcomes[1]			Functional Outcomes[2]			Patient-Reported SF-36 Physical Outcomes[3]		Persistent Postoperative Heel Pain (%)
	Baseline	*3 Months*	*12 Months*	*Baseline*	*3 Months*	*12 Months*	*RFP at Baseline*	*RFP at 12 Months*	*12 Months*
Yuan et al (2020)[16,]	N=31		N=31	N=31		N=31			
Percutaneous RF ablation, mean (SD)	7.87 (1.73)	NR	0.73 (1.28)[4]	42.73 (10.75)	NR	98.40 (4.24)[4]	NR	NR	NR
Open plantar fascia release, mean (SD)	8.81 (1.11)	NR	0.50 (1.41)[4]	39.63 (8.52)	NR	99.38 (2.5)[4]	NR	NR	NR
Huang et al (2018)[17,]	N=43	N=43	N=43	N=43	N=43	N=43	N=43	N=43	
Gastrocnemius recession, mean (SD)	6.86 (1.57)	2.43 (2.57)	1.57 (2.30)	39.14 (15.91)	78.86 (13.31)	87.00 (12.95)	54.38 (18.60)	86.88 (6.51)	NR
Radiofrequency microtenotomy, mean (SD)	7.21 (1.69)	3.65 (2.85)	1.50 (2.43)	42.00 (13.47)	71.64 (19.44)	88.54 (16.79)	54.46 (26.75)	82.50 (16.69)	NR
Both, mean (SD)	6.86 (1.77)	3.14 (3.81)	1.29 (2.22)	50.57 (18.75)	73.17 (22.45)	90.71 (13.51)	72.86 (26.75)	90.71 (9.76)	NR
Wang et al (2017)[14,]	N=34	N=34	N=34	N=34	N=34	N=34	N=34	N=34	N=34
Endoscopic plantar fasciotomy (95% CI)	7.2 (NR)	0.9 (NR)	1.3 (NR)	49.8 (NR)	92.1 (NR)	88.3 (NR)	8.3	83.3	0%
Open RF microtenotomy (95% CI)	7.3 (NR)	3.3 (NR)	0.9 (NR)	40.2 (NR)	75.2 (NR)	92.0 (NR)	12.5	79.0	9.1%
p	.421	.027	.324	.089	.084	.464	.595	.992	NR

Study	Pain Outcomes[1]			Functional Outcomes[2]			Patient-Reported SF-36 Physical Outcomes[3]		Persistent Postoperative Heel Pain (%)
	Baseline	*3 Months*	*12 Months*	*Baseline*	*3 Months*	*12 Months*	*RFP at Baseline*	*RFP at 12 Months*	*12 Months*
	Baseline	6 Months	12 Months	Baseline	6 Months	12 Months	PCS at Baseline	PCS at 12 Months	12 Months
Chou et al (2016)[6,]	N=84	N=84	N=84	N=84	N=84	N=84	N=84	N=84	N=84
Plantar fasciotomy (SD)	7.407 (1.185)	3.037 (3.006)	1.963 (2.653)	41.148 (14.392)	76.926 (23.362)	83.741 (20.594)	43.500 (17.238)	66.861 (25.551)	11%
RF microtenotomy (SD)	7.352 (1.580)	2.685 (2.821)	1.585 (2.389)	43.000 (14.907)	80.245 (19.620)	86.731 (18.238)	41.355 (17.587)	65.705 (20.314)	7.3%
Combination (SD)	7.667 (2.000)	1.667 (2.646)	0.556 (1.333)	46.000 (15.804)	94.25 (11.285)	91.667 (10.571)	47.167 (16.691)	51.861 (24.197)	33%
p	NR	NR	NR	NR	NR	NR	>.05	>.05	NR
	Baseline	6 Months	12 Months	Baseline	6 Months	12 Months	RFP at Baseline*	RFP at 12 Months*	12 Months
Tay et al (2012)[1,]	N=59	N=45	N=21	N=59	N=45	N=21	N=59	N=21	N=21
Percutaneous RF microtenotomy (95% CI)	7.48 (NR)	3.05 (NR)	3.00 (NR)	42.2 (NR)	76.60 (NR)	74.92 (NR)	25.0 (NR)	68.8 (NR)	NR
Open RF microtenotomy (95% CI)	7.56 (NR)	3.58 (NR)	0.78 (NR)	41.5 (NR)	68.64 (NR)	87.00 (NR)			NR
p	.858	NR	.035	.850	NR	.159	.009		NR

CI: confidence interval; NR: not reported; PCS: physical component score; RF: radiofrequency; RFP: role-functioning, physical; SD: standard deviation; SF-36: Short Form 36 Health Survey.
* Outcome was pooled for all treatment groups.
[1] Pain outcomes are based on visual analog scale component of the American Orthopaedic Foot & Ankle Society (AOFAS) hindfoot score.
[2] Functional outcomes are based on the AOFAS hindfoot or ankle-hindfoot total score.
[3] Patient-reported physical outcomes are based on the SF-36 Health Survey physical component score (PCS) or role functioning (physical) component (RFP) score, as specified.
[4] Outcomes reported at last follow-up.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Yuan et al (2020)[16,]	4. Conducted in a single country. 5. Pain scores were lower in the RF ablation group at baseline.				1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms. 3. Unclear timing of "last follow-up".
Huang et al (2018)[17,]	4. Conducted in a single country.	1. Outcomes not stratified by open vs. endoscopic versions of procedure.	1. Outcomes not stratified by open vs. endoscopic versions of procedure.		

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Wang et al (2017)[14,]				5. Clinical significant difference not prespecified.	1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms.
Chou et al (2016)[6,]	2. Minimum duration of conservative treatment program prior to failure not specified.	2. Outcomes not stratified by open vs. percutaneous versions of procedure. 3. Unequal distribution of open and minimally invasive (percutaneous) procedures with comparator.	1. Outcomes not stratified by open vs. endoscopic versions of procedure. 3. Unequal distribution of open and minimally invasive (endoscopic) procedures with intervention.	5. Clinical significant difference not prespecified.	1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms.
Tay et al (2012)[1,]	3. Study population is not representative of intended use. Mental health component scale scores statistically different at baseline between groups.		2. Not a standard comparator.	5. Clinical significant difference not prespecified.	1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms.

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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Yuan et al (2020)[16,]	1. Participants not randomly allocated.	1. Not blinded to treatment assignment.			1. Power calculation not reported.	3. Confidence intervals and/or p values not reported.
Huang et al (2018)[17,]	1. Participants not randomly allocated.	1. Not blinded to treatment assignment.			1. Power calculation not reported.	3. Confidence intervals and/or p values not reported.
Wang et al (2017)[14,]	1. Participants not randomly allocated.	1. Not blinded to treatment assignment.	1. Not registered.	1. High loss to follow-up or missing data.	1. Power calculation	3. Confidence intervals and/or p

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
	Intervention based on patient and surgeon choice.			5. Inappropriate exclusions. Fourteen patients with more than 1 foot and ankle pathology (unspecified) were deemed confounders whereas other studies have allowed this. Nine patients missed at least 1 follow-up appointment and were entirely excluded due to an incomplete dataset.	not reported.	values not reported.
Chou et al (2016)[6,]	1. Participants not randomly allocated.	1. Not blinded to treatment assignment. 3. Outcome not assessed by treating physician but unclear if blinded to treatment assignment.	1. Not registered.		1. Power calculation not reported.	3. Confidence intervals and/or p values not reported.
Tay et al (2012)[1,]	1. Participants not randomly allocated.	1. Not blinded to treatment assignment. 3. Outcome not assessed by treating physician but unclear if blinded to treatment assignment.	1. Not registered.	1. High loss to follow-up or missing data. 2. Inadequate handling of missing data.	1. Power calculation not reported.	3. Confidence intervals and/or p values not reported.

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; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

[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); 7. Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

[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; 5. Other.

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 3 and 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

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with lateral epicondylitis or wrist tendinopathy.

Interventions

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

Comparators

The following practice is currently being used to treat lateral epicondylitis and wrist 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 lateral epicondylitis include the arthroscopic release of the extensor carpi radialis brevis (ECRB) tendon.

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 VAS or NRS. A score reduction of at least 2 points is considered clinically meaningful. 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,]

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.

Review of Evidence
Randomized Controlled Trials
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 less than 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.

Study characteristics and results are summarized in Tables 5 and 6. Study relevance, design, and conduct limitations are summarized in Tables 7 and 8.

Table 5. Comparative Study Characteristics: Lateral Epicondylitis

Study	Study Type	Country	Dates	Participants	Intervention	Comparator(s)	Follow-Up
Lee et al (2018)[22,]	RCT	South Korea	2010-2015	Patients with refractory lateral epicondylitis who had failed a conservative therapy program of at least 6 months' duration, including 2 or more corticosteroid injections and ESWT	RF coblation microtenotomy via TOPAZ microdebrider electrode (Smith & Nephew) (n=22)	Arthroscopic tendon release of the ECRB tendon (n=24)	24 months
Hamlin et al (2018)[13,]	RCT	Scotland	NR	Patients with lateral epicondylitis who failed non-operative treatment with local steroid injections and physiotherapy	RF coblation microtenotomy via TOPAZ microdebrider wand (ArthroCare) (n=21)	Open release surgery (n=18)	12 months
Meknas et al (2013)[21,]	RCT	Norway	2006-2007	Patients with refractory lateral epicondylitis who failed a conservative therapy program of at least 1 year in duration	RF coblation microtenotomy via TOPAZ microdebrider electrode (ArthroCare) (n=13)	Open release surgery (n=11)	5 to 7 years

ECRB: extensor carpi radialis brevis; ESWT: extracorporeal shock-wave therapy; NR: not reported; RCT: randomized controlled trial; RF: radiofrequency.

Table 6. Comparative Study Results: Lateral Epicondylitis

Study	Pain Outcomes[1]		MEPS Functional Outcomes		DASH Disability Outcomes		Mean Grip Strength (SD)	
	VAS at Baseline	24 Months	Baseline	24 Months	Baseline	24 Months	Baseline, kg	24 Months, kg
Lee et al (2018)[22],	N=46	N=46	N=46	N=46	N=46	N=46	N=46	N=46
RF microtenotomy (SD)	7.27 (0.94)	1.50 (1.29)	53.9 (6.7)	95.7 (6.8)	60 (9)[a]	21 (12)[a]	19.97 (6.74)	27.31 (6.90)
Arthroscopic tendon release (SD)	7.33 (1.05)	1.41 (1.14)	55.2 (6.3)	95.4 (8.7)	57 (13)[a]	20 (11)[a]	20.20 (6.35)	25.75 (6.56)
p	.838	.802	NR	NR	NR	NR	.438	.905
	NRS at Baseline	12 Months	Baseline	12 Months	Baseline	12 Months	Baseline, lb	6 Weeks, lb
Hamlin et al (2018)[13],	N=39	N=39	N=39	N=39	N=39	N=39	N=39	N=39
RF microtenotomy (SD)	7.0 (NR)	-4.974 (0.626)	NR	NR	45.8 (NR)	-39.55 (4.956)	41.2 (NR)	60.0 (NR)
Open release (SD)	7.9 (NR)	-5.124 (0.702)	NR	NR	50.0 (NR)	-28.31 (6.252)	35.7 (NR)	49.3 (NR)
MD (SD)	NR	NR	NR	NR	NR	12.83 (7.927)	NR	NR
p	NR	.8536	NR	NR	NR	.1144	NR	.8601
	NRS at Baseline	5 to 7 Years	Baseline	5 to 7 Years	Baseline	5 to 7 Years	Baseline, kg	5 to 7 Years, kg
Meknas et al (2013)[21],	N=24	N=22	N=24	N=22	N=24	N=22	N=24	N=22
RF microtenotomy (SD)	7.1 (1.6)	1.4 (2.3)	55.4 (12.6)	96.4 (9.9)	NR	NR	28.3 (16.9)	33.8 (13.1)
Open release (SD)	6.4 (1.5)	1.3 (1.7)	61.9 (17.1)	96.0 (9.4)	NR	NR	29.1 (12.9)	37.7 (6.1)
p	NR	NR	NR	NR	NR	NR	NR	NR

DASH: Disabilities of the Arm, Shoulder, and Hand questionnaire; MD: mean difference; MEPS: Mayo Elbow Performance Score; NR: not reported; NRS: numerical rating scale; RF: radiofrequency; SD: standard deviation; VAS: visual analog scale.

[a] Values estimated from graphs.

[1] Pain outcomes are based on visual analog scale (VAS) or numerical rating scale (NRS) scores.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Lee et al (2018)[22],	3. Requirement to fail ESWT is not typical inclusion requirement for conservative therapy. Patients were heavily pre-treated.				2. Not sufficient sample size for harms.
Hamlin et al (2018)[13],					1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms.

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Meknas et al (2013)[21],					1. Not sufficient duration for long-term benefit. 2. Not sufficient sample size for harms.

ESWT: extracorporeal shock-wave therapy.
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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Lee et al (2018)[22],		1. Not blinded to treatment assignment.	1. Not registered.	1. Underpowered due to loss to follow-up.	3. Underpowered due to higher than anticipated dropout rate. Power based on interim analysis and not on clinically important differences.	3. Confidence intervals and/or p values not reported for all outcome measures.
Hamlin et al (2018)[13],		1. Patients were blinded with regard to surgical treatment until the final review. 3. Blinding of outcome assessments unclear.	2. MEPS scores were collected but were not reported.	1. Underpowered due to loss to follow-up.		3. Confidence intervals and/or p values not reported for all outcome measures.
Meknas et al (2013)[21],		1. Not blinded to treatment assignment. 3. Blinding of outcome assessments unclear. Treating physician made the initial clinical assessment prior to randomization.	1. Not registered.	1. High loss to follow-up or missing data. 2. Inadequate handling of missing data or varied delivery of clinical assessments. 4. Inadequate handling of crossovers. 6. Unclear ITT analysis.	1. Power calculation not reported.	3. Confidence intervals and/or p values not reported for all outcome measures.

ITT: intent to treat; MEPS: Mayo Elbow Performance Score.
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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

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

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with Achilles tendinopathy.

Intervention

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

Comparators

The following practice is currently being used to treat 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,]

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 VAS or NRS. A score reduction of at least 2 points is considered clinically meaningful.[13,] The Victoria Institute of Sport Assessment (VISA) questionnaire for Achilles tendinopathy (VISA-A) is typically utilized to assess functional, pain, and activity domains of

Achilles tendinopathy, where 100 represents a perfect score.[3,] Successful recovery is typically defined with scores >80.[24,]

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.

Review of Evidence

Randomized Controlled Trials

Morrison et al (2017) conducted a single-blind RCT evaluating RF coblation microdebridement compared to surgical decompression for patients with noninsertional 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. Study characteristics and results are summarized in Tables 9 and 10. Study relevance, design, and conduct limitations are summarized in Tables 11 and 12.

Table 9. Comparative Study Characteristics: Achilles Tendinopathy

Study	Study Type	Country	Dates	Participants	Intervention	Comparator	Follow-Up
Morrison et al (2017)[23,]	RCT	United Kingdom	2009-2014	Patients with refractory noninsertional Achilles tendinopathy who had failed a conservative therapy program of at least 6 months'	RF coblation microdebridement via TOPAZ microdebrider wand (ArthroCare) (n=20)	Surgical decompression (n=16)	6 months

Study	Study Type	Country	Dates	Participants	Intervention	Comparator	Follow-Up
				duration, with diagnosis confirmed via MRI. Patients utilized a physical therapy program during weeks 2 to 12 post-treatment.			
Al-Ani et al (2021)(NCT03274557)[25,]	RCT	Norway	2016-2018	Individuals with pain in the Achilles tendon with a duration of at least 6 months, impaired daily and sports activities, and evidence of tendinosis in the midportion of the Achilles tendon on magnetic resonance imaging (MRI). Patients with previous surgery to the Achilles tendon or severe active organic diseases were excluded; 75% male; participant race/ethnicity not reported.	RF microtenotomy (ArthroCare) (n=24)	Physical therapy (n=23)	2 years

MRI: magnetic resonance imaging; RCT: randomized controlled trial; RF: radiofrequency.

Table 10. Comparative Study Results: Achilles Tendinopathy

Study	Pain Outcomes				Functional Outcomes			
	Mean VAS at Baseline[a]	6 Months	MD (Range)	p	Mean VISA-A at Baseline	6 Months	MD (Range)	p
Morrison et al (2017)[23,]	N=36	N=36	N=36	N=36	N=36	N=36	N=36	N=36
RF microdebridement (Range)	5.6 (2 to 9)	2.6 (0 to 8)	-3.1 (-9 to 2)	<.001	31.4 (10 to 53)	60 (15 to 99)	28.7 (-15 to 66)	<.001
Surgical decompression (Range)	3.8 (1 to 7)	2.0 (0 to 7)	-1.8 (-6 to 4)	.012	42.4 (14 to 79)	66.7 (19 to 100)	24.3 (-10 to 61)	<.001
p	.0091	.5041	.193		.0471	.395	.569	
	Mean VAS at Baseline	**2 years**			**Foot and Ankle Outcome Score (FAOS) Quality of Life at Baseline**	**2 years**		
Al-Ani et al (2021)(NCT03274557)[25,]	N=47	N=38						
RF microtenotomy	7.2 ± 1.5	1.0 ± 1.4	NR	NR	38.0 ± 19.0	81.5 ± 20.9	NR	NR

Study	Pain Outcomes				Functional Outcomes			
	Mean VAS at Baseline[a]	6 Months	MD (Range)	p	Mean VISA-A at Baseline	6 Months	MD (Range)	p
(± standard deviation)								
Physical therapy (± standard deviation)	5.9 ± 1.3	3.1 ± 1.8	NR	NR	42.8 ± 17.8	53.2 ± 33.5	NR	NR
p	.004	.0002	NR	NR	.434	.0032	NR	NR

MD: mean difference; NR: not reported; RF: radiofrequency; VAS: visual analog scale: VISA-A: Victoria Institute of Sport Assessment (VISA) questionnaire for Achilles tendinopathy.
[a] Statistical analysis of covariance was adjusted for age, sex, and body mass index.

Table 11. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Morrison et al (2017)[23,]	1. Criteria for MRI confirmation of diagnosis are not specified. 3. Comparator group exhibited significantly less severe pain and functional symptom scores at baseline.			5. Clinical significant difference for VISA-A scale not provided. 6. Clinical significant difference for comparator not fully established.	1-2. Not sufficient duration for benefit or harms.
Al-Ani et al (2021)(NCT03274557)[25,]	1. MRI evaluation that was used lacked a second reviewer evaluation and had not undergone a test-retest procedure. 2. Significantly more patients in radiofrequency group had MRI evidence of intratendinous rupture change (p=.014) and higher Visual Analog Scale Pain scores (7.2 vs 5.9; p=.004) at baseline.		1. Inadequate description of techniques used to increase load during physical therapy.	5. Clinically important difference for Foot and Ankle Outcome Score (FAOS) Quality of Life not provided.	

MRI: magnetic resonance imaging; VISA-A: Victoria Institute of Sport Assessment (VISA) questionnaire for Achilles tendinopathy.
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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 12. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Morrison et al (2017)[23,]		1. Single-blind study. 2. Blinding of outcome assessment not clear.	1. Not registered. 2. Evidence of selective reporting. Planned 6-week outcome assessments were canceled due to postoperative restrictions.			3. Confidence intervals and/or p values not reported.
Al-Ani et al (2021)(NCT03274557)[25,]				1. 19% declined allocated treatment.	3. Power not based on clinical important differences in health outcomes, such as quality of life.	

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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

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 greater than 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

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with shoulder or rotator cuff tendinopathy.

Interventions

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

Comparators

The following practice is currently being used to treat shoulder or 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,]

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 VAS or NRS. A score reduction of at least 2 points is considered clinically meaningful.[13,] Functional outcomes may include Constant-Murley scores and range of motion.

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.

Review of Evidence

Randomized Controlled I 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 time point. 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.

Study characteristics and results are summarized in Tables 13 and 14. Study relevance, design, and conduct limitations are summarized in Tables 15 and 16.

Table 13. Comparative Study Characteristics: Rotator Cuff Tendinopathy

Study	Study Type	Country	Dates	Participants	Intervention	Comparator	Follow-Up
Al-Ani et al (2019)[28,]	RCT	Norway	2015-2016	Patients with rotator cuff tendinopathy with an average symptom duration of 6 months. Half of patients failed 1 to 3 corticosteroid injections.	RF coblation microtenotomy via TOPAZ microdebrider (ArthroCare) (n=13)	Arthroscopic subacromial acromioplasty (n=14)	2 years
Lu et al (2013)[27,]	RCT	China	2009-2010	Patients with refractory shoulder impingement syndrome and rotator cuff tendinopathy who had failed a conservative management program of at least 5 months.	RF coblation microtenotomy via TOPAZ microdebrider (ArthroCare) (n=40)	Arthroscopic subacromial decompression (n=40)	1 year

RCT: randomized controlled trial; RF: radiofrequency.

Table 14. Comparative Study Results: Rotator Cuff Tendinopathy

Study	Pain Outcomes[a]			Functional Outcomes[b]		
	Mean VAS at Baseline	2 Years	p	Mean at Baseline	2 Years	p
Al-Ani et al (2019)[28,]	N=27	N=27	N=27	N=27	N=27	N=27
RF microtenotomy (SD)	7.0 (1.5)	1.3 (2.1)	<.01	37.7 (16.1)	82.2 (13.2)	<.01

Study	Pain Outcomes[a]			Functional Outcomes[b]		
	Mean VAS at Baseline	2 Years	p	Mean at Baseline	2 Years	p
Arthroscopic acromioplasty (SD)	6.9 (1.4)	1.4 (2.1)	<.01	41.2 (10.3)	82.0 (13.0)	<.01
p	NS	NS		NS	NS	
Lu et al (2013)[27],	Mean VAS at Baseline (N=65)	1 Year (N=65)	N=65	Mean at Baseline (N=65)	1 Year (N=65)	N=65
RF microtenotomy (SD)	5.5 (1.7)	0.4 (1.1)	.031	66.8 (20.5)	96 (NR)[c]	NR
Arthroscopic decompression (SD)	5.3 (2.1)	0.3 (0.9)	.017	68.6 (15.6)	99 (NR)[c]	NR
p	.921	.631		.691	NR	

NR: not reported; NS: no significance; RF: radiofrequency; SD: standard deviation; VAS: visual analog scale.
[a] Pain outcomes are based on visual analog scale (VAS) or numerical rating scale (NRS) scores.
[b] Functional outcome measures are based on Constant-Murley scores.
[c] Scores estimated from graph.

Table 15. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Al-Ani et al (2019)[28],	2. Criteria for MRI grading of tendinosis are not specified. 3. Minimum conservative treatment program duration not standardized or specified.			2. MRI tendinosis score is not a validated outcome measure. 3. No reporting on harms. 5-6. Rationale for clinical significant difference not provided or supported.	2. No reporting on harms.
Lu et al (2013)[27],	3. Minimum conservative treatment duration was interrupted by other therapies at 8 weeks and shorter in total duration than most typical recommendations.			3. No reporting on harms. 5. Clinical significant difference not prespecified.	2. Not sufficient duration for harms.

MRI: magnetic resonance imaging.
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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 16. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Al-Ani et al (2019)[28],	3. Allocation concealment unclear.	1. Unclear blinding of treatment assignment.	1. Not registered.		3. Power not based on clinically important difference.	3. Confidence intervals and/or p values not reported.
Lu et al (2013)[27],		1. Unclear blinding of treatment assignment. 2. Independent observer not blinded to treatment received.	1. Not registered.	1. High loss to follow-up or missing data.	3. Power not based on clinically important difference.	3. Confidence intervals and/or p values not reported.

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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

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 one study was 18.7%. Larger studies with appropriate harms reporting are required to appropriately assess the technology.

Patellar Tendinopathy

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with shoulder or patellar tendinopathy.

Interventions

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

Comparators

The following practice is currently being used to treat 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 VAS or NRS. A score reduction of at least 2 points is considered clinically meaningful.[13,] 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.

Review of Evidence

Randomized Controlled 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.

Study characteristics and results are summarized in Tables 17 and 18. Study relevance, design, and conduct limitations are summarized in Tables 19 and 20.

Table 17. Comparative Study Characteristics: Patellar Tendinopathy

Study	Study Type	Country	Dates	Participants	Intervention	Comparator	Follow-Up
Owens et al (2002)[29,]	RCT	U.S.	NR	Female patients with chondral lesions symptomatic of patellar tendinopathy who had failed a 6-month course of conservative treatment.	RF coblation microdebridement via TOPAZ microdebrider (ArthroCare) (n=19)	Mechanical debridement (n=20)	2 years

NR: not reported; RCT: randomized controlled trial; RF: radiofrequency.

Table 18. Comparative Study Results: Patellar Tendinopathy

Study	Crepitus			Functional Outcomes[a]		
	Crepitus at Baseline	1 Year	2 Years	Mean at Baseline	1 Year	2 Years
Owens et al (2002)[29],	N=39	N=39	N=39	N=39	N=39	N=39
RF microtenotomy (95% CI)	100% (NR)	NR	55% (NR)	59.6 (53.5 to 64.8)	87.9 (83.3 92.5)	86.6 (81.4 to 91.8)
Mechanical debridement (95% CI)	100% (NR)	NR	32% (NR)	59.2 (53.4 to 64.9)	80.0 (74.6 to 85.4)	77.5 (72.2 to 82.8)
p	NR	NR	NR	NR	.023	.014

CI: confidence interval; NR: not reported; RF: radiofrequency.
[a] Functional outcomes are based on the Fulkerson-Shea Patellofemoral Joint Evaluation Score.

Table 19. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Owens et al (2002)[29],	3. Enrollment restricted to female patients only. Not representative of intended use.			2. Key pain outcomes not directly assessed. 3. No reporting on harms. 4. Not established and validated measurements. 5-6. Rationale for clinical significant difference not provided or prespecified.	2. No reporting collected for harms.

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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 20. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Owens et al (2002)[29],		2. Outcome assessment not performed by blinded independent observer.	1. Not registered.	1. High loss to follow-up or missing data. 2. No intent to treat analysis to support superiority claims.	1. Power calculation not reported.	3. Confidence intervals and/or p values not reported. Inconsistent p values reported for same outcome. Overlapping confidence intervals.

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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

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.

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 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).

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for the use of radiofrequency coblation tenotomy have been identified.

Medicare National Coverage

The Centers for Medicare & Medicaid Services have determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that "employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered."[32,]

However, the Centers for Medicare & Medicaid Services have not published a national coverage decision on radiofrequency coblation tenotomy for the musculoskeletal conditions addressed in this evidence review. In the absence of a national coverage determination, coverage determinations 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 21.

Table 21. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03854682	Surgical or Non-surgical Treatment of Plantar Fasciitis - A Randomized Clinical Trial	70	Jun 2025 (recruiting)
Unpublished			
NCT02304952	Eccentric Exercise or Radiofrequent Microtenotomy as Treatment of Chronic Lateral Epicondylalgia - a Randomized Controlled Trial	100	Sep 2018 (unknown)
NCT02275689	Alternative Treatment of Rotator Cuff Tendinopathy	34	Dec 2016 (completed)
NCT00534781[a]	Radiofrequency-based Plasma Microdebridement Compared to Surgical Microdebridement for Treating Achilles Tendinosis: A Prospective, Randomized, Controlled Multi-Center Study	60	Sep 2010 (completed)
NCT00189592[a]	Plantar Fasciosis Treatment Using Coblation® Prospective, Double-Blind, Randomized Controlled Study	45	Jun 2008 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Tay KS, Ng YC, Singh IR, et al. Open technique is more effective than percutaneous technique for TOPAZ radiofrequency coblation for plantar fasciitis. Foot Ankle Surg. Dec 2012; 18(4): 287-92. PMID 23093126
2. Davenport TE, Kulig K, Matharu Y, et al. The EdUReP model for nonsurgical management of tendinopathy. Phys Ther. Oct 2005; 85(10): 1093-103. PMID 16180958
3. Robinson JM, Cook JL, Purdam C, et al. The VISA-A questionnaire: a valid and reliable index of the clinical severity of Achilles tendinopathy. Br J Sports Med. Oct 2001; 35(5): 335-41. PMID 11579069
4. Lohrer H, David S, Nauck T. Surgical treatment for achilles tendinopathy - a systematic review. BMC Musculoskelet Disord. May 10 2016; 17: 207. PMID 27165287
5. Nirschl RP, Pettrone FA. Tennis elbow. The surgical treatment of lateral epicondylitis. J Bone Joint Surg Am. Sep 1979; 61(6A): 832-9. PMID 479229
6. Chou AC, Ng SY, Su DH, et al. Radiofrequency microtenotomy is as effective as plantar fasciotomy in the treatment of recalcitrant plantar fasciitis. Foot Ankle Surg. Dec 2016; 22(4): 270-273. PMID 27810027
7. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. Foot Ankle Int. May 2004; 25(5): 303-10. PMID 15134610

8. Riddle DL, Pulisic M, Pidcoe P, et al. Risk factors for Plantar fasciitis: a matched case-control study. J Bone Joint Surg Am. May 2003; 85(5): 872-7. PMID 12728038
9. Rano JA, Fallat LM, Savoy-Moore RT. Correlation of heel pain with body mass index and other characteristics of heel pain. J Foot Ankle Surg. 2001; 40(6): 351-6. PMID 11777230
10. Riggs BL, Hodgson SF, Hoffman DL, et al. Treatment of primary osteoporosis with fluoride and calcium. Clinical tolerance and fracture occurrence. JAMA. Feb 01 1980; 243(5): 446-9. PMID 7351765
11. Shiri R, Viikari-Juntura E, Varonen H, et al. Prevalence and determinants of lateral and medial epicondylitis: a population study. Am J Epidemiol. Dec 01 2006; 164(11): 1065-74. PMID 16968862
12. Struijs PA, Kerkhoffs GM, Assendelft WJ, et al. Conservative treatment of lateral epicondylitis: brace versus physical therapy or a combination of both-a randomized clinical trial. Am J Sports Med. Mar 2004; 32(2): 462-9. PMID 14977675
13. Hamlin K, Munro C, Barker SL, et al. Open release versus radiofrequency microtenotomy in the treatment of lateral epicondylitis: a prospective randomized controlled trial. Shoulder Elbow. Jan 2018; 10(1): 45-51. PMID 29276537
14. Wang W, Rikhraj IS, Chou ACC, et al. Endoscopic Plantar Fasciotomy vs Open Radiofrequency Microtenotomy for Recalcitrant Plantar Fasciitis. Foot Ankle Int. Jan 2018; 39(1): 11-17. PMID 29182482
15. Nayar SK, Alcock H, Vemulapalli K. Surgical treatment options for plantar fasciitis and their effectiveness: a systematic review and network meta-analysis. Arch Orthop Trauma Surg. Aug 2023; 143(8): 4641-4651. PMID 36596990
16. Yuan Y, Qian Y, Lu H, et al. Comparison of the therapeutic outcomes between open plantar fascia release and percutaneous radiofrequency ablation in the treatment of intractable plantar fasciitis. J Orthop Surg Res. Feb 18 2020; 15(1): 55. PMID 32070392
17. Huang DM, Chou AC, Yeo NE, et al. Radiofrequency Microtenotomy with Concurrent Gastrocnemius Recession Improves Postoperative Vitality Scores in the Treatment of Recalcitrant Plantar Fasciitis. Ann Acad Med Singap. Dec 2018; 47(12): 509-515. PMID 30636267
18. Weil L, Glover JP, Weil LS. A new minimally invasive technique for treating plantar fasciosis using bipolar radiofrequency: a prospective analysis. Foot Ankle Spec. Feb 2008; 1(1): 13-8. PMID 19825686
19. Yeap EJ, Chong KW, Yeo W, et al. Radiofrequency coblation for chronic foot and ankle tendinosis. J Orthop Surg (Hong Kong). Dec 2009; 17(3): 325-30. PMID 20065374
20. Sean NY, Singh I, Wai CK. Radiofrequency microtenotomy for the treatment of plantar fasciitis shows good early results. Foot Ankle Surg. Dec 2010; 16(4): 174-7. PMID 21047605
21. Meknas K, Al Hassoni TN, Odden-Miland Å, et al. Medium-Term Results After Treatment of Recalcitrant Lateral Epicondylitis: A Prospective, Randomized Study Comparing Open Release and Radiofrequency Microtenotomy. Orthop J Sports Med. Sep 2013; 1(4): 2325967113505433. PMID 26535247
22. Lee JH, Park I, Hyun HS, et al. A Comparison of Radiofrequency-Based Microtenotomy and Arthroscopic Release of the Extensor Carpi Radialis Brevis Tendon in Recalcitrant Lateral Epicondylitis: A Prospective Randomized Controlled Study. Arthroscopy. May 2018; 34(5): 1439-1446. PMID 29366739
23. Morrison RJM, Brock TM, Reed MR, et al. Radiofrequency Microdebridement Versus Surgical Decompression for Achilles Tendinosis: A Randomized Controlled Trial. J Foot Ankle Surg. 2017; 56(4): 708-712. PMID 28495412
24. Martin RL, Chimenti R, Cuddeford T, et al. Achilles Pain, Stiffness, and Muscle Power Deficits: Midportion Achilles Tendinopathy Revision 2018. J Orthop Sports Phys Ther. May 2018; 48(5): A1-A38. PMID 29712543
25. Al-Ani Z, Meknas D, Kartus JT, et al. Radiofrequency Microtenotomy or Physical Therapy for Achilles Tendinopathy: Results of a Randomized Clinical Trial. Orthop J Sports Med. Dec 2021; 9(12): 23259671211062555. PMID 34988234

26. Shibuya N, Thorud JC, Humphers JM, et al. Is percutaneous radiofrequency coblation for treatment of Achilles tendinosis safe and effective?. J Foot Ankle Surg. 2012; 51(6): 767-71. PMID 22974813
27. Lu Y, Zhang Q, Zhu Y, et al. Is radiofrequency treatment effective for shoulder impingement syndrome? A prospective randomized controlled study. J Shoulder Elbow Surg. Nov 2013; 22(11): 1488-94. PMID 23994459
28. Al-Ani Z, Jacobsen EW, Kartus JT, et al. Radiofrequency microtenotomy: a promising method for treatment of rotator cuff tendinopathy. Knee Surg Sports Traumatol Arthrosc. Dec 2019; 27(12): 3856-3863. PMID 31473769
29. Owens BD, Stickles BJ, Balikian P, et al. Prospective analysis of radiofrequency versus mechanical debridement of isolated patellar chondral lesions. Arthroscopy. Feb 2002; 18(2): 151-5. PMID 11830808
30. Schneider HP, Baca JM, Carpenter BB, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain. J Foot Ankle Surg. 2018; 57(2): 370-381. PMID 29284574
31. Hegmann KT, Hoffman HE, Belcourt RM, et al. ACOEM practice guidelines: elbow disorders. J Occup Environ Med. Nov 2013; 55(11): 1365-74. PMID 23963225
32. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination for Thermal Intradiscal Procedures (TIPs) (150.11). 2009; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=324. Accessed November 21, 2022.

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	23405	Tenotomy, shoulder area; single tendon
	23406	Tenotomy, shoulder area; multiple tendons through same incision
	23410	Repair of ruptured musculotendinous cuff (e.g., rotator cuff) open; acute
	24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
	24358	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open
	24359	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open with tendon repair or reattachment
	25290	Tenotomy, open, flexor or extensor tendon, forearm and/or wrist, single, each tendon
	27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia

Type	Code	Description
	27606	Tenotomy, percutaneous, Achilles tendon (separate procedure); general anesthesia
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/01/2024	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
New Policy **Policy Statement:** N/A	**Radiofrequency Coblation Tenotomy for Musculoskeletal Conditions 7.01.165** **Policy Statement:** I. Radiofrequency coblation tenotomy is considered **investigational** as a treatment for musculoskeletal conditions, including but not limited to, the following conditions: A. Plantar fasciitis B. Lateral epicondylitis C. Wrist tendinopathy D. Shoulder or rotator cuff tendinopathy E. Achilles tendinopathy F. Patellar tendinopathy