

# **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

## **INTERVENTIONAL PROCEDURES PROGRAMME**

### **Interventional procedure overview of radiofrequency ablation for symptomatic interdigital (Morton's) neuroma**

Interdigital (Morton's) neuroma affects one of the nerves leading to the toes. It can cause a burning pain in the ball of the foot and pain, tingling and numbness in the toes.

In this procedure, a thin probe is inserted at the base of one of the toes and into the affected nerve. An electric current passed through the probe destroys the nerve with radiofrequency heat energy.

### **Introduction**

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

### **Date prepared**

This IP overview was prepared in 30 March 2015.

### **Procedure name**

- Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma

### **Specialist societies**

- British Orthopaedic Foot and Ankle Society
- The Society of Chiropractors and Podiatrists
- British Society of Skeletal Radiologists

## Description

### ***Indications and current treatment***

Symptomatic interdigital (Morton's) neuroma is caused by perineural fibrosis which creates scar tissue, resulting in compression of an interdigital nerve. It usually occurs between the metatarsal heads of the third and fourth toes but can sometimes occur between the second and third toes. Symptoms include severe intermittent pain, a burning sensation, and paraesthesia in the front part of the sole of the foot extending into the toes.

Initial management of symptomatic Morton's neuroma includes rest, anti-inflammatory medications, using an orthosis in the shoe and wearing a different type of shoe. Injection of steroids and local anaesthetic may be used. Persistent symptoms may be treated by cryoablation or surgical removal of the nerve (neurectomy).

### ***What the procedure involves***

Radiofrequency ablation (RFA) for symptomatic Morton's neuroma is a percutaneous treatment, which is usually done as an outpatient procedure under local anaesthesia. Using imaging guidance, an RFA probe attached to a generator is inserted into the web space between the toes and into the area of the neuroma. Controlled pulses of radiofrequency energy are delivered, which cause thermal ablation of the nerve. After the procedure, a steroid injection is usually given to reduce pain and inflammation. Patients are discharged as soon as comfortable and advised to limit their walking for 1 or 2 days. Any pain is managed with analgesics. The procedure can be repeated if necessary after a few weeks.

## Literature review

### ***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to radiofrequency ablation for symptomatic interdigital (Morton's) neuroma. The following databases were searched, covering the period from their start to 30-03-15: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with symptomatic interdigital (Morton's) neuroma.
Intervention/test	Radiofrequency ablation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### ***List of studies included in the IP overview***

This IP overview is based on 182 patients from 5 case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

**Table 2 Summary of key efficacy and safety findings on radiofrequency ablation for symptomatic interdigital (Morton's) neuroma**

**Study 1 Finney W (1989)**

**Details**

Study type	Retrospective case series
Country	USA (single centre)
Recruitment period	1977–86
Study population and number	n=71 patients (79 nerve lesions) 35% (28/79) presented in the second web space, 59% (47/79) in the third web space, 5% (4/79) in fourth web space. Mean duration of symptoms: not reported.
Age and sex	mean 54 years; (67/71) female
Patient selection criteria	Patients with symptomatic Morton's neuroma treated previously (12 by surgical excision, 68 by a variety of pads, shoe alterations, orthotic devices, and cortisone injections).
Technique	Radiofrequency ablation (using Radionics nerve lesion generator) was performed. The foot is prepared and local anaesthesia injected proximally between the involved metatarsal necks and distally between the involved toes. An insulated or Teflon-coated active electrode is passed dorsal to plantar, between the metatarsal necks and just inferior to them. An inactive electrode (used as grounding needle) is passed beneath the metatarsal ligament. The location is conformed through fluoroscopy or radiograph. The active electrode tip temperature is adjusted to 85°C and it is moved gently within the sagittal plane, dorsal to plantar and proximal to distal, until a pain response similar to neuroma is obtained. The temperature is maintained for 90 seconds. The symptoms resolve within 30–45 seconds until neurolysis occurs. 80% (57/71) of patients had 1 procedure; 27% (19/71) had 2; and 3% (3/71) had 3 procedures.
Follow-up	<b>Not reported.</b>
Conflict of interest/source of funding	Not reported

**Analysis**

**Follow-up issues:** not clear.

**Study design issues:** small sample size, retrospective review of patients, patients responded to a mailed questionnaire. Pain responses were assessed by 3 different questions: pain assessment done with a 0–5 numerical pain intensity scale (0 being absence of pain and 5 being severe pain).

No ultrasound guidance was used during the procedure.

**Study population issues:** 41 were left feet and 38 were right feet. Eight patients had bilateral neuromas.

**Key efficacy and safety findings**

Efficacy	Safety								
<p>Number of patients analysed: <b>71 patients (79 nerve lesions)</b></p> <p><b>Pain score before and after treatment (on a pain scale 0-5)</b></p> <table><tr><td></td><td>Mean pain rating</td></tr><tr><td>Preoperatively</td><td>4.53</td></tr><tr><td>Postoperatively</td><td>2.02</td></tr><tr><td>Difference*</td><td>2.51 (or an average of 56% improvement in symptoms)</td></tr></table> <p>*no statistical significance reported</p> <p><b>Symptom relief after treatment (rated as worse, same, improved or gone)</b></p> <p>71% (56/79) of the patients reported that their symptoms were improved or completely gone. 5% (4/79) patients stated their symptoms were worse and 24% (19/79) reported they were same.</p> <p><b>Satisfaction with treatment</b></p> <p>68% (54/71) patients said they were pleased with the treatment and 32% (25/71) were not pleased with the treatment. The patients with prior excisional surgery (n=12) responded similarly to RFA as those with no prior surgery (n=68).</p> <p><b>Absence from work:</b> Average 1.5 days (range 0–7 days).</p> <p>Postoperative pain medications were taken by 20% of the patients.</p>		Mean pain rating	Preoperatively	4.53	Postoperatively	2.02	Difference*	2.51 (or an average of 56% improvement in symptoms)	<p><b>Complications</b></p> <p><b>Burns:</b> 2 patients incurred burns at the inactive (grounding) electrode site (as a result of the electrode being placed too superficially). These patients were absent from work for a week each.</p>
	Mean pain rating								
Preoperatively	4.53								
Postoperatively	2.02								
Difference*	2.51 (or an average of 56% improvement in symptoms)								
Abbreviations used: NPS, numerical pain score; RFA, radiofrequency ablation.									

## Study 2 Genon M (2010)

### Details

Study type	Retrospective case series (survey)
Country	Australia (single centre)
Recruitment period	2006–08
Study population and number	n= <b>37 patients (38 neuromas)</b> 53% (20/38) presented in the second web space, 47% (18/38) in the third web space. Mean duration of symptoms: at least 12 months (in 28 patients)
Age and sex	Not reported
Patient selection criteria	Patients with symptomatic Morton's neuroma in whom conservative management failed
Technique	Radiofrequency ablation (using Neurotherm NT 500) was performed as a day procedure. Using an antiseptic technique, a guide needle with the insulating cannula was used to locate the neuroma. The needle was introduced from the dorsum of the appropriate inter-metatarsal space, 2–2.5cm proximal to the skin web fold. The needle was inserted deep to the transverse metatarsal ligament and adjusted to the point of maximal tenderness, assumed to be in the main body of the neuroma. Leaving the cannula in situ, the guide needle was removed and then an RFA electrode was inserted. Sedation was then administered. Current intensity increased until the temperature reached 90°C. The electrode was left in for 3 minutes to ablate the neuroma. After the procedure, local anaesthetic was injected. The patient was allowed to bear weight as tolerated and was discharged the same day.
Follow-up	<b>average 10.6 months (range 3–21 months)</b>
Conflict of interest/source of funding	None

### Analysis

**Follow-up issues:** limited follow-up.

**Study design issues:** small sample size, retrospective review of patients, survey was undertaken. Pain assessment done with a 0–10 numerical pain intensity scale.

No ultrasound guidance was used during the procedure.

**Study population issues:** 22 were left feet and 16 were right feet.

**Key efficacy and safety findings**

Efficacy	Safety																															
<p>Number of patients analysed: <b>37 patients (38 neuromas)</b></p> <p><b>Resolution of symptoms % (n)</b></p> <table><tr><td>Complete relief</td><td>18.4 (7/38)</td></tr><tr><td>Partial relief</td><td>55.3 (21/38)</td></tr><tr><td>No relief</td><td>26.3 (10/38)</td></tr></table> <p><b>Resolution of symptoms according to location of neuromas</b></p> <table><tr><th>Location of neuromas</th><th>complete/partial relief % (n)</th></tr><tr><td>Second web space (n=20)</td><td>50%</td></tr><tr><td>Third web space (n=18)</td><td>100%</td></tr></table> <p>Patients who reported no relief had neuromas in second web space.</p> <p>84% of patients with third web space neuromas were satisfied compared with 45% of those with neuromas in second web space.</p> <p><b>Numerical pain scores (NPS)</b></p> <table><tr><th></th><th>pre-RFA</th><th>post-RFA</th></tr><tr><td>Median NPS</td><td>9.0 (8.0–9.0)</td><td>5.0 (3.0–8.0)</td></tr><tr><td>Median NPS in patients with complete relief (n=7)</td><td>9.0</td><td>2.0</td></tr><tr><td>Median NPS in patients with partial relief (n=21)</td><td>9.0</td><td>5.0</td></tr><tr><td>Median NPS in patients with no relief (n=10)</td><td>9.0</td><td>9.0</td></tr></table> <p><b>Patient satisfaction % (n)</b></p> <table><tr><td>Satisfied</td><td>86.8 (32/37)</td></tr><tr><td>Not satisfied</td><td>13.2 (5/37)</td></tr></table> <p>83.7% patients said they would have the procedure again.</p> <p><b>Repeat RFA treatment</b></p> <p>Two patients with no relief had repeat treatment but were not satisfied with the outcome. No further treatment was provided to these patients.</p> <p><b>Progressing to surgical excision</b></p> <p>Overall, 29% (11/38) patients (3 with partial relief and 8 with no relief) underwent surgical excision of the neuromas. The time to surgery was not reported. 6 had complete relief, 3 had partial relief, 1 had no change in symptoms and 1 got worse. The average NPS decreased from 6.9 to 2.7.</p>	Complete relief	18.4 (7/38)	Partial relief	55.3 (21/38)	No relief	26.3 (10/38)	Location of neuromas	complete/partial relief % (n)	Second web space (n=20)	50%	Third web space (n=18)	100%		pre-RFA	post-RFA	Median NPS	9.0 (8.0–9.0)	5.0 (3.0–8.0)	Median NPS in patients with complete relief (n=7)	9.0	2.0	Median NPS in patients with partial relief (n=21)	9.0	5.0	Median NPS in patients with no relief (n=10)	9.0	9.0	Satisfied	86.8 (32/37)	Not satisfied	13.2 (5/37)	<p><b>Complications</b></p> <p>None related to RFA.</p>
Complete relief	18.4 (7/38)																															
Partial relief	55.3 (21/38)																															
No relief	26.3 (10/38)																															
Location of neuromas	complete/partial relief % (n)																															
Second web space (n=20)	50%																															
Third web space (n=18)	100%																															
	pre-RFA	post-RFA																														
Median NPS	9.0 (8.0–9.0)	5.0 (3.0–8.0)																														
Median NPS in patients with complete relief (n=7)	9.0	2.0																														
Median NPS in patients with partial relief (n=21)	9.0	5.0																														
Median NPS in patients with no relief (n=10)	9.0	9.0																														
Satisfied	86.8 (32/37)																															
Not satisfied	13.2 (5/37)																															
Abbreviations used: NPS, numerical pain score; RFA, radiofrequency ablation.																																

## Study 3 Moore JL (2012)

### Details

Study type	Retrospective case series
Country	USA (single centre)
Recruitment period	2007–10
Study population and number	n=29 patients (32 feet) All neuromas located within the second or third intermetatarsal space.
Age and sex	age range 23–73 years; 76% (22/29) female
Patient selection criteria	Patients with symptomatic neuroma pain of the foot not relieved by routine conservative treatments (injections for 4–8 weeks), diagnosed by clinical presentation and physical examination. There were no inclusion or exclusion criteria in the study.
Technique	Maximum point of tenderness was marked and anaesthesia was first administered, then a sharp tip probe was inserted from dorsal to plantar at the area of maximum pain under fluoroscopy. This was replaced with an RFA electrode, and the radiofrequency thermoneurolysis therapy process initiated at a temperature of 85°C for 90 seconds. The probe was removed and 4 mg dexamethasone was injected into the surgical site and a bandage applied. Patients were advised to bear weight as tolerated, use anti-inflammatory drugs if needed and followed up at regular intervals.
Follow-up	<b>Average 13 months (range 6 months to 3 years)</b>
Conflict of interest/source of funding	None

### Analysis

**Follow-up issues:** 2 patients were lost to follow-up after 1 month.

**Study design issues:** Small sample size, retrospective study. Final pain assessment was done at 6 months; none of the patients were using anti-inflammatory drugs.

**Study population issues:** 3 patients had neuroma pain bilaterally. One patient had type 2 diabetes. Four patients were unable to accurately pinpoint the area of pain and a second RFA procedure was done distally to assure pain relief.

### Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: <b>29 patients (32 feet)</b></p> <p><b>Symptom relief (rated as some relief, complete relief or no relief)</b> 83% (24/29) patients reported complete relief of symptoms (return to activity with no pain or disability) 1 month after RFA treatment. 17% (5/29) patients had minimal to no relief of symptoms (1 underwent open surgery, 2 were lost to follow-up and 2 were satisfied with minimal relief).</p> <p><b>Recurrence</b> One patient reported recurrence at 9 months, which was successfully treated with a combination of anaesthetic and steroid injection (bupivacaine/triamcinolone).</p> <p><b>Return to normal activities</b> All patients returned to normal shoes and activities within 2 days.</p> <p>Abbreviations used: RFA, radiofrequency ablation.</p>	<p><b>Complications</b> <b>Superficial cellulitis</b> (after 5 days, treated with a week's course of antibiotics) in 1 patient.</p>



## Study 4 Chuter GSJ (2013)

### Details

Study type	Retrospective case series
Country	Australia (single centre)
Recruitment period	January–September 2011
Study population and number	n= <b>25 patients (30 feet)</b> 40% (12/30) presented in the second web space, 60% (18/30) in the third web space. Mean duration of symptoms: 3.8 years (range 6 months to 15 years) Size of neuromas: average 10.7 mm (range 4–21 mm)
Age and sex	Mean 55 years; 84% (21/25) female
Patient selection criteria	Patients with Morton's neuroma (confirmed by MRI, ultrasound, or clinical history and examination), persistent or recurrent symptoms, presented for neurectomy but referred for radiofrequency ablation, tried previous methods of conservative management (80% orthotics, 60% cortisone injections). Patients with previous excision or recurrence (for example, stump neuromas) and 1 patient with neurofibromatosis were excluded.
Technique	Ultrasound-guided radiofrequency ablation (using Neurotherm NT 500) of Morton's neuroma performed by a single radiologist under local anaesthetic in an outpatient clinic. 5 cycles of 2 minutes each were used; with the probe tip maintain a temperature of 81°C. Steroid injection was used at the time of procedure. Treatment was repeated after 4 weeks if needed.  Average number of treatment sessions was 1.6 (range 1–3). Patients were reviewed 4 weeks later with a follow-up ultrasound scan and RFA was repeated if still symptomatic. If unsatisfied after 3 treatment sessions, they were referred back to clinic for further management (surgical excision).
Follow-up	<b>6 months</b>
Conflict of interest/source of funding	None

### Analysis

**Follow-up issues:** 6 months follow-up.

**Study design issues:** Small sample size.

**Study population issues:** only patients with primary Morton's neuroma were included. There were 19 left feet and 11 right feet. All patients had neuromas confirmed at the time of treatment ('focal well circumscribed anechoic lesion in the interdigital web space'). Eight feet had additional neuromas in the adjacent web space (second or third) treated with radiofrequency ablation. Three patients had asymptomatic bilateral bunions (hallux vagus) of which 2 had bilateral symptomatic neuromas.

**Key efficacy and safety findings**

Efficacy	Safety								
<p>Number of patients analysed: <b>25 patients (30 feet)</b></p> <p><b>Change in visual analogue pain scores (measured on a VAS scale 0–10)*</b></p> <table><tr><td></td><td>Pre-treatment</td><td>6 months post-treatment</td><td>p value</td></tr><tr><td>VAS pain score on activity mean (range)</td><td>6.0 (3–9)</td><td>1.7 (0–8)</td><td>&lt;0.001</td></tr></table> <p>Only 4 patients at pain at rest prior to RFA and all had pain on activity.</p> <p>*higher score representing worst ever pain.</p> <p>There was no statistically significant difference in the mean reduction in VAS between second (9 feet) and third web space (13 feet) neuromas (4.3 versus 3.3, p=0.299).</p> <p><b>Symptom improvement</b></p> <p>The average overall symptom improvement (defined as ‘as described by the patient’, no further explanation given) was 76% (range 0–100%).</p> <p><b>Satisfactory outcome:</b></p> <p>At 6 months 87% (26/30) of feet had a satisfactory outcome (not defined in the paper) without the need for further surgery.</p> <p>No statistically significant correlation was found between pain or outcome, and any of the following: age, gender, site, size, number, symptom duration, activity level or previous treatment.</p> <p>32% (8/25) patients described the experience as unpleasant but would have the procedure again as first line treatment. Those who had surgery preferred RFA as first-line treatment.</p> <p><b>Progression to surgical excision:</b> 10% (3/30).</p> <p>One patient had no improvement, 1 had 40% improvement but wanted surgery, and 1 had 100% improvement initially but had recurrence within 6 months. Subsequent surgery resolved symptoms in all.</p>		Pre-treatment	6 months post-treatment	p value	VAS pain score on activity mean (range)	6.0 (3–9)	1.7 (0–8)	<0.001	<p><b>Complications</b></p> <p><b>Temporary posterior tibial nerve irritation</b> (for 3 weeks, resolved): 1</p> <p><b>Ongoing unchanged pain</b> (no obvious cause): 1</p>
	Pre-treatment	6 months post-treatment	p value						
VAS pain score on activity mean (range)	6.0 (3–9)	1.7 (0–8)	<0.001						
Abbreviations used: VAS, visual analogue score; RFA, radiofrequency ablation.									

## Study 5 Deniz S (2015)

### Details

Study type	Case series (prospective)
Country	Turkey (single centre)
Recruitment period	2010–2011
Study population and number	n=20 patients (22 neuroma) 32% (7/22) present in the second web space, 59% (13/22) in the third web space, 9% (2/22) in fourth webspace.
Age and sex	Mean 48.4 years; 80% (16/20) female
Patient selection criteria	Patients with Morton's neuroma and symptomatic neuroma pain in the foot not relieved by routine conservative treatment, evaluated by a specialised orthopaedist. Patients with diabetic foot or neuropathy, coagulopathy, problems with venous drainage of the lower extremity, Burger's disease and those not treated by conventional treatment were excluded.
Technique	Pulsed radiofrequency ablation was performed under sedation and local anaesthetic. Ultrasound was used to confirm the placement of probe in the correct spaces. A straight RF cannula is first placed through the neuroma and then a RF electrode is placed in the cannula and therapy performed at 42 degrees for 300 seconds. Bupivacaine 5 mg is then injected and cannula removed. Patients are observed for 2 hours and then discharged.
Follow-up	Mean 9 months
Conflict of interest/source of funding	None reported

### Analysis

**Follow-up issues:** minimum follow-up was 7 months with maximum follow-up of 15 months.

**Study design issues:** Small sample size. Pain level measured on a numerical rating scale from 0 to 10. Successful pain control, comfort when walking (yes or no) and satisfaction level (satisfied or not satisfied) were also evaluated.

**Study population issues:** 2 patients had 2 space neuroma.

### Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: <b>20 patients (22 neuroma)</b></p> <p><b>Change in pain score</b></p> <p>The mean numerical pain rating score of patients was <math>7.1 \pm 0.26</math> before the procedure and <math>3.3 \pm 0.54</math> at 6-month follow-up (<math>p &lt; .0001</math>).</p> <p><b>Symptom improvement</b></p> <p>90% (18/20) reported somewhat relief of symptoms after treatment and only 10% (2/20) reported no change in symptoms. Successful pain control (a <math>\geq 50\%</math> decrease in pain) was reported in 60% (12/20) of patients. Wearing shoes and walking without any pain was reported in 80% (16/20) patients.</p> <p><b>Satisfaction:</b> 60% (12/22) patients reported excellent satisfaction with this procedure.</p>	<p><b>Complications</b></p> <p><b>superficial cellulitis: 1</b></p> <p><b>moderate hematoma: 1</b></p> <p>Both patients were treated with antibiotic agents, non-steroidal anti-inflammatory drugs and elevation of the foot.</p>
Abbreviations used: RFA, radiofrequency ablation.	

## ***Efficacy***

### **Pain scores**

A case series of 25 patients (in 30 feet) with symptomatic interdigital (Morton's) neuroma reported a statistically significant reduction in pain scores on activity after ultrasound-guided radiofrequency ablation (RFA) treatment. Pain scores were measured on a visual analogue scale (assessed on a scale of 0–10, with lower scores indicating less pain) and were an average 6.0 at baseline compared with 1.7 at 6-month follow-up ( $p < 0.001$ )<sup>4</sup>.

A case series of 37 patients (38 neuromas) for whom conservative management failed and who had RFA, reported median numerical pain scores (assessed on a scale of 0–10, with lower scores indicating less pain). Pain scores decreased from 9.0 at baseline to 5.0 at an average follow-up of 10.6 months. In those who reported complete resolution of symptoms ( $n=7$ ) and partial relief ( $n=21$ ) the median numerical pain score reduced from 9.0 to 5.0 ( $p$  value not reported). In those who had no relief ( $n=10$ ) it did not change<sup>2</sup>.

A case series of 20 patients (22 neuromas) for whom conservative management failed and who had pulsed RFA reported that the mean numerical pain rating score was  $7.1 \pm 0.26$  before the procedure and  $3.3 \pm 0.54$  at 6 month follow-up ( $p < 0.0001$ ).

### **Symptom improvement**

The case series of 25 patients reported that the average overall symptom improvement (as described by patients, not otherwise defined) was 76%<sup>4</sup>.

The case series of 37 patients (38 neuromas) reported that for 74% of neuromas there was complete or partial resolution of symptoms and for 26% there was no benefit from RFA treatment at an average follow-up of 10.6 months. All patients with neuromas in the third web space ( $n=18$ ) reported complete or partial relief of symptoms compared with only 50% of those with second web space neuromas ( $n=20$ )<sup>2</sup>.

A case series of 29 patients (in 32 feet) reported that 83% (24/29) patients had complete relief of symptoms at 1 month after RFA treatment and 17% (5/29) had minimal to no relief of symptoms<sup>3</sup>.

The case series of 20 patients (22 neuromas) reported that 60% (12/20) patients achieved successful pain control (a  $\geq 50\%$  decrease in pain) after the treatment. Comfort wearing shoes and walking without pain was reported in 80% (16/20) patients.

### **Repeat RFA treatment**

The case series of 37 patients reported that 2 patients with no symptom relief had repeat RFA treatment but were not satisfied with the outcome at an average follow-up of 10.6 months. No further treatment was offered<sup>2</sup>.

### **Patient satisfaction**

The case series of 37 patients reported that 87% (32/37) of patients were satisfied with RFA treatment at an average follow-up of 10.6 months. Most patients (84%) said that they would have the procedure again<sup>2</sup>.

The case series of 25 patients reported that at 6 months 87% (26/30) of feet had a satisfactory outcome (not defined) without the need for further surgery. It was reported that 32% (8/25) of patients described the experience as unpleasant but would have the procedure again as first-line treatment<sup>4</sup>.

A case series of 71 patients reported that 68% (54/71) of the patients were satisfied with RFA treatment and 32% (25/71) were not satisfied with RFA treatment<sup>1</sup>.

The case series of 20 patients reported that 60% (12/22) patients had excellent satisfaction with this procedure.

### **Recurrence**

The case series of 29 patients (in 32 feet) reported symptom recurrence in 1 patient at 9-month follow-up. This was successfully treated with an injection of steroid and local anaesthetic<sup>3</sup>.

### **Progression to surgical removal**

Progression to surgical removal of the neuromas was reported for 29% (11/38) of neuromas (3 neuromas in patients with partial relief and 8 neuromas in patients with no symptom relief) in the case series of 37 patients (38 neuromas) at an average follow-up of 10.6 months. Of the patients who had surgical removal, 6 patients had complete relief of symptoms, 3 had partial relief, 1 had no change in symptoms and 1 got worse. The average numerical pain score decreased from 6.9 to 2.7 (p value not reported)<sup>2</sup>.

Surgical removal was reported in 10% (3/30) neuromas after the procedure in the case series of 25 patients. One patient had no improvement after RFA, 1 had 40% improvement but wanted surgery, 1 had 100% improvement initially but symptoms recurred within 6 months. Subsequent surgery resolved symptoms in all<sup>4</sup>.

## **Safety**

### **Pain**

Ongoing, unchanged pain after RFA treatment was reported in 1 patient in the case series of 25 patients. Further investigations found no obvious cause for his symptoms<sup>4</sup>.

### **Superficial cellulitis**

Superficial cellulitis 5 days after RFA treatment was reported in 1 patient in a case series of 29 patients. This was treated with a course of antibiotics<sup>4</sup>.

Superficial cellulitis was reported in 1 patient in the case series of 20 patients. This was treated with antibiotics, non-steroidal anti-inflammatory drugs and elevation of the foot<sup>5</sup>.

### **Haematoma**

Moderate haematoma was reported in 1 patient in the case series of 20 patients. This was treated with antibiotics, non-steroidal anti-inflammatory drugs and elevation of the foot<sup>5</sup>.

### **Temporary nerve irritation**

Irritation of the posterior tibial nerve for 3 weeks after the procedure was reported in 1 patient in a case series of 25 patients. This resolved completely<sup>4</sup>.

### **Burns**

Burns at the site of the inactive (grounding) electrode (explained by the authors as a result of the electrode being placed too superficially) were reported in 2 patients in an early case series of 71 patients published in 1989. These patients were each off work for a week<sup>4</sup>.

### ***Validity and generalisability of the studies***

- There are no randomised controlled trials. Only 4 small retrospective case series have been published on this procedure.
- Most of the patients were women.
- One study used ultrasound and steroid injection in the treatment protocol<sup>4</sup>.
- There was a lack of long-term follow-up in the included studies.

### ***Existing assessments of this procedure***

There were no published assessments from other organisations identified at the time of the literature search.

***Related NICE guidance***

There is currently no NICE guidance related to this procedure.

**Specialist advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to where comments are considered voluminous, or publication would be unlawful or inappropriate. Eleven Specialist Advisor Questionnaires for radiofrequency ablation for symptomatic interdigital (Morton's) neuroma were submitted and can be found on the [NICE website](#).

**Patient commentators' opinions**

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

**Issues for consideration by IPAC**

Studies on the use of radiofrequency ablation for symptomatic interdigital (Morton's) neuroma are limited.

## References

1. Finney W et al (1989). Treatment of Morton's neuroma using percutaneous electrocoagulation. *Journal of the American Podiatric Medical Association*. 79: 615-8.
2. Genon MP, Chin TY, Bedi HS and Blackney MC (2010). Radio-frequency ablation for the treatment of Morton's neuroma. [Review]. *ANZ Journal of Surgery* 80 (9) 583-585.
3. Moore JL, Rosen R, Cohen J, and Rosen B (2012). Radiofrequency thermoneurolysis for the treatment of Morton's neuroma. *Journal of Foot & Ankle Surgery* 51: 20-22.
4. Chuter GS, Chua YP, Connell DA, and Blackney MC (2013). Ultrasound-guided radiofrequency ablation in the management of interdigital (Morton's) neuroma. *Skeletal Radiology* 42 (1) 107-111.
5. Deniz S, Purtuloglu T, Tekindur S et al (2015). Ultrasound-Guided Pulsed Radio Frequency Treatment in Morton's Neuroma. *Journal of the American Podiatric Medical Association* 105 (4) 302-306.



## Appendix A: Additional papers on radiofrequency ablation for symptomatic interdigital (Morton's) neuroma

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Bregman PJ (2012). Radiofrequency thermoneurolysis for the treatment of Morton's neuroma. Journal of Foot & Ankle Surgery 51 (3) 405.			Letter in response to article.
Gobbi, F., Mazzetti, R., et al (2014). Ultrasound guided radiofrequency ablation of Morton's neuroma: Preliminary results. Regional Anesthesia and Pain Medicine. Conference: 33rd Annual European Society of Regional Anaesthesia and Pain Therapy, ESRA Congress 2014 Seville Spain. Conference Start: 20140903 Conference End: 20140906. Conference Publication: (var.pagings).39 (5 S (var.pagings) e302-e303.	Prospective cohort study 2013 n=16 (20 feet) patients Ultra-sound guided radiofrequency ablation Follow-up: 6 months	No post-procedure complications. At the end of the procedure (about 15 minutes) patients could immediately walk and go back to their daily activities. In 3 cases it was necessary to repeat the RF treatment. Dysesthesias reported by 75% of patients in the area of the treated nerve regressed on average after 4 weeks. Pre-treatment pain was present in 100% of cases. Based on preliminary data currently available, 75% of patients reported a virtually full reduction of pain after the RF treatment, 16% a very limited reduction, 9% no reduction. Conclusions: The preliminary study of ultra-sound guided radiofrequency ablation of MN shows a significant regression to disappearance of the pain symptoms. Available data on the duration of the treatment efficacy show a good short-medium term outcome (1-3 months) and are encouraging on the medium-long term (6 months).	Conference abstract.

## **Appendix B: Related NICE guidance for radiofrequency ablation for symptomatic interdigital (Morton's) neuroma**

There is currently no NICE guidance related to this procedure.

## Appendix C: Literature search for radiofrequency ablation for symptomatic interdigital (Morton's) neuroma

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	18/08/2015	Issue 8 of 12, August 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	18/08/2015	Issue 7 of 12, July 2015
HTA database (Cochrane Library)	18/08/2015	Issue 3 of 4, July 2015
MEDLINE (Ovid)	18/08/2015	1946 to August week 1 2015
MEDLINE In-Process (Ovid)	18/08/2015	August 17, 2015
EMBASE (Ovid)	18/08/2015	1974 to 2015 week 33
PubMed	20/08/2015	n/a
<a href="#">JournalTOCS</a>	18/08/2015	n/a

Trial sources searched on

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

### Medline search strategy

- 1 ablation techniques/ (1161)
- 2 denervation/ (13295)

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- 3 catheter ablation/ (23481)
- 4 radio waves/ (6150)
- 5 ((radiofrequen\* or radio-frequen\* or "radio frequen\*") adj4 (denervat\* or ablat\*)),ti,ab. (12833)
- 6 (RFA or (rf adj4 ablat\*)),ti,ab. (5733)
- 7 ((catheter\* or prob\* or needle\* or electro\* or heat\*) adj4 (denervat\* or ablat\*)),ti,ab. (9358)
- 8 ((ultrasound\* or ultra-sound\*) adj4 guid\*)),ti,ab. (16382)
- 9 or/1-8 (63757)
- 10 Foot/ (21202)
- 11 nerve compression syndromes/ (9410)
- 12 Metatarsal Bones/ (2743)
- 13 Neuroma/ (2480)
- 14 Peripheral Nervous System Neoplasms/ (4113)
- 15 ((morton\* or plantar\* or interdigital\* or inter-digital\* or inter-metatarsal\* or intermetatarsal\*) adj4 (neurectom\* or syndrome\* or neuroma\* or entrap\* or neuralgi\* or neuritis\* or metatarsalgi\*)),ti,ab. (640)
- 16 (metatarsophalangeal\* adj4 (joint\* or articulat\*) adj4 (nerve\* or compress\* or pain\* or numb\* or burn\* or sore\* or swell\* or discomfort\* or ache\* or dysesthesia\* or tender\* or tingl\* or cramp\*)),ti,ab. (110)
- 17 ((toe\* or foot\* or feet\* or meta-tarsal\* or metatarsal\* or tarsal\* or (plantar\* adj4 digital\*)) adj4 (nerve\* or compress\* or pain\* or numb\* or burn\* or sore\* or swell\* or discomfort\* or ache\* or dysesthesia\* or tender\* or tingl\* or cramp\*)),ti,ab. (5684)
- 18 or/10-17 (43673)
- 19 9 and 18 (278)
- 20 animal/ not human/ (3999797)
- 21 19 not 20 (182)
- 22 limit 21 to ed=20150330-20150831 (9)