Open release versus radiofrequency microtenotomy in the treatment of lateral epicondylitis: a prospective randomized controlled trial

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Abstract

Background: Optimal surgical treatment of lateral epicondylitis remains uncertain. Recently, radiofrequency microtenotomy (RFMT) has been proposed as a suitable treatment. We compared RFMT with standard open release (OR) in this prospective randomized controlled trial.

Methods: In total, 41 patients with symptoms for at least 6 months were randomized into two groups: 23 patients had RFMT and 18 had OR. Two patients from RFMT withdrew. Each patient underwent Numerical Rating Scale (NRS) pain score, grip strength and Disabilities of the Arm, Shoulder and Hand (DASH) scores pre-operatively and at 6 weeks. Pain and DASH scores were repeated at 6 months and 12 months.

Results: NRS pain scores improved by 4.8 points for RFMT and by 3.9 points for OR. There was a significant improvement in both groups from pre-operative scores, although there was no statistically significant difference between the groups at 1 year. Grip strength improved by 31% in the RFMT group compared to 38% in OR. There was no significant difference between the initial and 6 weeks scores or between treatments. At 1 year, DASH was 39.8 points for RFMT and 24.4 points for OR. There was a significant improvement in both groups from pre-operative scores, although there was no statistically significant difference between the groups at 1 year.

Conclusions: Both groups showed significant improvements and similar benefit to the patient. The results of the present study do not show any benefit of RFMT over the standard OR. As a result of the extra expense of RFMT, we therefore recommend that OR is offered as the standard surgical management.

Keywords

DASH, grip strength, lateral epicondylitis, open release, radiofrequency microtenotomy, tennis elbow

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Introduction

Lateral epicondylitis has long been recognized as a misnomer and it is now considered a tendinosis of the common extensor origin, most commonly extensor carpi radialis brevis. The debate over aetiology is as strong as that over management, although all agree that repetitive micro trauma is the causative factor. Whether this is secondary to ischaemia, shear forces, protein kinase activation, thermal injury or stress shielding still remains unclear. There are four recognized stages from the initial injury leading to fibrosis and calcification.^{1–6}

The diagnosis is usually clinical with tenderness in the region of the common extensor origin, weakness of the grip and pain on resisted dorsiflexion of the wrist and fingers. Diagnostic tests are not usually performed. An absence of neovascularization and grey scale change

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on ultrasound may exclude lateral epicondylitis, whereas findings of degeneration and injury at the common extensor origin on magnetic resonance imaging (MRI) do not correlate well with clinical findings. Changes on investigations such as these have been shown not to be reliable when compared with symptoms described by patients and with the clinical signs encountered. This may be a result of the presence of other pathologies, although the condition can also be clinically present in the absence of positive imaging. The most reliable way of diagnosing lateral epicondylitis is clinically.¹

This is a common condition,⁷ and a majority of patients respond to non-operative management of which there are many.⁸ No single treatment has been shown to be clearly superior to the rest.^{9–11} Non-operative measures include physiotherapy, eccentric exercises, shock wave therapy,^{12,13} radiofrequency lesioning, laser, acupuncture, topical nitrates, straps, and injections of corticosteroid,³ botulinum toxin, autologous blood or platelet rich plasma.^{11,13–15} For those with refractory symptoms, further surgical options include microtenotomy and open release (OR), with or without reconstruction. Many techniques for release have been described that can be performed either open or arthroscopically.¹

Open release has been the traditional operative treatment of choice, although radiofrequency microtenotomy (RFMT) is another option that has been introduced relatively recently. Although its method of working is debated,^{16,17} human trials have suggested RFMT to be a safe and effective treatment but not superior to OR.^{18–20} One of these trials was a simple cohort study evaluating the effectiveness of microtenotomy with no control.²⁰ The only available randomized controlled trial, whose results are reported at 18 months¹⁹ and 5 years to 7 years,¹⁸ also compared OR with microtenotomy but had a very small sample size with no pre-trial power calculation.^{18,19}

It is therefore unclear what the optimal surgical management of refractory lateral epicondylitis is and whether the advent of RFMT brings significant benefits over traditional OR.

The aim of this prospective randomized controlled study was to compare the efficacy of OR and RFMT in the surgical management of lateral epicondylitis and determine whether one is superior to the other.

Materials and methods

Power calculation

A pre-trial power calculation was performed to ensure that there were adequate numbers in both arms of the trial to detect a statistically significant change in primary and secondary outcome measures. A sample size

of 22 per group had 80% power to detect a difference in mean change of 2 on the NRS pain score with a two-sided significance level of 0.05 using an independent *t*-test. Similarly, there was 89% power to detect a difference with a mean change of 10 on the Disabilities of the Arm, Shoulder and Hand (DASH) score. This difference also had a two-sided significance level of 0.05 using an independent *t*-test. As a result of recruited patients being removed from the study, as explained below, a post-hoc power analysis was performed. This showed that our results had a 90% power to detect a change of 2 in the NRS and thus we did not re-open recruitment at that stage. We used 2 on the NRS pain score because the study by Salaffi et al.²¹ showed that this best correlated with 'much better' on the patient global impression of change, which is a validated rating system in patients with chronic musculoskeletal pain. We used a change of 10 on the DASH score because Schmitt and Fabio²² showed this to be the minimal clinically important difference.

Study protocol

The inclusion criteria for the present study were patients who had a clinical diagnosis of lateral epicondylitis and who had failed non-operative treatment with local steroid injections and physiotherapy. Patients were excluded if they were unable to provide written, informed consent and if they had ipsilateral arm pathology that would interfere with assessment. Ethics committee approval was obtained through the North of Scotland Research Ethics Committee, study number: 11/AL/0385. The trial was undertaken in accordance with CONSORT guidelines as shown in the CONSORT flow diagram (Figure 1).

Fifty patients were eligible and recruited. All patients had lateral sided elbow pain, which was made worse on resisted wrist dorsiflexion with tenderness over the common extensor origin. All patients had tried conservative management unsuccessfully, including at least one steroid injection. Only 41 patients were randomized to take part in the study. Nine patients awaiting randomization and surgery were sent to another treatment facility because of waiting time pressures. These patients were therefore removed from the study.

Patients were randomized via sealed envelope, which was opened by the operating surgeon on the day of surgery. The envelopes were prepared with 25 slips per group each indicating open or TOPAZ at the start of the trial; these were then shuffled, numbered and opened consecutively. The patients were blinded and the procedure that they underwent was only revealed after the final assessment. The assessors were not blinded. The OR group had 18 patients and the

Figure 1. CONSORT 2010 flow diagram.

RFMT had 23 patients. Two patients withdrew from the study following the 6-months telephone review because they no longer wished to take part. Data collected up until withdrawal were included for analysis.

Operative technique

Both treatments were performed under general anaesthetic as a day case. The incisions were the same from both procedures, with a 5-cm incision based over the lateral epicondyle. Patients were blinded with regard to the surgical intervention that they underwent until the final review.

Open release. A distally based horseshoe shaped flap was raised in the common extensor origin, the underlying bone surface was smoothed and any obvious inflammatory or degenerate tendon debrided. The flap was not repaired. The capsule was not breached, nor was the joint entered.

Radiofrequency microtenotomy. The common extensor origin was identified and, using a TOPAZ Microdebrider coblation Wand (Arthrocare, Austin, TX, USA), multiple passes were made with the tip through the tendon at approximately 5-mm intervals to varying depths and for varying lengths of time.

Postoperatively, patients were managed in a bulky bandage for 48 h and were then mobilized as able. They were advised not to perform any heavy lifting for 6 weeks. Both groups were given the same postoperative instructions.

Outcomes

Primary outcome measure recorded was NRS pain score at 12 months with secondary outcome measures NRS pain score at 6 weeks and 6 months, grip strength and DASH scores. These were recorded pre-operatively, as well as at 6 weeks, 6 months and 12 months postoperatively.

Grip strength was measured using a Jamar[®] Hydraulic Hand Dynamometer (Lafayette Instrument Company, Lafayette, IN, USA). The patients were instructed to sit with their shoulder at 90° forward flexion and elbow fully extended, aiming to reflect the position of most difficulty for those with tennis elbow. Position 3 provided a comfortable grip for all patients. Their maximal grip strength was then measured in pounds of force. We used the maximum score from three trials.

We used DASH as opposed to quick DASH because it gives greater precision in measurement of pain and arm function and we considered this would be prudent because these treatments have previously been shown to give similar results.

Statistical analysis

Statistical analysis was performed using Prism, version 7 (GraphPad Software, Inc., La Jolla, California, USA). All variables were continuous and therefore we used an independent *t*-test with a two-sided significance level of 0.05 to investigate the change in each outcome from baseline and compared this between the two groups. Although our data were not always normally distributed, the two groups had matching distributions and so a *t*-test was still valid, in accordance with our original design and allowing a consistent comparison.

Results

The demographics including hand dominance, participation in sports and occupational activity level were similar between the two groups, with no statistical differences (Table 1). Lateral epicondylitis in our group occurred more commonly in the dominant hand with a ratio of 3 : 2 and more commonly in women to men in a similar ratio. Baseline data were also similar between the two groups.

Pain NRS scores showed a significant improvement in both groups at all time points. Initial scores were 7.0 in

Table 1. Comparison of group demographics.

	RFMT	Open
Sex	16 female; 7 male	10 female; 8 male
Age (years)	49.3 (37 to 64)	46.3 (36 to 56)
Dominance	9 n 14 d	7 n 11 d
Occupation (n)		
Unemployed	3	2
Sedentary	7	5
Light	9	6
Moderate	4	5
Injections (n)	3.5	3
Regularly plays sports (n)	10	10

RFMT = radiofrequency microtenotomy, n = non-dominant, d = dominant.

the RFMT group and 7.9 in the OR group. At 6 weeks, RFMT had a mean (SD) improvement of -2.285 (0.5174) ($p=0.0001$) and OR had -4.689 (0.6012) ($p=0.0001$), with OR showing -2.716 (0.8105) points greater improvement, which was significant ($p=0.0021$). At 6 months, RFMT had improved -4.548 (0.7727) ($p=0.0001$) and OR was -4.801 (0.7148) ($p=0.0001$). At 1 year, RFMT was -4.974 (0.626) ($p=0.0001$) and OR was -5.124 (0.7024) ($p=0.0001$). The two groups were not significantly different (6 months: $p=0.8043$; 1 year: $p=0.8536$) (Figure 2).

DASH scores showed a significant improvement from pre-operative scores in both groups at all assessments. Pre-operative scores were 45.8 in the RFMT group and 50.0 in the OR group. At 6 weeks, RFMT had a mean improvement of 18.68 (4.876) ($p=0.0004$) and OR had 14.56 (6.085) points ($p=0.0230$). At 6 months, RFMT had improved 33.31 (5.369) points ($p=0.0001$) and OR 23.62 (6.03) points ($p=0.0004$). At 1 year, RFMT was 39.55 (4.956) points ($p=0.0001$) and OR was 28.31 (6.252) points ($p=0.0001$). The two groups were not significantly different at any time point. The mean difference between the two groups was 6.028 (6.43) points at 6 weeks ($p=0.3556$), 9.845 (7.879) at 6 months ($p=0.2198$) and 12.83 (7.927) at 12 months ($p=0.1144$) (Figure 3).

Grip strength was initially measured 41.2 lb in the RFMT group and 35.7 lb in the OR group. For RFMT, grip strength improved by 31% as opposed to 38% in OR, although there was no significant difference between the initial and 6-week scores

Figure 2. Graph showing the mean difference in Pain Numerical Rating Scale (NRS) score at each time point.

Figure 3. Graph showing the mean difference in Disabilities of the Arm, Shoulder and Hand (DASH) score at each time point.

Figure 4. Graph showing the difference in Grip Strength score at 6 weeks.

(RFMT: $p=0.9770$; OR: $p=0.2845$), nor between the two groups ($p=0.8601$) (Figure 4).

There was one superficial wound infection that cleared with a short course of oral antibiotics in the OR group. Two patients in the RFMT group who had continuing symptoms underwent OR after they completed the final assessment of the present study. At 6 months and 12 months, they were the only two patients (9%) in the RFMT group not to have an improvement. Interestingly, after these two patients underwent OR as a second procedure, one had an excellent result at 1 year (DASH score and NRS pain score both 0), whereas the other patient was still experiencing significant symptoms and considered that the second procedure had not helped either (DASH score of 66.7 and NRS pain score of 10). There were also two patients (11%) in the OR group whose symptoms showed no improvement.

Discussion

Radiofrequency coblation technology was initially developed for cardiac patients. It uses radiofrequency to break down the tissue at lower temperatures (40°C to 70°C) compared to radiofrequency ablation (70°C to 90°C) and other forms of electrosurgery (i.e. diathermy and lasers) (400°C to 600°C).^{20,23} The radiofrequency is applied to an ionic solution, such as saline. It excites the particles within saline to a point where they have sufficient energy to overcome molecular bonds within the tissue.²⁴ Histological studies of treated tissue showed angiogenesis along with changes in biochemical markers such as fibroblastic growth factor and vascular endothelial growth factor (VEGF).²⁴ Medlock et al.²⁵ found reduced levels of angiogenic growth factors in tendinosis of the rotator cuff and hypothesized that the angiogenic effects of radiofrequency coblation could aid treatment. A subsequent trial using nonhuman Achilles tendon showed angiogenic healing response to radiofrequency coblation with elevated levels of VEGF and α_v integrin.²⁶ Yet another study has suggested that degeneration or ablation of nerve fibres may be the mechanism by which pain is relieved.¹⁶

In 2005, Tasto et al.²⁴ reported the results of the first group of patients treated with radiofrequency coblation for lateral epicondylitis. They found significant improvements in Pain NRS scores, grip strength, DASH scores and quality of life scores, which was sustained over at least 2 years of follow-up. Patients demonstrated no complications. Patients were also assessed using MRI. Eleven of the 13 patients showed radiological signs of tendinosis; 10 of these showed improvement on follow-up scans.²⁴

In 2008, Meknas et al.¹⁹ compared radiofrequency microtenotomy to OR. They found that the

microtenotomy group had significant pain relief at 3 weeks, whereas the open group did not. Both groups at follow-up subsequently had significant pain relief and no difference between the two treatments. There was no difference between the groups in grip strength or Mayo Elbow Performance Scores. They also used dynamic infrared thermography to assess their patients and found that all patients had an area of increased temperature over or near (within 2 cm) of the lateral epicondyle. This had resolved postoperatively in 78% of patients and correlated well with those who had a reduced Pain NRS score.¹⁹ In 2013, Meknas et al.¹⁸ published the 5-year to 7-year follow up of the same group of patients, showing a sustained benefit over this time frame.

The results of the present study show that Pain NRS scores improved significantly at 6 weeks, 6 months and 12 months in both groups but, in contrast to Meknas et al.^{18,19}, we found that the OR group had a significantly greater improvement at the 6-week point, although this was not sustained, with both groups being similar at later follow-up. In keeping with this, DASH scores at 6 weeks were lower in the RFMT group but still demonstrated a significant improvement over baseline. However, the microtenotomy group scores were much higher than the open group at 6 months and 12 months. The DASH scores at 12 months showed a 12.83-point difference favourable to RFMT. Although this is above both the minimal detectable change 12.2 points and the minimal clinically important difference of 10.2 points,²³ it failed to reach statistical significance as a result of high variability and cross-over in our results. The range of results was high in both groups with 103.4 points of variation in the RFMT group compared to 98.9 points in the OR group, with a 91% cross-over between the range of the two groups. In keeping with Meknas et al.^{18,19}, we found no difference in grip strength.

In terms of health economy, the radiofrequency technique requires the additional expense of the probe, whereas, OR can be performed with minimal equipment. The results of the present study and those of previous studies^{18,19,24} would suggest the extra expense cannot be justified, although this could be offset if RFMT were being performed under local anaesthetic as an outpatient.

There is no statistical benefit of one treatment modality over another in the present study, although its limitations may contribute to this. An increased sample size may help to counteract the wide range of results found in the present study, particularly in the DASH score. Given that tennis elbow is traditionally considered to be self-limiting, it would be interesting to add a control arm to a study such as the present one. Because of the necessity of blinding, sham surgery would be required, which is difficult to justify and

ethical approval would be difficult to obtain. A follow-up of 1 year is sufficient to give an initial assessment of effect of each treatment modality, although the results of the present study show that improvements in DASH scores in the RFMT group continued to increase at both 6 months and 12 months. Further improvements may have been evident with a longer follow-up and it would be interesting to investigate whether the improvements that we recorded are sustained. It is also worth noting that a study using patient questionnaires as outcome measures is subject to the limitations of that particular tool, as well as whether it is sufficiently sensitive to show differences in the effects of two treatment modalities. DASH scores, however, have been validated for tennis elbow and are shown to correlate well with the more specific Patient-Rated Tennis Elbow Evaluation Questionnaire.²⁷

The present study adds to the limited information when comparing effect of OR versus RFMT in the surgical management of refractory lateral epicondylitis. It concurs with the only other prospective randomized study available in that there is no significant benefit of one against the other. This is relevant given the prevalence of this condition and will inform clinicians in their decision regarding its management.

Conclusions

Radiofrequency microtenotomy and OR are both safe and effective techniques for the surgical treatment of refractory lateral epicondylitis. For both groups, at all time points, there were significant improvements compared to pre-operative measurements. There was no statistical significance between the two groups for any outcome at the final measurement. We therefore cannot conclude definitively that one treatment is more effective in clinical terms. Given that RFMT has not been shown to be more effective or safe than OR, the significant extra expense of RFMT cannot be justified on the background of a study indicating that it provides no clear treatment benefit or lower risk profile. We would recommend patients be offered OR as the surgical management option in the treatment of refractory lateral epicondylitis.

Declaration of Conflicting Interests

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Ethical Review and Patient Consent

Trial registered with North of Scotland Research Ethics Committee. Study number: 11/AL/0385. www.hra.nhs.uk.

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