MUSCULOSKELETAL



Treatment of chronic lateral epicondylosis: a randomized trial comparing the efficacy of ultrasound-guided tendon dry needling and open-release surgery

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Received: 18 January 2022 / Revised: 22 March 2022 / Accepted: 3 April 2022 (© The Author(s), under exclusive licence to European Society of Radiology 2022

Abstract

Objective Evaluate the efficacy of ultrasound-guided dry needling and open-release surgery in reducing pain and improving function in workers with lateral epicondylosis refractory to at least 6 months of nonsurgical management.

Methods We randomly assigned participants in a 1:1 ratio to receive dry needling or surgery. The primary outcome was the Patient Rated Tennis Elbow Evaluation (PRTEE) score at 6 months. Secondary outcome measures examined the impact of these techniques on professional activity, grip strength, and Global Rating of Change and Satisfaction scales. Statistical analyses included mixed-effects models and Fisher's exact tests.

Results From October 2016 through June 2019, we enrolled 64 participants. Two participants were excluded, and data from 62 participants (48 ± 8 years, 33 men) with a mean duration of symptoms of 23 ± 21 months were analyzed. Baseline characteristics were similar in both groups. In the intention-to-treat analysis, no treatment-by-time interaction was observed ($F_{(4,201)} = 0.72$; p = .58). The least-squares mean difference from baseline in PRTEE scores at 6 months was 33.4 (CI 25.2 – 41.5) in the surgery group and 26.9 (CI 19.4 – 34.4) in the dry needling group (p = .25). The proportion of successful treatment was 83% (CI 63 – 95%) and 81% (CI 63 – 93%) in the surgery and dry needling groups, respectively (p = 1.00). Changes in secondary outcomes were in the same direction as those of the primary outcome. No adverse event occurred.

Conclusions Ultrasound-guided dry needling resulted in comparable improvement in outcome scores on scales of pain, physical function, and global assessment of change and satisfaction than open-release surgery.

Trial registration ClinicalTrials.gov Identifier: NCT02710682

Key Points

- In patients with chronic lateral epicondylosis, ultrasound-guided tendon dry needling provides comparable therapeutic efficacy to open-release surgery.
- Ultrasound-guided tendon dry needling allows for an earlier return to work and may be less costly than open-release surgery.
- Care management guidelines should recommend treatment by ultrasound-guided tendon dry needling before open-release surgery.

Keywords Dry needling · Tendinopathy · Tennis elbow · Outcome assessment health care · Ultrasonography interventional

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Abbreviations

CI	95% confidence interval	
GEE	Generalized Equation Estimation model	
IT	Intention to treat	
PP	Per protocol	
PRP	Platelet-rich plasma	
PRTEE	Patient Rated Tennis Elbow Evaluation	
QuickDASH	Disabilities of the Arm, Shoulder, and Hand	
RA-WIS	Work Instability Scale for Rheumatoid	
	Arthritis	

Introduction

Lateral epicondylosis is a debilitating upper extremity condition with a high prevalence in 45- to 64-year-old workers [1]. The term epicondylosis rather than epicondylitis better reflects this tendinopathy's degenerative and micro traumatic nature. The impact on patients' quality of life and the economic burden from health care costs, work productivity loss, and workers' compensation is substantial [2]. While there is no standard protocol for treating lateral epicondylosis, current management is typically initiated with nonsurgical therapies. An arsenal of management options is used in clinical practice without consensus, including home exercise programs, nonsteroidal anti-inflammatory drugs, injections (corticosteroids, platelet-rich plasma (PRP), autologous blood, dextrose), bracing, tendon dry needling, physiotherapy, and shockwave therapy. While some of those approaches are known to improve patient outcomes in the short term, most have not proven their long-term superiority over an absence of treatment [3].

Over the past 15 years, PRP injections for treating tendinopathies have gained popularity. The underpinning theory is that once activated by mediators, blood platelets release growth factors into the tendon, triggering the repair process. Several recent systematic reviews and meta-analyses report insufficient scientific evidence supporting the superiority of PRP injections over placebo, sclerosing or autologous blood injections, and standalone dry needling [4–8]. To inject substances into the tendon, dry needling, also called fenestration of the tendon, is usually performed first. This technique causes intra-tendinous bleeding, which promotes the influx of plate-lets and may confound the actual effect of injecting autologous blood or PRP.

Surgical treatment of epicondylosis is justified as a second line—i.e., after the failure of medical treatment. Studies report 70 to 80% efficacy although the quality of scientific evidence remains low [9]. Even today however, surgery is considered the ultimate treatment for refractory lateral epicondylosis. No study has so far compared the efficacy of ultrasound-guided dry needling with that of surgery. The primary objective of this study was to evaluate the efficacy of ultrasound-guided dry needling and open-release surgery in reducing pain and improving function in workers with lateral epicondylosis refractory to at least 6 months of medical treatment. We hypothesized that dry needling effectively treats chronic lateral epicondylosis and constitutes a valid therapeutic alternative to surgery.

Material and methods

The Research Ethics Committee of our academic institution approved this prospective, randomized trial. All participants signed informed consent. The study was registered in the registry ClinicalTrials.gov (NCT02710682), and the study's protocol was published previously [10].

Recruitment of participants We recruited participants through various outreach approaches such as newspapers, primary health care providers, and orthopedic outpatient clinics. Two fellowship-trained orthopedic surgeons with 18 and 13 years of experience examined the participants to confirm the diagnosis and verify the eligibility criteria.

The inclusion criteria were as follows: workers aged between 25 and 67 years old with unilateral epicondylosis refractory to nonsurgical management carried out for at least 6 months; pain intensity on resisted dorsiflexion of the wrist, middle finger, or both $\geq 4/10$ on a numerical rating scale where 0 = no pain and 10 = worst pain imaginable. Table 1 lists the exclusion criteria.

Enrollment visit The research assistant met with the eligible participants and informed them of the study details. Participants who agreed to take part in the study then signed the consent form and completed the self-administered

Table 1 Exclusion criteria

- · Tumor or infectious etiology of elbow pain.
- Corticosteroid injection received in the last 3 months.
- \bullet Tear $\geq 50\%$ of the surface of the common extensor tendon as measured by ultrasound.
- · Autologous blood or PRP injections.
- Hemorrhagic diathesis; anticoagulation therapy (platelet count < 50,000 \times 10⁻⁶/L; INR > 2).
- Local infection.
- History of surgery or fracture of the elbow.
- Inflammatory arthritis or osteoarthritis of the elbow.
- · Cervical radiculopathy.
- Pregnancy or plans to become pregnant during the study.
- · Inability to respond to questionnaires in French or English.
- Inability to provide informed consent due to mental health disorder.

questionnaires. Then, a fellowship-trained musculoskeletal radiologist with 23 years of experience performed an ultrasound examination of the patient's lateral elbow using an ACUSON S3000 scanner (Siemens Healthcare Limited), 14L5SP, and 14L5 MHz linear probes, according to a standardized protocol [10].

Randomization Participants were randomized into two groups in block sizes of 8: one group treated with surgery and the other treated with dry needling. One of the authors, not otherwise interacting with the participants, generated the randomization sequence. A second research assistant managed the consecutively numbered sealed envelopes containing the allocation group. The research assistant responsible for the patients' enrollment and follow-up visits remained blinded to the assignment sequence.

Interventions The same radiologist and another fellowship-trained musculoskeletal radiologist with 10 years of experience performed the dry needling interventions. First, ultrasound and power Doppler of the common extensor tendon were performed to identify the area of tendinosis and neovascularization and to plan the optimal approach to needle guidance. Then, the skin and subcutaneous tissues were anesthetized under aseptic conditions with 3 mL of 1% lidocaine and a 25G needle. Then, dry needling of the tendon was performed with a 22G needle under ultrasound guidance by passing the needle approximately 20–30 times along the long axis of the tendon to obtain softening of the area of tendinosis, which is usually at or near the enthesis, and

abrade the underlying bone [10] (Fig. 1) (video clip_1). Participants were provided with a 10-day prescription of analgesics (acetaminophen/codeine), a medical certificate for a 2-week sick leave, and a pamphlet detailing the recommendations during the 12 weeks following the procedure and illustrating the recommended elbow's stretching and strengthening exercises.

The two orthopedists performed the surgery using an open-release approach: incising the skin, reclining the extensor carpi radialis longus (ECRL) tendon, and excising the pathological tissue of the subjacent extensor carpi radialis brevis tendon. Then, the ECRL tendon was sutured back and the skin was closed [10]. Postoperative follow-up was provided at 2 weeks and 4 and 6 months or shorter intervals if unsatisfactory progress, as per usual care. Participants were instructed to avoid lifting anything heavier than a cup of coffee and to avoid extension of the wrist and fingers against resistance for the first 6 weeks. Attending physiotherapy was optional. In addition, the participants received a 10-day prescription of analgesics and at least 4- and up to 6-month medical certificates for sick leave.

The physician responsible for the dry needling or surgery recorded adverse events occurring during and up to 30 min after the intervention.

Outcome measures The primary outcome was the Patient Rated Tennis Elbow Evaluation (PRTEE) score measured 6 months post-intervention. For clinical significance defined as "much better" or "completely recovered," the reported minimal clinically important difference (MCID) is 11/100

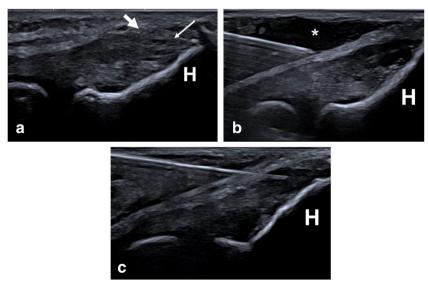


Fig. 1 Ultrasound-guided tendon dry needling in a 54-year-old woman with chronic lateral epicondylosis. **a** Long-axis US at the left lateral elbow shows a thickened, hypoechoic conjoint tendon (short arrow) with small anechoic clefts (long arrow) at the insertion on the humerus (H). **b** The subcutaneous tissues superficial to the aponeurosis of the extensor tendon

are anesthetized with 1% lidocaine (asterisk) using a 25G needle. **c** Then, dry needling is performed by passing a 22G needle multiple times along the long axis of the tendon. The needle is redirected to cover the affected tendon area and abrade the underlying cortex without exiting the tendon. See the video clip of the technique in the supplementary material reduction from baseline [11] and was considered a "successful treatment" in the statistical analyses.

Secondary outcome measures included the shortened version of the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) pain and disability module, and the QuickDASH Work module [12]. Presenteeism, defined as the ability to perform unrestricted tasks when the employee is at work, was measured using the Work Instability Scale for Rheumatoid Arthritis (RA-WIS) [13] validated for elbow pathology [14]. Patients' global impression of change regarding their condition, and level of satisfaction with treatment were respectively assessed with a scale ranging from 1 to 7 with "unchanged" as the midpoint and "considerably improved" or "extremely satisfied," and "very much worse" or "extremely dissatisfied" as anchors [15]. The research assistant measured the patient's pain-free grip strength using a Jamar Plus+ dynamometer [10]. We used the Medication Quantification Scale (MQS) [16] to assess medication use during the week preceding each follow-up time point.

Baseline and follow-up evaluations at 6 weeks and 3, 6, and 12 months At each time point, the participants completed the self-administered outcome questionnaires using an electronic database [17]. Pain-free grip strength was assessed onsite during the baseline and 6- and 12-month visits.

Sample size calculation and statistical analysis We calculated that a sample size of 56 participants divided equally into the 2 groups would provide each group with 80% power, at twosided alpha level of 0.05, to detect a clinically significant reduction in PRTEE scores (11/100) [11] at 6 months with a paired Student *t* test, assuming a group standard deviation at baseline of 20 [18, 19]. We enrolled 32 participants per group in accounting for an attrition rate of 15%. We performed the analyses according to the intention-to-treat (IT) principle and secondarily used the per-protocol (PP) approach, excluding participants who violated the protocol [20].

We modeled the primary outcome variable in two different ways. First, we used a linear mixed-effects model with treatment, time, and treatment interaction with time as fixed effects and patient-specific random intercepts. Second, we used a Fisher's exact test to determine whether the proportion of "successful treatment" at 6 months differed between groups.

We modeled the secondary outcome variables using a linear mixed-effects or a Generalized Equation Estimation (GEE) model with logit link. We used a Fisher's exact test to verify whether the proportion of patients who reported being "much or considerably improved," and those who were "satisfied or extremely satisfied" differed between the groups.

All available visits were considered in the IT approach for the linear mixed models, while only patients with follow-up until 12 months were considered in the PP approach. The learning effect of physicians performing the procedures was analyzed using linear regression. The proportion of successes for PRTEE at 6 months was compared between physicians with Pearson's chi-square test. The differences in baseline characteristics between participants, lost to follow-up or not, were tested using Pearson's chisquare or Wilcoxon's test. The analyses were performed by one of the authors using SAS software version 9.4 (SAS Institute Inc.).

Results

Participants From October 2016 through June 2019, a total of 269 individuals were screened by telephone interview, 110 individuals were assessed for eligibility criteria, and 64 participants were enrolled. One participant withdrew informed consent before receiving the intervention, and another participant was excluded because a complete avulsion of the conjoint tendon was diagnosed at the time of the baseline ultrasound exam. Consequently, data from 62 participants equally divided into each group were analyzed. The mean age of the participants was 48 ± 8 years, 53% were men, and the mean duration of symptoms was 23 ± 21 months. Six participants in the surgery group dropped out of the study before receiving the intervention. Two participants in the dry needling group had surgery instead owing to a mistake by the research assistant. Fifty-five participants (55/62; 89%) were included in the primary outcome analysis at 6 months post-intervention. Fifty-one participants (51/62; 82%) completed the 12-month evaluation. Figure 2 presents the trial enrollment and follow-up chart. Baseline demographic and clinical characteristics were similar in the two groups (Table 2). No adverse events occurred during the trial.

Primary outcome In the IT analysis, no treatment-by-time interaction was observed ($F_{(4,201)} = 0.72$; p = .58). Both groups demonstrated a significant improvement in the PRTEE scores between each visit (p < 0.05) except for the 3-month and 6-month visits (p > 0.05) (Fig. 3). The least-squares mean difference from baseline in PRTEE scores at 6 months was 33.4 (CI 25.2–41.5) in the surgery group and 26.9 (CI 19.4–34.4) in the dry needling group (p = 0.25). The mean changes in primary and secondary outcome scores from baseline for the IT analysis are provided in Table 3, and the results of the PP analysis are provided in the supplementary material (Supplementary material (SM) Table 1).

In the IT analysis, the proportion of successful treatment based on the PRTEE score at 6 months was (20 of 24) 83% (CI 63–95%) in the surgery group and (25 of 31) 81% (CI 63–

Table 2 Baseline characteristicsof the participants

Characteristics	Surgery $(N = 31)$	Fenestration $(N = 31)$
Age (years)	49.7 ± 7.4	46.7 ± 8.0
	(30.2 - 60.9)	(32.3 – 59.3)
Female sex	17 (54.8)	11 (35.5)
Body mass index (kg/m ²)	28.6 ± 5.8	27.7 ± 4.5
	(20.0 - 44.7)	(20.2 - 40.3)
Smoker	7 (22.6)	4 (12.9)
Right-hand dominant	22 (71.0)	29 (93.6)
Right elbow symptomatic	17 (54.8)	15 (48.4)
Duration of symptoms (months)	22.0 ± 19.7	23.3 ± 22.5
	(6.0–96.0)	(7.0 - 120.0)
Treatment(s) received before enrolling into the study (yes)		
Wearing a brace	28 (90.3)	21 (67.7)
Home exercise program	19 (61.3)	18 (58.1)
Physiotherapy	21 (67.7)	25 (80.7)
Shockwave therapy	3 (9.7)	1 (3.2)
Cortisone injections	19 (61.3)	21 (67.7)
Other treatments (acupuncture, osteopathy, occupational therapy)	11 (35.5)	15 (48.4)
Baseline outcome measures		
PRTEE	54.8 ± 17.4	52.7 ± 16.5
	(21.5 - 87.0)	(8.0 - 81.0)
QuickDASH pain/disability module	47.7 ± 16.8	48.8 ± 13.7
	(18.2 - 75.0)	(25.0 - 77.3.)
QuickDASH Work module	46.4 ± 27.8	55.2 ± 33.5
	(0.0 - 100.0)	(0.0 - 100.0)
RA-WIS	11.0 ± 5.5	9.2 ± 6.1
	(1.0 - 18.0)	(0.0 - 21.0)
Pain-free grip strength	55.6 ± 31.4	47.7 ± 18.5
	(4.6 - 109.1)	(17.0 - 80.2)

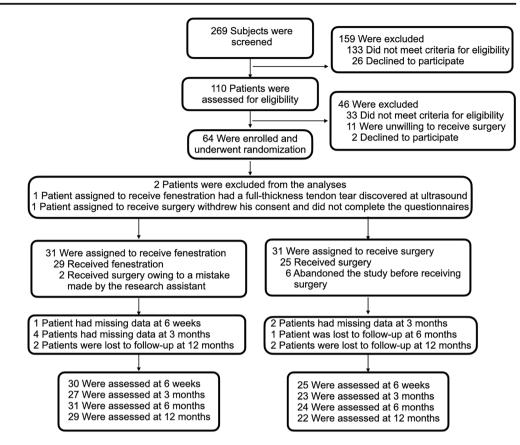
N, number. Continuous variables are presented as mean \pm standard deviation (range), while categorical variables are frequency (percentage). PRTEE: Patient Rated Tennis Elbow Evaluation total scores range from 0 to 100, with higher scores indicating worse pain and function. QuickDASH: for each module, total scores range from 0 to 100, with higher scores indicating higher level of pain and disability. RA-WIS: Work Instability Scale for Rheumatoid Arthritis total scores reflect a severity factor for instability at work: low < 10; moderate 10–17; severe > 17. Painfree grip strength: ratio (symptomatic side/asymptomatic side) × 100

93%) in the dry needling group (p = 1.00). When considering the participants who strictly adhered to the protocol (PP analysis), the proportion of successful treatment was (20 of 24) 83% (CI 63–95%) and (24 of 29) 83% (CI 64–94%) respectively (p = 1.00).

Secondary outcomes In the IT analysis, no treatment-by-time interaction was observed in the pain-free grip strength scores $(F_{(2,101)} = 0.83; p = .44)$ (SM Fig. 1a), the QuickDASH total scores $(F_{(4,200)} = 0.61; p = .66)$ (SM Fig. 1b), the RA-WIS scores $(F_{(4,201)} = 1.37; p = .25)$ (SM Fig. 1c), and the MQS $(F_{(3,140)} = 1.80; p = .15)$ (SM Fig. 1d). Both groups demonstrated a similar progressive improvement in all scores over 12 months.

A significant treatment-by-time interaction was observed in the QuickDASH Work scores ($F_{(4,199)} = 2.60$; p = .04) (Fig. 4). Whereas no significant difference between groups at each visit is demonstrated in the IT analysis, a significant difference between groups at 6 weeks (p = .049) and 3 months (p = .03) emerged in the PP analysis. Hence, the surgery group showed deterioration of function at work at 6 weeks and 3 months, followed by improvement at 6 and 12 months. In contrast, the dry needling group demonstrated a progressive and sustained improvement in function at work at each time point.

In the IT analysis, at 6 months post-intervention, 17 out of 24 participants (71%; CI 49 – 87%) in the surgery group, and 20 out of 31 participants (65%; CI 45 – 81%) in the dry



needling group indicated that they were *much* or *considerably improved* compared with before they had the treatment intervention (p = .77). Conversely, in the PP analysis, the proportion of participants declaring a significant improvement in their condition was 71% (CI 49 – 87%) and 69% (CI 49 – 85%) respectively (p = 1.00).

Fig. 2 Trial enrollment,

randomization, and follow-up

Similarly, 18 out of 24 participants (75%; CI 53 – 90%) in the surgery group, and 20 out of 31 participants (67%; CI 47 – 83%) in the dry needling group indicated that they were *satisfied* to *extremely satisfied* with their treatment (p = .56). In the PP analysis, the proportion of participants who were satisfied with their treatment was 75% (CI 53 – 90%) and 71% (CI 51 – 87%) respectively (p = 1.00). Figure 5 shows the evolution of patients' ratings of global change and satisfaction over 12-month follow-up.

Analysis of potential biases The proportion of PRTEE successes at 6 months did not differ depending on the operator (p = .81). Furthermore, the analysis showed no learning effect with time for all physicians (p = .3). All participants who dropped out before receiving the intervention, or were lost to follow-up at 6 months (7/62; 11%), came from the surgery group. Comparing the baseline characteristics of the "losses at 6-month follow-up" versus "others" revealed only one significant difference. The pain-free grip strength score was significantly higher in the "losses at follow-up" group (median:

71% vs 50%) (p = .04), suggesting less physical impairment in participants who declined the surgery or dropped out of the trial, compared with the other participants.

Discussion

This randomized trial comparing ultrasound-guided tendon dry needling with open-release surgery in workers with chronic lateral epicondylosis refractory to at least 6 months of medical treatment showed that both techniques effectively led to improved outcomes at 6-month follow-up. As assessed by the Patient Rated Tennis Elbow Evaluation (PRTEE) scores, in the intention-to-treat analysis, 83% of participants receiving surgery and 81% of those receiving dry needling were treated successfully (p = 1.00). When considering only the participants who strictly adhered to the research protocol (per-protocol analysis), the results were 83% in each group (p = 1.00). Secondary outcomes that measured pain-free grip strength, pain and disability, and pain medication intake showed comparable significant improvement over time in the two groups.

We examined the impact of each treatment on two at-work performance indicators. First, analysis of the shortened version of the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) Work scores revealed a different postintervention trajectory of the 2 groups over time. Thus, the

Outcomes	Surgery Mean difference (95% CI)	Fenestration Mean difference (95% CI)
PRTEE [‡]		
6 weeks	13.9 (8.0; 19.8) [†]	14.7 (9.3; 20.0) [†]
3 months	26.4 (18.9; 33.8) [†]	25.0 (18.1; 32.0) [†]
6 months	33.4 (25.2; 41.5) [†]	26.9 (19.4; 34.4) [†]
12 months	42.0 (33.2; 50.9) [†]	33.8 (25.7; 41.8) [†]
Pain-free grip	o strength*	
6 months	$-27.0(-45.2;-8.9)^{\dagger}$	$-41.5(-58.4;-24.5)^{\dagger}$
12 months	$-36.5(-55.6;-17.5)^{\dagger}$	$-41.7(-59.4;-24.1)^{\dagger}$
QuickDASH	Total [‡]	
6 weeks	2.7 (- 3.5; 8.9)	6.1 (0.4; 11.8) [†]
3 months	14.9 (7.2; 22.6) [†]	16.1 (8.8; 23.4) [†]
6 months	27.6 (19.3; 35.9) [†]	24.2 (16.5; 31.9) [†]
12 months	34.6 (25.7; 43.5) [†]	29.4 (21.3; 37.6) [†]
QuickDASH	Work [‡]	
6 weeks	- 10.2 (- 21.7; 1.3)	10.7 (0.3; 21.2) [†]
3 months	- 2.0 (- 16.5; 12.5)	21.7 (8.2; 35.2) [†]
6 months	17.3 (1.7; 32.8) [†]	28.2 (13.8; 42.6) [†]
12 months	34.6 (17.8; 51.4) [†]	35.1 (19.8; 50.5) [†]
RA-WIS [‡]		
6 weeks	4.8 (2.5; 7.1) [†]	1.8 (- 0.3; 4.0)
3 months	4.8 (2.1; 7.5) [†]	3.0 (0.5; 5.6) [†]
6 months	8.2 (5.3; 11.0) [†]	4.8 (2.1; 7.5) [†]
12 months	9.5 (6.5; 12.6) [†]	6.0 (3.2; 8.8) [†]
MQS*		
3 months	- 0.1 (- 1.4; 1.1)	0.7 (- 0.4; 1.9)
6 months	1.8 (0.2; 3.4) [†]	1.5 (0.1; 2.9) [†]
12 months	1.8 (- 0.01; 3.7) [†]	$2.4~(0.8; 4.0)^{\dagger}$

 Table 3
 Least-squares mean differences in primary and secondary outcomes between baseline, or 6 weeks in the case of the MQS score, and each trial time point (intention-to-treat analysis)

PRTEE: Patient Rated Tennis Elbow Evaluation scores range from 0 to 100, with higher scores indicating worse pain and function. Pain-free grip strength: ratio (symptomatic side/asymptomatic side \times 100). QuickDASH: for each module (Total and Work), total scores range from 0 to 100, with higher scores indicating higher level of disability. RA-WIS: Work Instability Scale for Rheumatoid Arthritis scores range from 0 to 23, with higher scores indicating greater instability at work. MQS: Medication Quantification Scale scores range from 0 with no upper limit. A higher score indicates a greater medication regimen. No values were recorded at baseline. The baseline MQS score was obtained at 6 weeks post-intervention

[‡]A positive difference indicates an improvement in PRTEE scores, QuickDASH (Total and Work) scores, or RA-WIS score respectively

*A negative difference indicates an improvement in pain-free grip strength ratio, or an improvement in MQS score

[†] Indicates a statistically significant (p < 0.05) least-squares mean difference from the comparative value

surgery group showed deterioration in the scores at the 6-week and 3-month visits before improving at 6 months and 12 months. In contrast, the dry needling group demonstrated a gradual and sustained improvement in the scores from baseline to 12 months post-intervention. This difference may have resulted from the long absence from work (4 to 6 months) and a more extended rehabilitation period following surgery. Conversely, participants in the dry needling group observed a 2-week leave of absence from work and followed a 12-week home exercise program to resume their activities earlier. Therefore, the return to work following dry needling occurred more rapidly than after surgery. Dry needling is a percutaneous technique performed with a small gauge needle. There is no skin incision; there is no tissue resection; and there is no wound healing, all of which facilitate a more rapid recovery from dry needling compared to surgery.

Second, the Work Instability Scale for Rheumatoid Arthritis (RA-WIS) scores, a scale assessing presenteeism, showed no difference between groups. Both groups demonstrated progressive improvement with a clinically significant reduction in the RA-WIS score at 6 and 12 months postintervention and a status corresponding to a low probability of the need for adjustments to perform the required tasks [21] upon their return to work following the intervention. However, an earlier return to work occurred in the dry needling group representing a significant benefit.

Secondary outcomes that measured patient assessment of improvement and satisfaction showed that most patients reported being "much or considerably improved" and "satisfied to extremely satisfied" similarly in both groups at 6 and 12 months post-intervention (p > .05). However, the evolution of scores over the 12 months demonstrated a tendency for higher satisfaction scores in the surgery group at the 6-week and 3-month times compared to the dry needling group. The fact that participants in the surgery group were on leave of absence from work during that time, as opposed to the dry needling group, might explain this tendency.

A systematic review showed that few studies have investigated the efficacy of a standalone tendon dry needling technique for the treatment of lateral epicondylosis [22]. Some of these studies were uncontrolled [23-25] or used a technique without ultrasound guidance [26, 27], whereas others reported on different procedures such as percutaneous ultrasonic tenotomy [28, 29] and dry needling akin to acupuncture techniques [30, 31]. Stenhouse et al conducted a prospective randomized controlled study comparing a technique of ultrasound guidance dry needling similar to ours to the technique combined with an injection of autologous conditioned plasma in 28 patients with chronic lateral epicondylosis [32]. Patients received two treatments at 1-month interval. Both groups demonstrated clinically significant improvement defined as at least a 25% reduction in visual analog pain scale score from baseline at 6 months. The difference between groups was not significant. Our trial found that one ultrasound-guided dry needling intervention effectively treated chronic lateral epicondylosis.

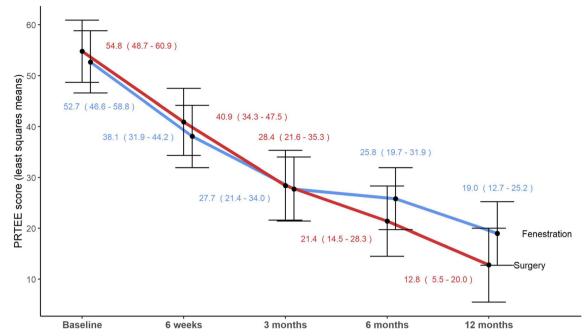


Fig. 3 Patient Rated Tennis Elbow Evaluation (PRTEE) total scores over the 12-month follow-up period (intention-to-treat analysis). PRTEE scores range from 0 to 100, with higher scores indicating worse pain and function. The values in parentheses are 95% confidence intervals

(also indicated by the bars). All available visits were considered in the linear mixed models. The between-group difference at each time point was not significant (p > 0.05)

A recent systematic review examining 6 high-level evidence studies comparing open, arthroscopic, and percutaneous surgery for chronic lateral epicondylosis concluded to no significant differences in clinical outcomes at 1-year followup [33]. All surgical techniques demonstrated significant improvement from baseline. However, the lack of standardization in data reporting precluded statistical comparisons of outcome scores between studies. Nevertheless, the results of our

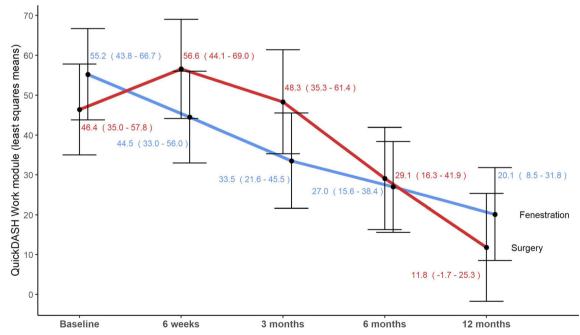


Fig. 4 Shortened version of the Disabilities of the Arm, Shoulder, and Hand (4-item QuickDASH) Work scores over the 12-month follow-up period. (Intention-to-treat analysis). QuickDASH Work scores range from 0 to 100, with higher scores indicating higher level of disability. The values in parentheses are 95% confidence intervals (also indicated by

the bars). All available visits were considered in the linear mixed models. The between-group differences at each time point did not reach statistical significance (p > .05) in the intention-to-treat analysis. However, a significant difference between groups at 6 weeks (p = .049) and 3 months (p = .03) emerged in the per-protocol analysis (not shown)

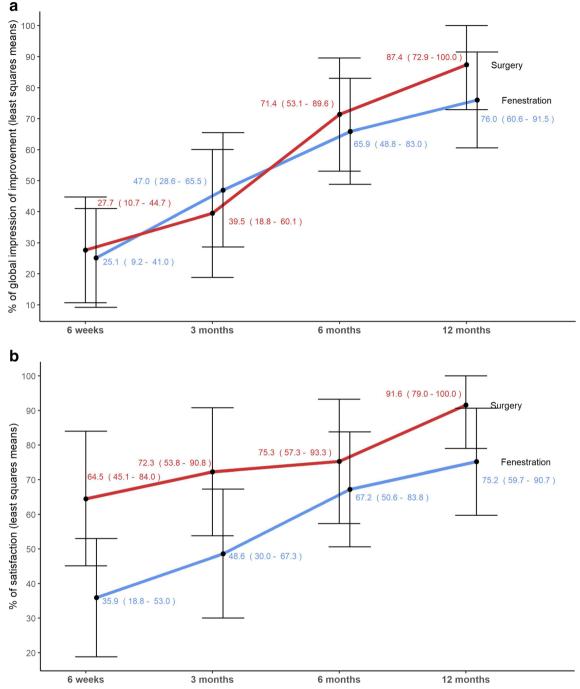


Fig. 5 Patients' rating of global change (A) and satisfaction (B) scores over the 12-month follow-up period (intention-to-treat analysis). The values in parentheses are 95% confidence intervals (also indicated by the bars). All available visits were considered in the GEE models. No significant treatment-by-time interaction was observed in the patients' ratings of global impression of change (F(3) = 2.18; p = .53) nor in the

trial are consistent [9, 32, 33] or superior [34] to those of previous trials.

Our trial has limitations. First, it was not possible to conceal trial group assignment from patients or physicians. Second, 11% of participants abandoned the trial, all assigned to the surgery group, introducing a selection bias. Although these

satisfaction scores (F(3) = 1.95; p = .58). Patients' ratings of global impression of change improved over time and the between-group differences at each time point were not significant (p > .05). Satisfaction scores improved over time. The between-group difference at 6 weeks was statistically significant (p = .03) in the intention-to-treat analysis but not in the per-protocol analysis (p = .12) (not shown)

participants could have presented a favorable prognosis, the study's conclusions remained unchanged in the sensitivity analysis. Finally, all enrolled patients had chronic refractory lateral epicondylosis of at least 6 months and were eligible for surgical treatment. As such, the conclusions regarding the clinical outcomes following ultrasound-guided dry needling

might not be generalizable to other clinical groups, including patients with acute or subacute lateral epicondylosis. Future trials using a pragmatic methodology could address this question.

In conclusion, ultrasound-guided tendon dry needling, also called fenestration of the tendon, for chronic lateral epicondylosis resulted in comparable scores on scales of pain, physical function, patients' global impression of change, and treatment satisfaction than open-release surgery. Furthermore, this minimally invasive technique allows for an earlier return to work and may be less costly than open-release surgery. Therefore, clinical practice guidelines should recommend treatment by ultrasound-guided tendon dry needling before surgery in cases of chronic lateral epicondylosis.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00330-022-08794-4.

Acknowledgements The authors would like to thank Siemens Healthcare Limited for the loan of the ACUSON S3000 ultrasound machine for the duration of this project.

We thank The University of Leeds for granting us permission to use the Leeds Rheumatoid Arthritis Work Instability Scale (RA-WIS) in this trial.

Funding This study has received funding from the *Institut de recherche Robert-Sauvé en santé et en sécurité du travail* (#2015-0034).

Nathalie J Bureau is supported by a research scholarship from the *Fonds de Recherche du Québec – Santé (FRQ-S)* and the *Fondation de l'Association des Radiologistes du Québec* (FRQS-ARQ 266408).

Declarations

Guarantor The scientific guarantor of this publication is Nathalie J Bureau.

Conflict of interest The authors of this manuscript declare relationships with the following companies: Siemens Healthcare Limited.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

Methodology

• prospective

- · randomized controlled trial
- · performed at one institution

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