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Original article

Ultra minimally invasive sonographically guided carpal tunnel release: An external pilot study



A. Capa-Grasa^a, J.M. Rojo-Manaute^{b,*}, F.C. Rodríguez^c, J.V. Martín^c

^a Department of Physical and Rehabilitation Medicine, University Hospital La Paz, Madrid, Spain

^b Department of Orthopaedic Surgery, University Hospital Point-à-Pitre, 534, impasse Lalande L'houezel, 97190 Gosier, Guadeloupe

^c Department of Orthopaedic Surgery, University Hospital Gregorio Marañón, Madrid, Spain

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ABSTRACT

Background: Authors have reported better outcomes, by reducing surgical dissection for carpal tunnel syndromes requiring surgery. Recently, a new sonographically guided technique for ultra minimally invasive (Ultra-MIS) carpal tunnel release (CTR) through 1 mm incision has been described.

Hypothesis: We hypothesized that a clinical trial for comparing Ultra-MIS versus Mini-open Carpal Tunnel Release (Mini-OCTR) was feasible.

Materials and methods: To test our hypothesis, we conducted a pilot study for studying Ultra-MIS versus Mini-OCTR respectively performed through a 1 mm or a 2 cm incision. We defined success if primary feasibility objectives (safety and efficacy) as well as secondary feasibility objectives (recruitment rates, compliance, completion, treatment blinding, personnel resources and sample size calculation for the clinical trial) could be matched. Score for Quick-DASH questionnaire at final follow-up was studied as the primary variable for the clinical trial. Turnover times were studied for assessing learning curve stability. **Results:** Forty patients were allotted. Primary and secondary feasibility objectives were matched with the following occurrences: 70.2% of eligible patients finally recruited; 4.2% of randomization refusals; 26.6 patients/month recruited; 100% patients receiving a blinded treatment; 97.5% compliance and 100% completion. A sample size of 91 patients was calculated for clinical trial validation. At final follow-up, preliminary results for Quick-Dash substantially favored Ultra-MIS over Mini-OCTR (average 14.54 versus 7.39) and complication rates were lower for Ultra-MIS (5% versus 20%). A stable learning curve was observed for both groups.

Conclusions: The clinical trial is feasible. There is currently no evidence to contraindicate nor withhold the use of Ultra-MIS for CTR.

Level of evidence: III.

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1. Introduction

With an incidence of 1 to 3 and a prevalence of 50 cases per 1000 person-years, carpal tunnel syndrome (CTS) is the most diagnosed entrapment neuropathy [1,2]. Surgery can be considered as a first effective option in CTS if there is clinical evidence of median nerve denervation [1,3–5]. The incision's size for carpal tunnel release (CTR) has been described as classic (> 4 cm) [6,7], limited (2–4 cm) [6,7], mini (1.0–2 cm) [4,7,8], percutaneous (0.4–0.6 cm) [4,9,10]

and ultra minimally invasive (≤ 1 mm) [11]. When comparing CTR techniques with different incision lengths, the smaller incisions show a faster return to work and better cosmetic results [6,12] and lower pain rates [4,8,13–16]. Endoscopic CTR has shown clinical superiority to classic open CTR (OCTR) [1,3,4,8,17], however, concerns persist over incomplete releases in cadavers [1,6,8,17,18] and complications to neurovascular structures and tendons [1,4,8,17]. Mini-OCTR has matched endoscopic CTR in clinical results and morbidity [1,4,5,19,20], however there is concern that part of the procedure is performed blindly (Blind mini-OCTR) [1,4,5,21].

Recent anatomic findings [22] suggest that a complete nerve release is possible by sectioning the deepest fibrous layer without intruding into the more superficial palmar anatomy, which is rich in nerve fibers that may elicit local pain when surgically injured [4,23].

Mini and percutaneous approaches have been described using ultrasounds [4,8–11]. In their first work, Nakamichi et al. [8]

Abbreviations: CTR, carpal tunnel release; CTS, carpal tunnel syndrome; Mini-OCTR, mini-open CTR; OCTR, classic open CTR; SEM, standard error of the mean; TCL, transverse carpal ligament; Ultra-MIS, ultra minimally invasive surgery.

* Corresponding author.

E-mail address: k2rojo@yahoo.com (J.M. Rojo-Manaute).

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compared a distal anterograde ultrasound assisted Mini-OCTR against OCTR and, in their later study [4], they compared an ultrasound-guided percutaneous CTR to an ultrasound assisted Mini-OCTR. Both works [4,8] reported significant clinical differences regarding grip, pain and scar tenderness (until the 6th week) and less scar sensitivity (until the 13th week) that favored the technique with the smallest approach. Other authors [9,10] have described in cadavers a proximal retrograde ultrasound-guided CTR using an arthroscopic trocar, reporting safe and successful results.

Rojo et al. [11] have shown that an ultrasound-guided Ultra-MIS CTR can be achieved safely and effectively in cadavers and that the release can be specifically restricted to the deepest fibrous layer of the carpal tunnel (TCL and deep investing fascia of the forearm), preserving the anatomy superficial to TCL [11]. The Ultra-MIS skin incision is 4 to 12 times smaller than the percutaneous approaches [4,8–10] and it is, to our knowledge, the smallest described surgical approach for CTR. However, Ultra-MIS CTR has not been performed clinically.

The purpose of this study was to evaluate feasibility for a randomized, single-centre, clinical trial comparing Ultra-MIS with Mini-OCTR for CTR in patients with CTS.

2. Materials and methods

This was a one-centre individual randomized, parallel group, controlled, superiority external pilot study [24] conducted in Madrid, Spain, in an ambulatory office-based setting at our third level referral hospital. Patients were consecutively recruited and operated between October and December, 2009 and followed up for 3 months. Eligible participants had clinical signs [25] of primary CTS and a positive electrodiagnostic test. Exclusion criteria were hand/wrist pathology or malformations, secondary CTS, treatment trial with local corticosteroid injection, age under 18, or any previous injury on any hand. Previous criteria for ambulatory surgical care exclusion were also applied [26]. Outcome assessors were blinded by taping the patient's wrists. Patients followed concealed allocation (1:1), by an independent blocked computer generated list, to one of two surgical treatments: Ultra-MIS or Mini-OCTR.

Ultra-MIS consisted of an ultrasound-guided percutaneous retrograde release of the deepest fibrous layer of the carpal tunnel through a ≤ 1 mm proximal incision (Fig. 1), located at the distal forearm, as described by Rojo-Manaute et al. [11] and shown in Fig. 2. Mini-OCTR was performed as described by Zyluk et al. [21], using mini-retractors and surgical scissors through a 2 cm curved skin incision 6 mm ulnar and parallel to the thenar crease, in line with the long axis of 4th finger and ending just distal to the transverse wrist crease (Fig. 3). In the Mini-OCTR group, the superficial and intermediate fibrous layers [11,22] were divided and the TCL was released as far distally as the fat around the superficial vascular arch; proximally, the antebrachial intermediate and deep fibrous layers [11,22] were divided as far as 1 cm proximal to the pisiform.

Success was determined if all feasibility objectives for the pilot study were matched: (1) primary objectives, safety (defined as no neurovascular morbidity) and efficacy (no CTS relapse), 3 months after surgery; (2) secondary objectives, as defined in Table 1; and (3) sample size calculation for the clinical trial, based on the data for the primary outcome measure of the main study (Quick-DASH) at final follow-up.

Variables for the clinical trial were also studied in this pilot study, looking for evidence for contraindicating or withholding the use of Ultra-MIS, (1) preoperatively: symptoms duration, Quick-DASH, employment status (labour/retired) and previous conservative treatments; (2) intraoperatively: turnover time per procedure, defined as the minutes between two consecutive patients entering the same operating room [26]. Turnover times



Fig. 1. Surgical details for Ultra-MIS CTR. A. Distal volar forearm approach (first available antebrachial skin crease 2 cm or greater proximal to the pisiform). B. Skin incision right after and 48 hours postsurgical release (enlarged image).

Table 1
Secondary feasibility objectives.

Variable	Definition of success	Results
Recruitment rates [24,27–29]	$\geq 70\%$ of eligible patients recruited [30] $\leq 5\%$ of eligible patients refused randomization [31] ≥ 10 patients randomized at our centre per month, on average	40 (70.2%) of 57 eligible patients recruited 2 (4.2%) refused randomization 26.6 patients/month randomized
Blinding [29,32]	$> 90\%$ of the randomized patients received treatment in a blinded manner	100% received blinded treatment
Compliance [28]	$> 90\%$ of our patients attended all follow-up dates	Compliance was 97.5%
Completion [27]	More than 90% came to our last follow-up	Completion was a 100%
Personnel resources [27]	The process time for concealment (surgical wound taping) and data-gathering in our protocol could not overload our personnel resources	Concealment overloaded our resources and was modified: patients avoided revealing their palms to data collectors. Suspected complications were assessed by an independent experienced hand surgeon without revealing the study group

Values show mean $\pm$ SEM. * $P < 0.05$.

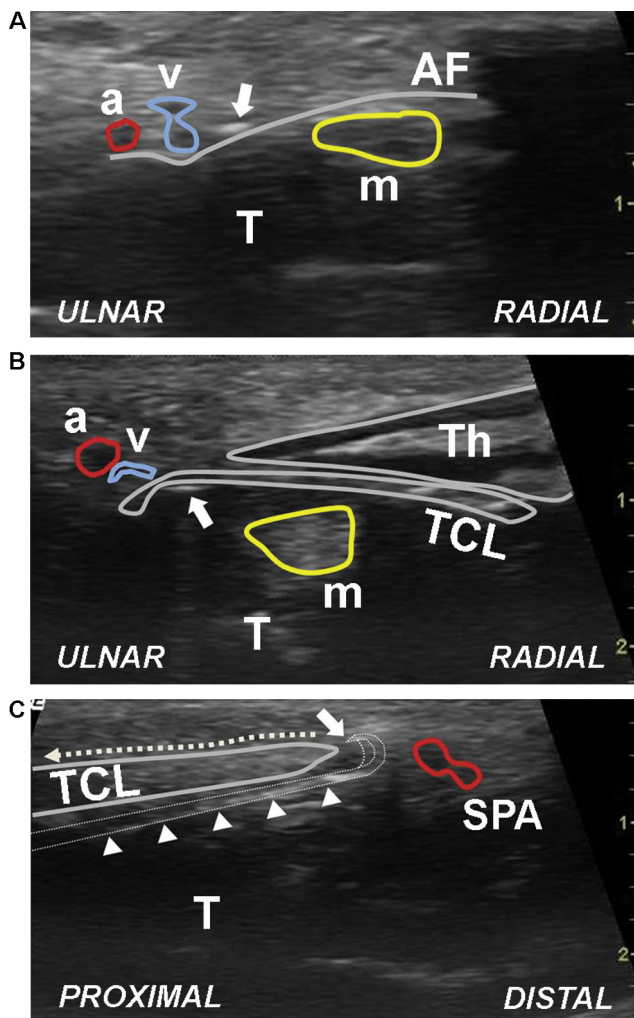


Fig. 2. Description of the Ultra-MIS CTR. A (axial plane): piercing of the AF to the underlying flexor tendon space (Abbocath 16G). B (axial plane): intracanal advance of Acuflex 3.0-mm diameter hook knife (010600; Smith & Nephew PLC, London, England) through the previous Abbocath's tunnel. C (sagittal plane): positioning of the hook knife in the distal cutting point (2–3 mm proximal to the SPA) and retrograde release of the deepest fibrous layer (back pulling of the hook knife while applying volar pressure) to the exit through the point of entry. AF: antebrachial fascia; a: ulnar artery; v: ulnar vein; m: median nerve; T: flexor tendon space; Th: thenar eminence; TCL: transverse carpal ligament; SPA: superficial palmar arch; white arrow: tip of the surgical instrument; white triangles: body of the surgical instrument; dotted arrow line: surgical release path.

were used for studying our learning curve following the methods described by Rojo-Manaute et al. [26]. A learning curve was defined as “stable” (no more significant learning) if the linear coefficient of determination (R^2) for turnover time was less than 0.26 [26]. A data committee (ACG, FCR, MVM and JVM) reviewed R^2 for the last 10 procedures in each surgical group; (3) 1, 3 and 6 weeks and 3 months postoperatively: Quick-DASH (administered by the examiner), Grip Strength Rate (JAMAR, Hydraulic Hand Dynamometer, Bolingbrook, IL, USA) and two points discrimination were recorded, and patients were asked to recall [33] the recovery time (days) until they stopped using pain killers, had full wrist range of motion and performed their daily activities (including work); and (4) complications.

All Ultra-MIS were performed by the second author using a portable, real-time, linear array ultrasound scanner (LOGIQ Book XP Pro, 5–11 MHz 8L, GE Healthcare, Madrid, Spain). Mean, standard error of the mean (SEM) and range were recorded (SPSS 15.0, Inc, Chicago, IL). t -test and χ^2 (significant at $P < 0.05$) were

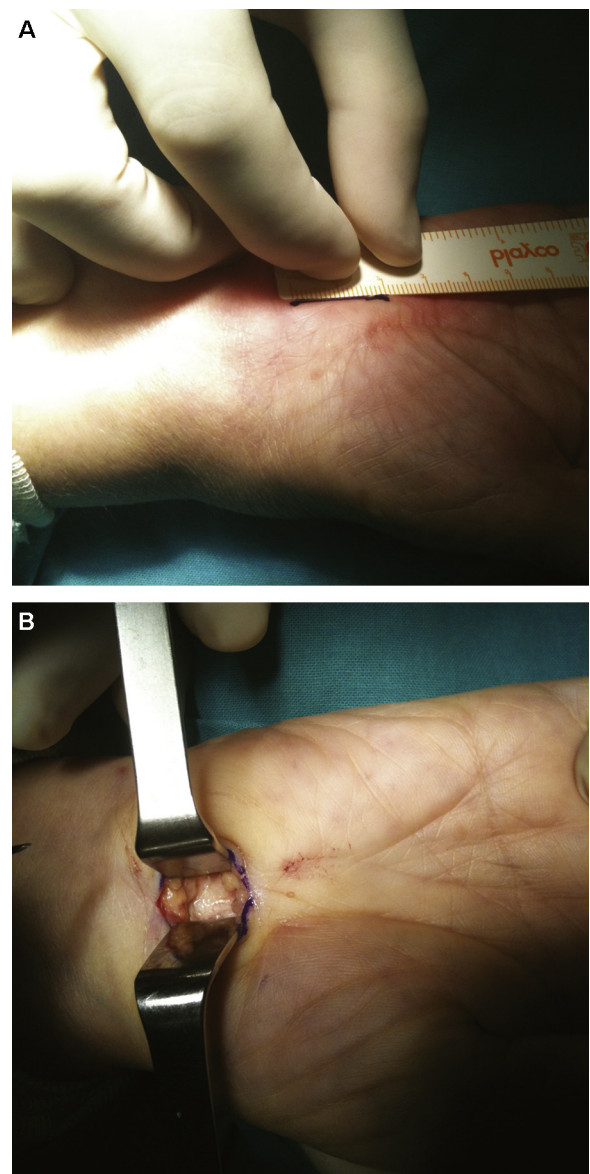


Fig. 3. Surgical details for Mini-OCTR. A. Location and incision size. B. Surgical approach.

treated as preliminary (no power calculations performed). Institutional review board approval and written informed consent were obtained for this study.

3. Results

Forty of 57 eligible patients were randomly allocated to Ultra-MIS or Mini-OCTR group (Fig. 4) showing respectively no significant differences in: average age, 62.5 (range, 31–83) versus 58.4 (range, 30–83) years; presurgical symptom duration, 37.4 (range, 4–118) versus 37.9 (range, 2–137) months; labor status, 12 versus 11 employed; nor sex, 2 versus 3 males. Primary objectives were matched in both groups. Results for secondary feasibility objectives are shown in Table 1.

Results for our pilot study for Quick-DASH and Grip Strength Rate are shown in Fig. 5. Comparing Ultra-MIS versus Mini-OCTR, patients required an average ($\pm$ SEM) of: (1) 2.1 ± 0.72 versus 14.23 ± 3.18 days for stopping oral analgesics; (2) 1.65 ± 0.76 versus 7.8 ± 2.69 days for complete wrist extension; (3) 2.5 ± 0.75 versus 11.75 ± 3.82 days for complete wrist flexion; (4) 1.86 ± 1.59

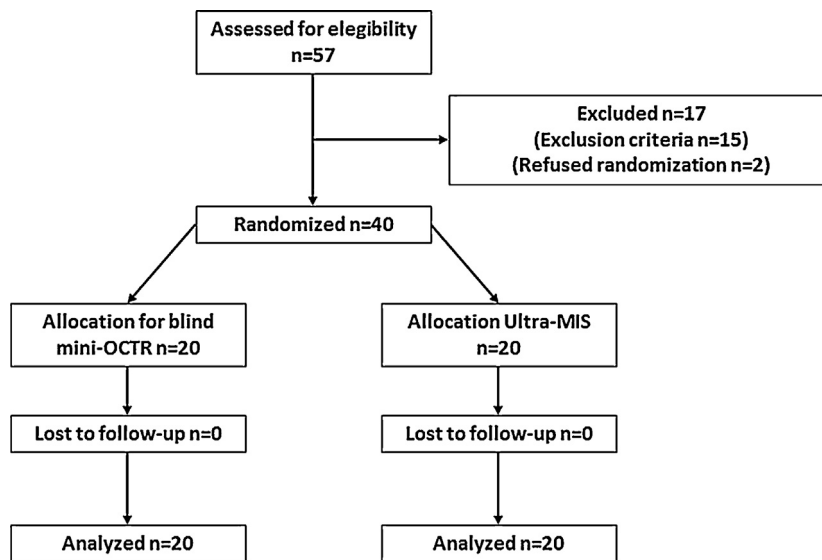


Fig. 4. Patient flow diagram showing participant progress.

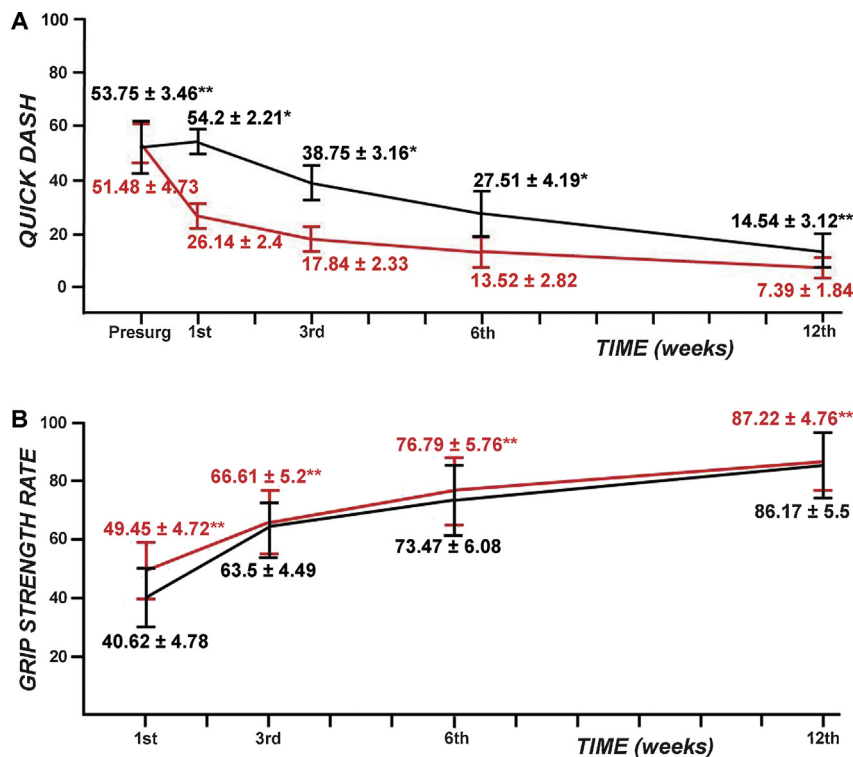


Fig. 5. Quick-DASH (A) and Grip Strength Rate (B) after Ultra-MIS (red) or Mini-OCTR (black) measured preoperatively (Presurg) and postoperatively (3, 6 and 12 weeks). Quick-DASH measured in 0–100 scale. Grip Strength Rate for the operated hand was expressed as a percentage of the individual's normal grip calculated as: strength of dominant uninjured side – 10% = calculated normal strength of the injured non-dominant side; or strength of non-dominant uninjured side + 10% = calculated normal strength of the injured dominant side [34]. Values show mean ± 2 SEM. Mini-OCTR vs Ultra-MIS: * $P < 0.05$; ** $P > 0.05$.

versus 12.6 ± 9.04 days for relieving paresthesia; and (5) 4.35 ± 1.45 versus 25.85 ± 5.37 days for returning to their normal daily living (including work activities). Differences between groups were statistically significant except for the days taken for relieving paresthesia ($P > 0.05$). No complications were registered in either group.

For the last 10 cases in each group, the average ($\pm$ SEM) turnover time was significantly lower for Ultra-MIS (19.1 ± 1.41 minutes) than for Mini-OCTR (25.8 ± 1.73 minutes), however, learning curves were stable for both groups ($R^2 = 0.15$ and $R^2 = 0.05$, respectively, $P < 0.05$).

We calculated a sample size of 82 patients (power: 80%; confidence level: 95%) using Epidat 3.1, based on the mean $\pm$ standard deviation values for Quick-DASH in the Mini-OCTR (14.54 ± 13.95) and Ultra-MIS (7.38 ± 8.23) groups. To ensure sample size, we will include 10% more patients in the final study (91 in total).

4. Discussion

The rationale for developing alternative CTR options is to reduce morbidity from surgical collateral damage to non-etiological

structures [1,4,5,7,8]. Although sonographic percutaneous approaches [4,9,10] use the smallest surgical approach to date, there are questions about their generalizability: e.g., large list of contraindications [4,8], release extent at the deepest layer portions [4,9,10], best approach location [4,23,30], best advancing direction of the instrument [34,35] and size of the instrument's acoustic shadows. On the basis of the perceived limitations of the prior techniques [4,8–10], Rojo-Manaute et al. [11] have recently developed a safe and effective sonographically guided Ultra-MIS CTR in cadavers. The main technical advantages of Ultra-MIS are: (1) the Acufex blade's 2-mm width allows for a 1-mm incision, its 1-mm thickness produces a small sonographic shadow and its 3-mm diameter matches the transverse carpal ligament thickness [11,22,31]; (2) the distal volar forearm approach allows targeting isolately the deepest fibrous layer of the carpal tunnel [11,22] while avoiding injuring the denser innervation at the palm, all of which may reduce morbidity and postoperative pain [5,7,9,15,22,23,36]. Since Ultra-MIS CTR has not been performed clinically, the present study should help to design a clinical trial proving its feasibility.

The first goal of our pilot study was to evaluate our specific feasibility objectives for a future clinical trial. Our results showed that: (1) CTR was safe (no neurovascular complications) and effective (no relapses) in both groups; (2) we matched our objectives for recruitment (criteria of eligibility were sufficient), blinding, compliance and completion rates (Table 1); and (3) the protocol would need modifications to the concealment of the surgical wound to data collectors. Taping the wrists created an overload in our personnel resources so we instructed patients to avoid revealing their wound to the data collector, however, this created a potentially suboptimal concealment that is a limitation to this study (Table 1). In the subsequent clinical trial, patients will be given a dressing to cover their skin wound before entering the data collector's office in each postsurgical visit. Although, to our knowledge, there is no guideline in literature for setting a proper threshold for recruitment rate among eligible patients, Choi et al. [37] set a similar threshold (70%) and their study was later cited by Thebane [27] as an example of a setting up good thresholds. Regarding the sample size for our pilot study ($n=40$), several authors [24,27,28] have discussed that a sample size calculation is not necessary for pilot studies, suggesting that sample size should depend on the parameter(s) to be estimated and that a general rule of thumb is to take 30 patients or greater [24,38]. However, there is not much consensus since in the analysis performed by Arnold et al. [29] the median number of patients in the studies that they included was 52 (average 59.6, range 20–120). Therefore, our sample size was above the recommendations given by Lancaster and inside the range recommended by Arnold.

The second goal of this study was to study our patient's response to the intervention. Our early results showed that Ultra-MIS had a larger recovery of physical function and symptoms in less postoperative time than Mini-OCTR, nevertheless, Grip Strength Rate did not show significant differences between groups throughout the study (Fig. 5); however these results should be interpreted with caution since pilot studies are not designed for hypothesis testing and its results are not supported by a sample size with adequate power [24,27,29]. Our subsequent trial would allow us to properly compare the clinical outcomes of the two techniques. Ultra-MIS used less turnover time per procedure than mini-OCTR and our learning curves were “stable” in our last 10 procedures in both groups. In this work, we required to assess “stability” because the total economic costs of a procedure are directly dependant on turnover times and these, in turn, are dependent on learning curves [26]. Learning curves plot performance with respect to ability over time, thus, if a clinician is learning, the curve will follow a so-called “power law of practise”. Data for learning curves is obtained from the “power law” slope and fit to a model. The slope indicates the

speed at which learning occurs (not needed for this study) and the curve fit can be measured using a statistical model under the generalized linear model. We used a linear regression model to fit our numerical continuous variables and interpreted R^2 as “stable” (weak learning influence) for $R^2 < 0.26$; and a final sample size of 91 patients was determined [26]. For sample size calculations, our follow-up period was limited to three months based on Nakamichi's [4,8] previous results since, for most of their clinical data, they only reported significant differences up to the sixth week. The Quick-DASH was established as our primary variable due to its known validity, reliability and responsiveness for monitoring upper limb physical function and symptoms in several languages (including Spanish).

In conclusion, a prospective, randomized clinical trial, comparing Mini-OCTR versus Ultra-MIS, is feasible in terms of potential safety and efficacy, processing and resource objectives and sample size calculations. While a randomized trial is still needed for generalizing its clinical use, to our knowledge, there is currently no evidence to neither contraindicate nor withhold the use of Ultra-MIS in patients with symptomatic CTS and a positive electrodiagnostic tests.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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