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ORIGINAL ARTICLE
Hand/Peripheral Nerve

Partial Versus Total Trapeziectomy Thumb Arthroplasty: An Expertise-based Feasibility Study

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Background: There are numerous surgical techniques for the treatment of first carpometacarpal joint osteoarthritis, however, controversy exists as to whether outcomes differ between techniques. This feasibility study aimed to determine if a large-scale, health-related quality of life and functional outcomes study comparing 2 surgical techniques, complete trapeziectomy with ligament reconstruction and tendon interposition (T + LRTI) versus partial trapeziectomy and tendon interposition (PT + TI) arthroplasty, is possible.

Methods: Patients with advanced stage arthritis (Eaton stages II–IV) of the thumb were invited to undergo either T + LRTI or PT + TI at 1 of the 2 hand surgery practices. Feasibility outcomes included: (1) Process: recruitment rate; (2) Resources: eligibility rate, eligibility criteria, retention, and compliance rates (completion of health-related quality of life questionnaires, Disabilities of the Arm, Shoulder, and Hand, EuroQol-5D-3L, and SF-36, and functional measurements, grip, key pinch, and tip pinch strength, at 1-week preoperatively and 1, 3, 6, and 12 months postoperatively); (3) Management: determining the practices' commitment to the study; and (4) Scientific: calculation of the variances and treatment effect sizes (ES) of differences between procedures. Data from baseline measurements and 6-month follow-up were used for analysis.

Results: Sixty patients were screened, of which 34 (57%) were eligible for surgery. Twenty-one (81%) of the 26 ineligible patients were excluded due to previous or additional planned surgical procedures on the same hand, particularly carpal tunnel release (n = 17). Twenty patients consented; 12 in the T + LRTI and 8 in the PT + TI group. The highest completion rate for the 3 questionnaires and the functional measurements, for both groups was at 6-month time point. Compliance rates for questionnaire completion at 6-months were calculated at 50% and 75% for the T + LRTI and PT + TI group, respectively. Functional measurement completion rate was 50% and 63% for T + LRTI and PT + TI groups, respectively. Treatment ES were group dependent, with Disabilities of the Arm, Shoulder, and Hand, EuroQol-5D-3L usual activities and anxiety/depression showing a large ES in the PT + TI group; the T + LRTI group showed large ES in EQ-5D state of health today.

Conclusions: Authors conclude that a large-scale study is feasible and dependent on: (1) increasing sample size to account for the high attrition rate; (2) liberalizing inclusion criteria to include patients with carpal tunnel syndrome; (3) allotting more time at follow-up visits to ensure completion of all measurements; and (4) increasing staff involvement (ie, develop rapport with patients and maintain stability with research assistants). *(Plast Reconstr Surg Glob Open 2018;6:e1705; doi: 10.1097/GOX.0000000000001705; Published online 19 March 2018.)*

BACKGROUND

Osteoarthritis (OA) of the basal joint of the thumb is a common disorder affecting 1 in 4 women and 1 in 12 men.[1] There is a variety of treatment options, both surgical and nonsurgical, depending on the severity of symptoms. Traditionally, treatment has been stage-based[2]; stage I with ligament reconstruction, stage II and III with 1 of hemitrapeziectomy, joint fusion or implant arthroplasty,

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and stage IV with complete trapeziectomy with or without ligament reconstruction.[3] Effective treatment of advanced disease (stages II–IV) is contingent on the removal or replacement of the entire joint surface. This can be achieved through several means including: (1) simple joint fusion, which will alleviate pain, but results in a significant mobility deficit[4]; (2) implant arthroplasty, which has been shown to have implant failure and joint instability[4]; and (3) trapeziectomy with ligament reconstruction and tendon interposition (T + LRTI), the most common intervention to treat OA in the carpometacarpal joint (CMCJ).[5,6]

To date, 3 randomized controlled trials (RCTs) have been performed comparing the effectiveness of the above-mentioned procedures: T + LRTI and simple trapeziectomy (ST),[7] T + LRTI, ST and trapeziectomy with soft-tissue interposition,[8] and T + LRTI, ST and trapeziectomy with PL interposition.[9] Although these studies added important information to the literature, they experienced common limitations in conducting RCTs including, small sample size and bias imparted by unblinded assessors.[7–9] In addition, 4 systematic reviews have been published comparing outcomes (pain, physical function, and range of motion) following the above-mentioned procedures. Although these reviews revealed that no one procedures is superior to the others,[4,10–12] patients receiving T + LRTI experienced more complications in comparison with those receiving ST (RR = 2.21; 95% CI, 1.18–4.15).[12] However, some patients receiving ST reported pain and weakness due to proximal migration of the first metacarpal and shortening of the thumb ray.[9]

Preserving a portion of the trapezium, through a partial trapeziectomy and interposition, could maintain the stability at the scaphotrapezial joint, thereby preserving grip and pinch strength.[13,14] Reports exist on partial trapeziectomies in which the distal trapezium is excised, and the void is filled with interpositional material. The first reported procedure resected only the articular surface of the trapezium and used the Flexor Carpi Radialis tendon as the interpositional material.[15] A similar procedure, reported in 2002, used both the Flexor Carpi Radialis and a costochondral allograft as interpositional material.[16] Lastly, a case-report described a procedure where only the distal trapezium and proximal metacarpal articular surfaces were excised, and the deep and dorsal capsular tissue were used as interpositional material.[17] Positive outcomes were reported from these procedures with 83.6% of patients reporting complete pain relief,[15] high levels of function with minimal postoperative symptoms[16] and no pain at the base of the thumb or difficulties in daily living at 30 months postoperative.[17] Although outcomes were encouraging, reports lacked preoperative measurements from which to make reliable outcome comparisons.[17] The ideal study therefore would be a head-to-head comparison between a partial trapeziectomy and total trapeziectomy.

Before undertaking a large definitive trial, it is recommended that investigators first perform a feasibility study.[18] Therefore, the primary aim of the current feasibility study was to assess the practicality of achieving the following targets in such definitive trial: (1) process (adequate recruitment); (2) resources (eligibility criteria, retention, and compliance); (3) management (time allocation for data collection); and (4) scientific outcomes [safety, treatment effect sizes (ES), and variances]. The secondary objective was to calculate the treatment ES and variances between the procedures. We hypothesized that such a prospective cohort design is feasible in a future large-scale study.

METHODS

This prospective cohort feasibility study utilized an expertise-based design, eliminating the dilemma of the surgical learning curve.[19] Each of the 2 authors, C.L. and A.T., used their preferred technique for management of thumb CMCJ OA.

The 2 surgical techniques were (1) complete trapeziectomy with T + LRTI performed by CL and (2) partial trapeziectomy and tendon interposition (PT + TI) performed by AT. Both procedures are outlined in **Supplemental Digital Content 1** and illustrated in Figure 1, respectively. To our knowledge, the PT + TI technique as described herein has not been reported in the literature. The outcomes measured in this study were health-related quality of life (HRQOL) and functional outcomes.

The study took place between March 2012 and November 2015 at St. Joseph's Hospital (an academic center under McMaster University) in Hamilton, Ontario, Canada. This study was approved by the Hamilton Integrated Research Ethics Board under the project number 11–3530.

Sample Size

As the aim of this study was to assess the feasibility of a future full-scale clinical trial, there was no formal sample size calculation. A sample size of 15 patients per group, for a total of 30 patients, was deemed sufficient by the authors.

Inclusion and Exclusion Criteria

Inclusion criteria were (1) diagnosis of advanced stage (Eaton stages II–IV) CMCJ OA of the thumb; (2) willingness to undergo surgery for CMCJ OA; (3) over the age of 18 years; (4) able to provide informed consent; and (5) ability to read and comprehend English to complete the HRQOL questionnaires.

Exclusion criteria were (1) diagnosis of Eaton stage I CMCJ OA of the thumb; (2) under the age of 18 years; (3) presence of any concomitant hand pathology (including rheumatoid arthritis, neuropathy, carpal tunnel syndrome (CTS), and traumatic arthritis); and (4) previous surgery on

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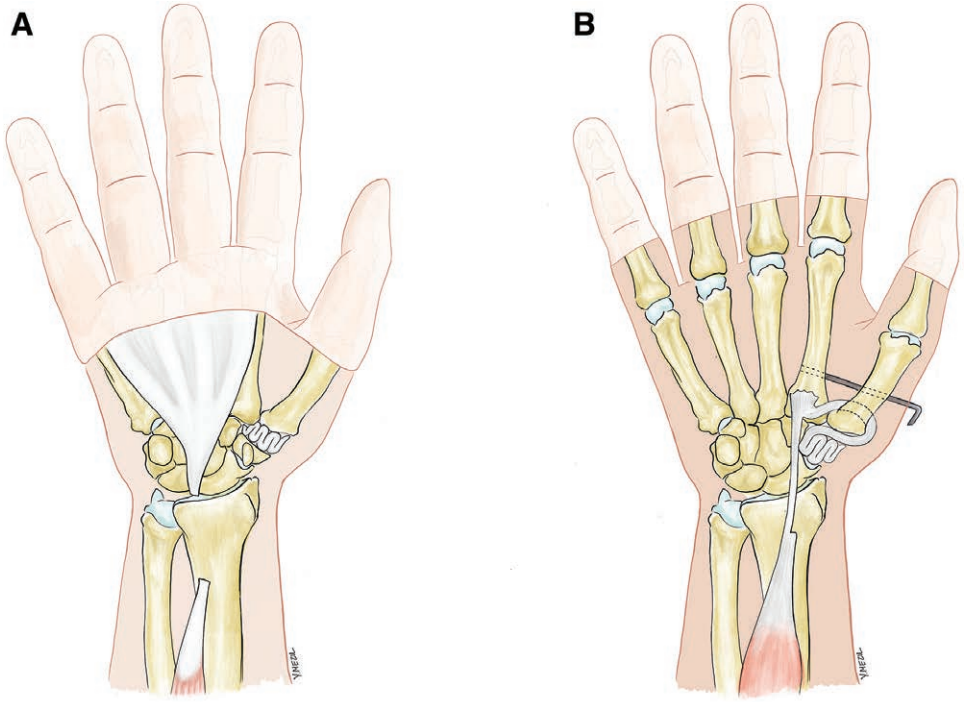

Fig. 1. A, Partial trapeziectomy with Palmaris longus interposition. B, Total Trapeziectomy with ligament reconstruction and tendon interposition.

the same hand or currently under consideration for hand surgery.

Recruitment

Patients were recruited from the practices of CL and AT. Each patient was screened by their respective surgeons and given the details of the study. If eligible and interested, the patient was approached by the surgeon or research assistant (RA) to consent to participate in the study.

Data Collection and Patient Follow-up

HRQOL was measured using 3 questionnaires at 1 week before surgery (preoperative) and 1, 3, 6, and 12 months postoperatively. The 3 questionnaires: (1) The Short Form-36v2 (SF-36); (2) The Disabilities of the Arm, Shoulder, and Hand (DASH); and (3) The EuroQol-5D-3L (EQ-5D) were used, as suggested by Guyatt et al.[20] Guyatt et al.[20] recommended that 3 questionnaires, 1 generic, 1 condition-specific, and 1 utility measure should be used in a study where the HRQL is the primary outcome. Questionnaires were given to the patients during their follow-up visit; if the patient missed a follow-up appointment, the questionnaires were e-mailed or mailed with the patient's permission.

SF-36

The SF-36 is a generic quality of life questionnaire widely used to guide OA treatment in clinical trials as it is fairly sensitive to minimal perceptible clinical improvement.[21] The SF-36 includes 8 scales; 3 that measure physical health status: Physical Functioning, Role-Physical, and Bodily Pain, and 3 that measure the mental health status: Mental Health, Role-Emotional, and Social Functioning. Vitality and General Health scales are sensitive to both physical and mental health outcomes. The scores range from 0 (lowest score) to 100 (highest possible score).

DASH

The DASH is a validated region-specific quality of life questionnaire that has been used in several studies evaluating the effect of surgical interventions for CMCJ OA. The DASH represents disability experienced by the patient (0 = no disability; 100 = maximum disability). This questionnaire has been deemed both reliable and responsive in this patient population.[22,25–27]

Euro-QoL-5D

The EuroQol-5D is used to calculate utilities, which can then be transformed to quality-adjusted life years, a prerequisite of cost-effectiveness analysis. The EuroQol-5D is composed of 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 3 levels: no problems (0), some problems (1), and extreme problems (2). This instrument is validated and has previously been used to evaluate disorders of the hand such as OA.[22–24]

Functional Measurements

Functional measurements including (1) grip strength; (2) 2-point strength; and (3) key pinch strength were measured pre- and postoperatively at follow-up appointments[28] (**Supplemental Digital Content 1**).

Demographic Information

Patients provided standard demographic information, including but not limited to age, sex, employment status, and affected hand(s).

Surgical Techniques

The technique received by each patient was dependent on which surgeon they were referred to. Surgical techniques are discussed in **Supplemental Digital Content 1** and are illustrated in Figure 1 (**see pdf Supplemental Digital Content 1**, which displays the surgical techniques in detail, ***http://links.lww.com/PRSGO/A720***).

Adverse Events/Complications

Any operative and nonoperative adverse events that occurred over the follow-up period were recorded on the Adverse Event Form and dealt with in accordance with the local ethics board.

Analysis

Compliance was calculated using the number of questionnaires/functional assessments completed at the 6-month follow-up time as compared with the number of patients who consented to participate in the study.

Given the objectives of this study, outcome data were reported descriptively. Demographic information and functional assessments were analyzed using descriptive statistical techniques. Categorical data were reported as counts and percentages and differences examined descriptively. Continuous data were reported as means and SDs, and differences were examined descriptively using computed treatment ESs. As this is a feasibility study, no conclusions about the superiority of 1 technique over the other can be drawn. All analyses were performed using IBM SPSS Statistical Software, Version 24.02.[29]

RESULTS

Feasibility Outcomes

Process Outcome

Fifty patients were screened for eligibility; 25 patients in the T + LRTI and 30 patients in the PT + TI group. Twenty-six (5 from TLRTI and 21 from PT + TI) (43%) were excluded, resulting in 29 eligible patients. Twenty consented to participate in the study.

Resource Outcomes

T + LRTI Group

In the T + LRTI group, once the ineligible patients were removed, 20 patients remained; 12 of those 20 consented to participate. Reasons for exclusion and number of patients excluded were as follows: (1) Eaton stage 1 OA (n = 1); (2) previous/under consideration for future surgery on the same hand (n = 2); and (3) concomitant hand pathology (n = 2).

After the completion and collection of baseline questionnaires, 1 patient was excluded from the study as answers were based on sciatica not OA pain. Following the completion and collection of 1-month questionnaires, 1 patient was excluded as not all questionnaires were complete. Two patients, 1 following baseline and 1 following the 1-month mark asked to discontinue participation, a reason was not recorded.

Table 1. Compliance Rate for T + LRTI Group at Each Follow-up Time

Follow-up Time	Compliance	
Total Consented = 12	HRQOL, n (%)	Functional Measures, n (%)
Baseline	12 (100)	10 (83)
1-mo Postoperative	4 (33)	3 (22)
3-mo Postoperative	5 (42)	5 (42)
6-mo Postoperative	6 (50)	6 (50)
12-mo Postoperative	2 (17)	1 (0.08)

Table 2. Compliance Rate for PT + TI Group at Each Follow-up Time

Follow-up Time	Compliance	
Total Consented = 8	HRQOL, n (%)	Functional Measures, n (%)
Baseline	8 (100)	7 (88)
1-mo Postoperative	7 (88)	2 (25)
3-mo Postoperative	6 (75)	2 (25)
6-mo Postoperative	6 (75)	5 (63)
12-mo Postoperative	6 (75)	4 (50)

PT + TI Group

As reported, 21 of the 30 patients screened in the PT + TI group were deemed ineligible to participate. Reasons for exclusion and the number of patients affected are as follows: (1) previous or under consideration for future surgery of the same hand (n = 19); and (2) concomitant hand pathology (n = 2). Once ineligible patients were removed, 9 patients remained; 8 of whom consented to participate.

No patients in the PT + TI group requested termination of participation or were excluded.

The completion rate for HRQOL questionnaires and functional measurements can be found in Tables 1, 2 for T + LRTI and PT + TI groups, respectively.

While the 12-month follow-up appointment had higher compliance rate in questionnaire completion in the PT + TI group, the 6-month follow-up time-point was used as it had the highest compliance for both measures in both groups. Therefore, data from the 6-month time point was entered into analysis to compare to baseline (Fig. 2).

The demographic characteristics of the patients in both study groups are shown in Table 3.

Management Outcomes

Upon completion of data collection, it was evident that there were substantial gaps in data collected. Authors attribute this missed data to 1 or both of the following: (1) high turn-over rate of RAs; and/or (2) insufficient time allocation to follow-up appointments. During the course of the study, 3 different RAs took part in the recruitment and data collection process. The high turn-over rate of RAs resulted in lack of proper training and missed data collection opportunities.

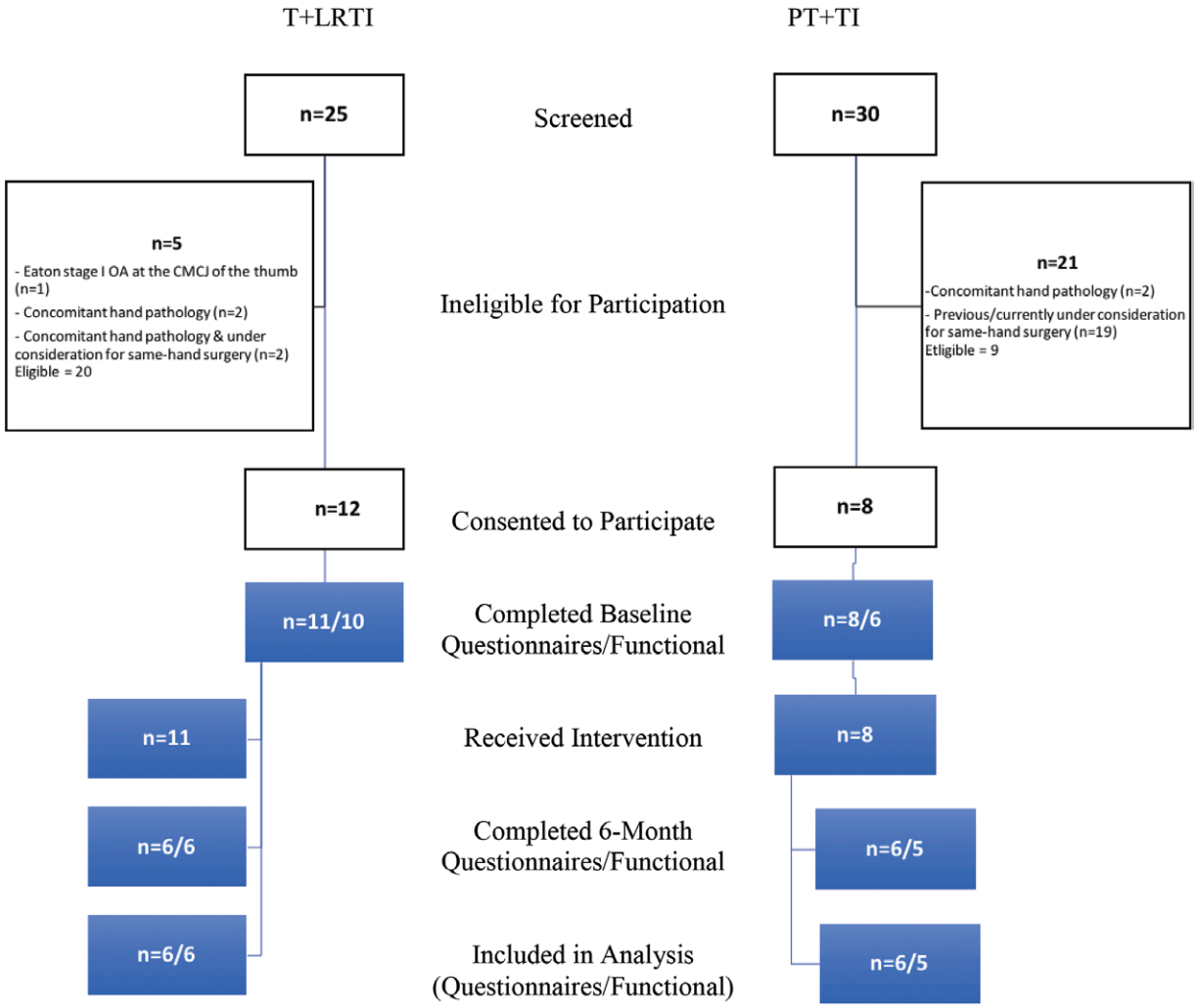

Fig. 2. Illustrates the screening, recruitment, and retention.

Scientific Outcomes

The treatment ESs were calculated for the PT + TI and T + LRTI group separately (Tables 4, 5, respectively). The SF-36 variables were grouped into the transformed physical and mental scores. In the PT + TI group, the DASH disability score, the EQ-5D usual activities and the EQ-5D anxiety and depression all were calculated as having a large ES. In the T + LRTI group, only the EQ-5D state of health today showed a large ES.

SF-36

Our findings indicate that physical status improved by 1.84 in patients who underwent PT + TI (SD = 3.57) and 1.21 in those that underwent T + LRTI (SD = 2.29). Mental status improved in the PT + TI group by 1.67 (SD = 1.87); however, declined by 0.60 (SD = 1.96) in the T + LRTI group. Table 6 illustrates the change in SF-36 scores from 1-week pre- to 6-months postoperative.

DASH

The PT + TI group of patients experienced less disability postoperatively ($\bar{x} = -20.48$, $SD = 21.63$) compared with the T + LRTI group ($\bar{x} = -5.58$, $SD = 10.11$).

EQ-5D

Patients who underwent PT + TI reported a decline of 0.33 points (SD = 0.52) in problems encountered with usual activities; patients in the T + LRTI group reported a decline of 0.17 points (SD = 0.75). PT + TI patients reported a 0.5 point decline (SD = 0.55) in problems with anxiety/depression; T + LRTI patients noted no change. When reporting state of health dimension on a scale, with 0 being "worst imaginable health state" and 100 being "best imaginable health state," PT + TI patients reported a 3.33 point (SD = 9.83) improvement, whereas T + LRTI patients reported a 4-point (SD = 6.03) decline. Table 7 summarizes the average EQ-5D responses at baseline and 6 months postoperative for both groups.

Functional Measurements

Strength measurements at the 6-month follow-up appointment showed decreased key pinch, and tip pinch strength for both groups. The T + LRTI patients showed a decrease in grip strength at 6 months postoperative, whereas PT + TI patients showed an increase (Table 8).

Table 3. Demographic Data of Patients Included in Analysis, by Group

Variables	T + LRTI (n = 6)	PT + TI (n = 6)
Age ($x \cdot (SD)$)	**64.8 (13.6)**	**57.3 (4.6)**
Sex		
Female	5	6
Male	1	0
Employment status		
Full-time	3	2
Part-time	0	1
Home-maker	0	1
Retired	3	2
Level of education		
Some high school	2	0
High school graduate	1	1
College graduate	1	3
University graduate	2	1
Not reported	0	1
Impact of health on employment status		
Yes	2	2
No	1	1
N/A	3	2
Not reported	0	1
Dominant hand		
Right hand	6	6
Hand affected by OA		
Right hand	4	1
Left hand	2	2
Both	0	3
Smoking status		
Nonsmoker	6	4
Current or past smoker	0	2

Table 4. Calculated Treatment ES for PT + TI Patients

HRQOL Scale	Δx	*Baseline SD*	ES
DASH			
Disability symptom score	-20.48	17.16	-1.19
EQ-5D			
Mobility	0.00	0.82	0.00
Self-care	0.00	0.84	0.00
Usual activities	-0.33	0.41	-0.82
Pain/discomfort	-0.33	0.63	-0.53
Anxiety/depression	-0.50	0.52	-0.97
State of Health Today	3.33	11.83	0.28
SF-36			
Transformed Physical Health Score	1.84	3.46	0.53
Transformed Mental Health Score	1.67	3.36	0.50

Adverse Events

No adverse events occurred during this study.

DISCUSSION

Summary

Our study was designed to assess the feasibility of a comparative study of T + LRTI versus PT + TI in which the outcomes were HRQOL and functional outcomes. Although no definitive conclusions can be made between the PT + TI and the T + LRTI surgical techniques with regard to HRQOL and functional measures, these preliminary results suggest that the PT + TI technique offers benefits to patients. These results are encouraging and suggest there is merit to investigate this minimalistic technique. As the T + LRTI is the most common procedure performed in North America and the present feasibility study shows slightly better results with PT + TI, we believe that equipoise exists to submit these 2 techniques to a definitive trial.

Table 5. Calculated Treatment ES for T + LRTI Patients

HRQOL Scale	Δx	*Baseline SD*	ES
DASH			
Disability symptom score	-5.58	8.23	-0.68
EQ-5D			
Mobility	0.00	0.41	0.00
Self-care	0.00	0.00	NA*
Usual activities	-0.17	0.52	-0.32
Pain/discomfort	-0.33	0.00	NA*
Anxiety/depression	0.00	0.41	0.00
State of Health Today	-4.00	5.05	-0.79
SF-36			
Transformed Physical Health Score	1.21	2.52	0.48
Transformed Mental Health Score	-0.60	0.94	-0.63

*Could not be calculated as Δx and baseline SD were 0.00.

Results indicate that the success of a future large trial will depend on addressing the pitfalls unmasked by the current study. Below are suggestions to ensure the success of a definitive future study:

1. Ensure consistent and reliable staff involvement at all study sites to maintain contact with patients and ensure attendance and completion of data collection at follow-up appointments.
   a. A single research coordinator per site should monitor proper conduct; there should be a protocol established before the initiation of the trial describing proper hand over if necessary.
2. Provide adequate time and a comfortable environment to patients to complete questionnaires and functional assessments. This is especially important in this population as thumb OA tends to occur in the elderly population. More time and a comfortable setting in which to complete the measurements was expressed by both the patients and the RAs; therefore, this is identified as a major concern in the current study.
   a. The authors suggest choosing 1 day either bi-weekly or monthly and schedule all study participants on that day. This would allow for more time to be allocated to patients and would help create a more comfortable environment. In the current study, it was found that the private office was much more conducive to research; while the authors recognize this is not feasible for all sites, allocating a specific day for study patients could help minimize the feeling of being rushed.
3. Include patients despite CTS diagnosis.
   a. Since the inception of the current study, there has been evidence to show that the coexistence of CTS and thumb OA is very common, with up to 43% of patients presenting with both conditions (Lutsky et al.[30]). Future studies should enroll patients de-

Table 6. Average SF-36 Results from Preoperative to 6-month Follow-up for T + LRTI and PT + TI Groups

	T + LRTI (n = 6)		PT + TI (n = 6)	
Variables	**Pre $\bar{x}$ (SD)**	**Post $\bar{x}$ (SD)**	**Pre $\bar{x}$ (SD)**	**Post $\bar{x}$ (SD)**
Physical functioning	45.46 (6.21)	48.61 (4.80)	40.55 (7.46)	40.27 (11.29)
Role—physical	47.87 (9.63)	50.32 (9.63)	36.85 (11.94)	45.83 (9.00)
Bodily pain	42.33 (4.63)	44.93 (7.66)	36.20 (7.17)	43.74 (7.05)
General health	54.44 (4.30)	54.36 (6.57)	46.82 (11.70)	51.82 (11.59)
Vitality	58.33 (6.24)	56.77 (5.13)	47.41 (8.99)	50.53 (6.47)
Social functioning	54.12 (6.68)	55.94 (2.23)	42.31 (11.78)	45.94 (13.36)
Role—emotional	55.88 (0)	55.88 (0)	50.70 (8.40)	51.34 (7.54)
Mental health	59.86 (1.99)	61.27 (0)	51.42 (5.27)	54.42 (6.81)
Transformed physical score	36.35 (2.52)	37.56 (2.87)	33.52 (3.46)	35.37 (3.01)
Transformed mental score	44.66 (.94)	44.06 (1.78)	40.76 (3.63)	42.44 (3.52)

Table 7. Average EQ-5D Results from 1-week Preoperative to 6-months Postoperative for T + LRTI and PT + TI Groups

	T + LRTI (n = 6)		PT + TI (n = 6)	
Variables	**Pre $\bar{x}$ (SD)**	**Post $\bar{x}$ (SD)**	**Pre $\bar{x}$ (SD)**	**Post $\bar{x}$ (SD)**
Mobility	1.17 (0.41)	1.17 (0.41)	1.67 (0.82)	1.67 (0.82)
Self-care	1.00 (0)	1.00 (0)	1.50 (0.84)	1.50 (0.84)
Usual activities	1.33 (0.52)	1.17 (0.41)	1.83 (0.42)	1.50 (0.55)
Pain/discomfort	2.00 (0)	1.67 (0.52)	2.00 (0.63)	1.67 (0.52)
Anxiety/depression	1.17 (0.41)	1.17 (0.41)	1.67 (0.52)	1.17 (0.41)
State of Health Today	89.50 (5.05)	85.50 (7.71)	75.00 (11.83)	78.33 (11.26)

Table 8. Functional Measurements of Patients Who Received PT + TI, T + LRTI, and Combined Total

		T + LRTI		PT + TI		Total	
Measures	**Time Point**	***n***	**$\bar{x}$ (SD)**	***n***	**$\bar{x}$ (SD)**	***n***	**$\bar{x}$ (SD)**
	1-wk Preoperative	5	19.6 (16.4)	5	15.6 (5.4)	10	17.6 (11.7)
Grip strength (kg)	6-mo Postoperative	4	16.6 (8.1)	3	16.3 (4.1)	7	16.5 (6.2)
Key pinch strength (kg)	1-wk Preoperative	5	6.9 (8.0)	5	4.3 (3.4)	10	5.6 (6.0)
	6-mo Postoperative	4	4.7 (2.0)	3	3.4 (0.42)	7	4.1 (1.6)
Tip pinch strength (kg)	1-wk Preoperative	5	5.5 (5.6)	5	3.4 (1.7)	10	4.4 (4.0)
	6-mo Postoperative	4	4.0 (1.2)	4	3.2 (1.4)	7	3.6 (1.6)

spite CTS diagnosis. A subgroup analysis of presence or absence of CTS could be performed and asked as a priori question.

4. As the recruitment and retention rates were lower than expected, having a larger sample size would help to ensure an adequate final sample.
   a. Involving more surgeons/sites could help with this.
5. Ensure a true randomized design to provide high-level evidence and detect differences in outcomes between groups.
   a. Utilize an expertise-based randomized control trial design where each surgeon involved in the study performs the procedure that they are considered an "expert" in.
   b. An agreement should be made to explain the intent to transform all individual practices into a "common practice" for the purpose of the trial. For example, if the patient in front of them (that they are currently treating/recruiting) gets randomized into the procedural group that is not their "expertise" they will send the patient to their colleague that is considered the "expert" at that procedure.
   c. It is important that the above process is explained to patients before the initiation of the study.
6. Consider looking at the influence of: (1) age; (2) sex; (3) medical comorbidities; (4) menopausal status; and (5) Eaton stage on outcomes.
   a. The addition of these variables would not affect sample size needed if the study was a true RCT design.

The current study had 2 major weaknesses; the nonrandomization design and the gap in data collection. If a randomized design was used, it may have unmasked issues with patient. Despite the unmasked obstacles, we believe a larger trial is possible if the above suggestions are taken. With regard to the data collection, large amounts of potential data were lost due to the high-level turnover of RAs. The authors recognize that a plan for such a situation should have been in place before the initiation of the study and have provided suggestions to avoid this situation above.

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