

Comparison between standard ligament reconstruction and tendon interposition vs adding an interference screw for flexor carpi radialis fixation. A pilot study

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ABSTRACT

Introduction: The traditional ligament reconstruction and tendon interposition (LRTI) procedure requires a trapeziectomy with the reconstruction of the palmar oblique ligament. Introduction of an interference screw (IS) during the tendon interposition is intended to improve tensioning of the beak ligament reconstruction and limit subsidence which may increase stability for the patient postoperatively.

Material and methods: Non-inferiority, clinical, blinded, and randomized trial was performed. Twenty patients were randomized to one of the two treatment groups (Standard LRTI vs LRTI + IS). Four patients did not receive surgery during the allotted time. Finally, 16 patients (8 per group) had completed follow-up data at the end of the designated 2-year follow up.

Results: Equivalent functional and radiographic outcomes were found. Trapezial height at 2 years was 4.44 mm for standard LRTI and 3.83 mm for LRTI with screw. At the end of the follow up period both groups had comparable grip strength. Mean improvement of DASH score, VAS and EQ5D was similar in both groups, showing good outcomes for both procedures.

Conclusion: Ligament reconstruction and tendon interposition with and without interference screw has shown equivalent results in a 2-year follow-up related to stability and functional outcomes. Interference screw is a safe and reliable technique with no difference in pain or complication rates.

Level of evidence: Therapeutic II.

1. Introduction

Thumb carpometacarpal (CMC) osteoarthritis is the second most common type of degenerative arthritis in the hand after the distal interphalangeal joints.^{1–3} It has been demonstrated to be more frequent in postmenopausal women with an incidence of 33%.^{3,4}

Trapeziometacarpal osteoarthritis limits the function of the thumb significantly compromising the quality of life for patients.⁴ In 1949,

Gervis⁵ described an isolated trapeziectomy as a reliable treatment option for these patients. With follow up, this was associated with patients complaining of weakness and instability due to the subsidence of the metacarpal through the empty trapezial space. For that reason, overtime some modifications to the original procedure had been implemented. Finally, in 1986 Burton and Pellegrini⁶ introduced the well-known trapeziectomy with LRTI procedure using the flexor carpi radialis tendon (FCR), which has been widely performed for many years.

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Nowadays, thumb basilar osteoarthritis has many different surgical options, such as joint fusion or replacement, isolated trapeziectomy, trapeziectomy with tendon interposition (T + TI), and trapeziectomy with ligament reconstruction and tendon interposition (T + LRTI). This last procedure has multiple fixation methods described for the reconstruction.^{2,7–13}

The traditional LRTI procedure requires a trapeziectomy with the reconstruction of the palmar oblique ligament. Reconstruction of this ligament is normally achieved by passing half of the complete flexor carpi radialis tendon (FCR) through a bone tunnel at the base of the first metacarpal and then suturing of the tendon onto itself with a non-resorbable suture.⁶ This suture could be a point of failure of the reconstruction. Introduction of an interference screw during the tendon interposition may provide an adequate method for the surgeon to ensure proper tensioning of the beak ligament reconstruction, limit subsidence and increase stability of the thumb for the patient postoperatively. The aim of this investigation was to compare the postoperative patient outcomes between two groups: standard LRTI procedure versus an LRTI procedure with the addition of an interference screw fixation device (LRTI + IS). This study also acted as a pilot study to assess feasibility and sample size calculation for a definitive randomized control trial.

2. Material and methods

After institutional ethics committee approval, a single-center, randomized, treatment and control, non-inferiority trial was conducted, with 2-arm parallel group of 20 participants. Patients with primary thumb CMC arthritis refractory to conservative treatments were randomized to standard LRTI or LRTI with interference screw.

The patients were recruited from a single referral center, they were allocated in a randomized fashion pre-operatively using a sealed opaque envelope, 1:1 into the two treatment groups, 10 per group following the CONSORT statement. Patients were blinded as to which group they were randomized. Randomization occurred on the day the patient consented to an operative procedure and study participation.

Patients were included in the study if they had (1) first CMC primary osteoarthritis refractory to conservative treatment, (2) age 18 or older, (3) CMC primary osteoarthritis including concomitant STT osteoarthritis, (4) able to read and understand English and (5) availability for a 2-year follow up. The exclusion criteria included (1) inflammatory arthritis, (2) active infection in the first CMC joint, (3) concomitant neuropathy, (4) previous surgical procedure on the thumb, (5) active or status post Complex Regional Pain Syndrome (CRPS), (6) presence of subchondral cysts that may interfere with interference screw stability (7) severe 'Z' deformity that may require complementary stabilization of the metatarsophalangeal joint, (8) unwilling to participate in the research project and (9) contralateral first CMC joint surgery, in order to have a comparative side for range of motion evaluation.

All patients followed the same postoperative protocol. At week 2, the sutures were removed and a thumb spica cast was applied. At 6 weeks, the cast was removed, and a standard occupational therapy protocol was started to improve range of motion and strength. An assessor performed the follow up that consisted of an evaluation at three, six, twelve and twenty-four months of the thumb range of motion, pinch and grip strength (range of motion evaluated with a hand goniometer, and pinch and grip strength with a dynamometer set at the second position by the research coordinator, all of them, measured as a percentage compared with contralateral side), and trapezial height (measured as a percentage compared with preoperative radiographs by the surgeon). The assessment was blinded both to the therapist and the assessor.

A subjective patient evaluation was also included with the DASH (Disability of the Arm, Shoulder, and Hand) questionnaire and a pain score on a visual analogue scale (VAS). The Euroqol-5D (EQ-5D) questionnaire was used as a general quality of life measure.

2.1. Statistical analysis

Change from baseline value was calculated as Baseline – week (X). This methodology was used across all values by a third party statistician, blinded to treatment arms. Distributions were tested using Shapiro-Wilks test for normality, error bars were calculated using 95% confidence intervals, normally distributed outcomes were tested using standard T-tests methods, while non-normally distributed outcomes with the Mann-Whitney U test. Statistical analysis was performed using R open source software.

2.2. Surgical technique

A standard dorsoradial incision over the base of the thumb is performed, between the glabrous and non-glabrous skin, subcutaneous dissection is performed taking care of not damaging radial nerve sensory branches, fascia is opened between the abductor pollicis longus and extensor pollicis brevis tendons and both tendons are retracted, capsulotomy is performed longitudinally and peeled until trapezium is completely exposed, a crossed-shaped osteotomy of the trapezium is performed with an oscillating saw and the bone is removed in four pieces, protecting the FCR tendon underneath to avoid iatrogenic injury. Having the base of the thumb fully exposed, a guide pin for the Bio-Tenodesis Screw System (Arthrex, Inc., Naples, Florida) is utilized a positioned 1.5 cm proximal to the articular surface and perpendicular to the metacarpal using the thumb nail plate as reference, the guide will be exiting at the volar ulnar aspect of the thumb aiming to the insertion of the beak ligament, the tunnel will be enlarged until 4.5mm or 5mm is achieved with a cannulated drill bit.

At this point the FCR tendon is harvested making two transverse 1 cm incisions separated by 10 cm from the distal volar creast. Once the tendon is identified and pulled through the tunnel, the tension of the thumb is set up manually, whereas the interference screw is positioned flat to the metacarpal surface, the remnant of the tendon is folded into an “accordion” manner and placed into the trapezium empty area (Fig. 1).

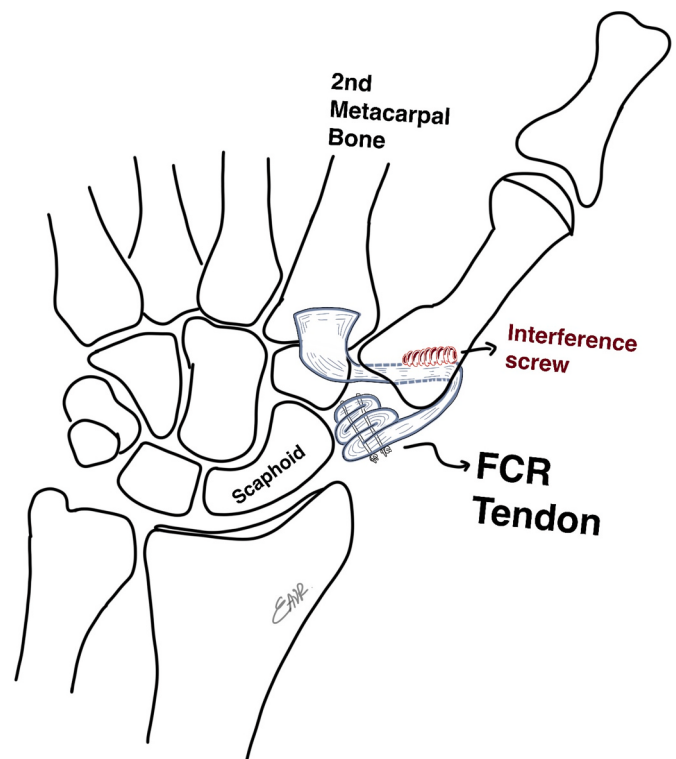


Fig. 1. Surgical technique LRTI + IS.

After this, capsule and fascia are repaired with 4.0 Poligrecaprone 25 suture and skin closed with 5.0 Nylon suture. Finally, the wound is covered with sterile dressing and placed in a plaster thumb spica splint until follow up in 2 weeks.

For standard LRTI, similar technique was performed, bone tunnel was positioned in the same place and FCR tendon was secured with 2.0 Ethylene terephthalate suture in position with thumb tension set up manually. Same dressing and splint were applied.

2.3. Rehabilitation protocol

Postoperative protocol is divided in three phases:

Phase 1: six weeks with a thumb spica cast, maintaining arm elevated and fingers movement to avoid swelling.

Phase 2: exercise program applied by an occupational therapist followed by a home-based program orientated to recover active thumb movement. Exercises include thumb flexion and extension as hitchhiker position, adduction and abduction, tip pinch, and circumduction motion. At the end of this period, full motion is recovered with some residual stiffness treated with stretching exercises.

Phase 3: At 9-week follow-up, the strengthening period is initiated with exercises involving a putty that provides some resistance when squeezed, this allows more targeted muscle strengthening than a squeeze ball. This period will extend for 2–3 months until the patient feels strength and function have improved.

3. Results

Twenty patients were randomized to one of the two treatment arms. Due to administrative circumstances with the hospital equipment, four patients cancelled their participation in the study and their surgery was reprogrammed. Finally, 16 patients (8 per group) had complete follow-up data at the end of the designated 2-year follow up (Fig. 2).

Most of the patients were women (81.25%) with a mean age at

procedure of 60 years old for standard LRTI and 62.6 years old in the LRTI + IS group. (Table 1). No other differences were found in base line demographics in both groups.

Trapezial height was measured in posteroanterior and oblique views of the radiographs at every postoperative evaluation. At the beginning of the study, both groups had similar trapezial height. In the twenty-four month follow-up, the average height was 4.44 mm for standard LRTI and 3.83 mm for LRTI with screw, $p = 0.47$ (Fig. 3).

Despite clinical differences in the preoperative values on grip strength (Standard LRTI = 21.25 kg vs LRTI + IS = 15.02 kg $p = 0.17$), at the end of the follow up period, both groups had comparable grip strength (Standard LRTI = 22.45 kg vs LRTI + IS = 23.29 kg, $p = 0.10$).

Range of motion of the thumb was similar for both groups preoperatively. We identified improvement in palmar and radial range of motion of the thumb postoperatively for all the participants (standard LRTI 50° vs 31° ; LRTI + IS group 48° vs 31°).

Tip, lateral and 3 jaw pinch tests were evaluated in all the studied patients. All of them showed no improvement in comparison with preoperative evaluation in any of the follow up time periods (Fig. 4).

DASH score showed significant improvement for both groups compared with preoperative results, with a reduction of 28.8 and 23.4

Table 1

Demographic characteristics of the two groups.

		LRTI ^a (n = 8) n %		LRTI + IS ^b (n = 8) n %	
Age		60 (49–78)		62.6 (53–76)	
Gender	Masculine	1	12.5	2	25
	Feminine	7	87.5	6	75
Handedness	Right	3	37.5	2	25
	Left	5	62.5	6	75

^a LRTI: Ligament reconstruction and tendon interposition.

^b LRTI + IS: Ligament reconstruction and tendon interposition + interference screw.

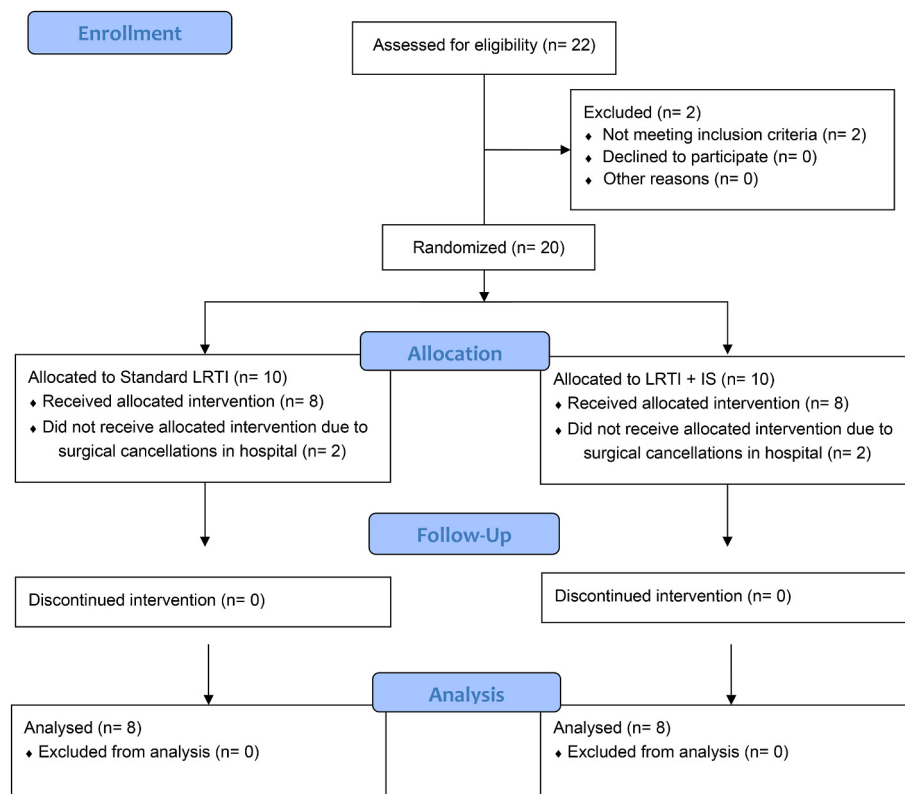


Fig. 2. CONSORT flow chart of the patients.

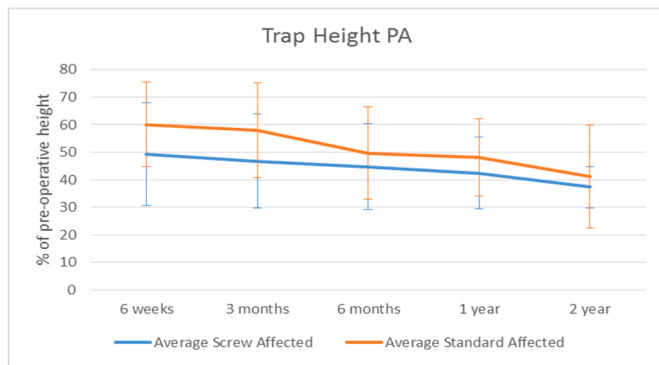


Fig. 3. Posteroanterior radiographs with trapezoidal height measured in mm expressed as a percentage comparing LRTI + IS vs Standard LRTI on the affected side.

points for LRTI + IS vs standard LRTI group respectively. At the end of the follow up, DASH score was less than 20 points for each group (Fig. 5).

Mean improvement in VAS pain scores were similar in both groups, 4.00 for standard LRTI compared with 4.44 for LRTI + IS. EQ5D scale identified equal improvement in patient's quality of life, with non-statistically significant results for both groups (LRTI vs LRTI + IS), $p = 0.42$.

Minor complications related to the use of cast and residual stiffness at the beginning of physiotherapy were reported in both groups in one patient for each group. There were no major complications reported in either group, none of the patients required revision surgery.

4. Discussion

According with the results displayed in this research, standard LRTI and LRTI with interference screw had shown comparable results with 2-year follow-up in terms of stability and functional outcomes (Fig. 6). Meta-analysis found short-term results between 3 months and 1 year, however no longer follow-up data have been discussed.³ The aim of this study was to provide a safer and simpler variation to the original technique by adding an interference screw that secures FCR tendon in the bone tunnel during the ligament reconstruction. The objective is to avoid the elongation of the ligament, reduce thumb instability and

reproducibility of the procedure. No major complications nor revisions were reported but a bigger sample size is necessary to clarify this. Operating and tourniquet time were not displayed in this report since they were similar in both groups.

According to our data, palmar and radial abduction range of motion improved for both groups. Grip strength had also improved after the 2-year follow up but no statistically significant difference was identified between treatment groups. Tip, lateral and 3 jaw pinch were evaluated and had no change in comparison with the preoperative evaluation. A similar outcome has been reported in larger cohorts long term studies.⁹ Mean improvement of DASH score, VAS and EQ5D was similar in both groups, showing good outcomes in both procedures.

The LRTI procedure has been routinely and widely performed worldwide, some surgeons categorized this technique as the gold standard surgery for trapeziometacarpal osteoarthritis for many years. Different surgical methods have been described to treat CMC OA of the thumb including some hand surgeon's preference for an isolated trapeziectomy. There are reported similar clinical, radiological and functional outcomes of these procedures, making treatment decisions difficult and controversial.^{13–15}

In recent years, literature regarding this topic has improved showing some higher quality evidence, Liu et al.³ presented a meta-analysis where they included 8 studies, 7 of them were randomized controlled trials confirming that there is no difference in key pinch strength, DASH

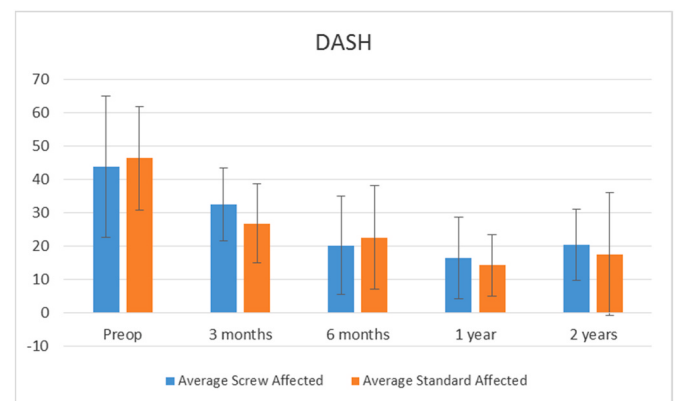


Fig. 5. DASH score values comparing LRTI + IS vs Standard LRTI.

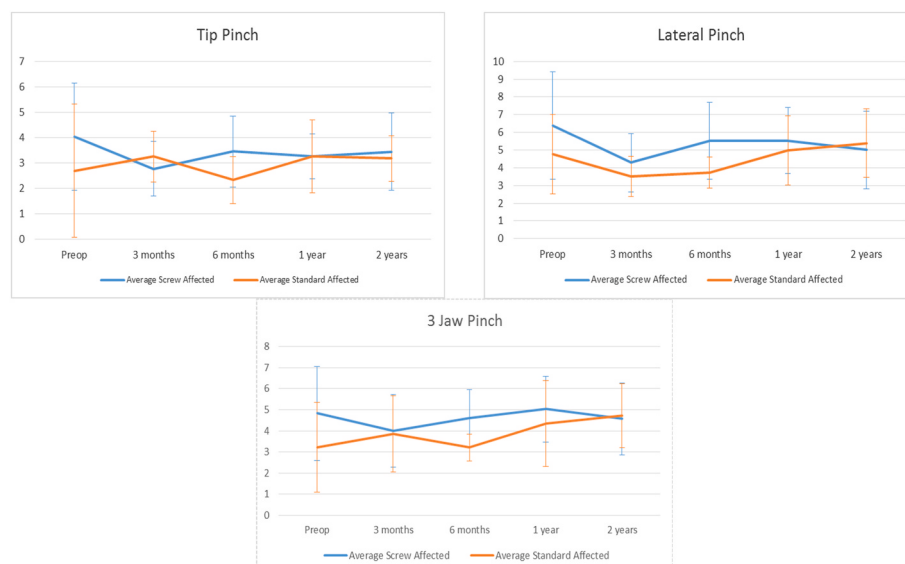


Fig. 4. Comparison of tip, lateral and 3 jaw pinch tests measured in kg between LRTI + IS vs Standard LRTI on the affected side.

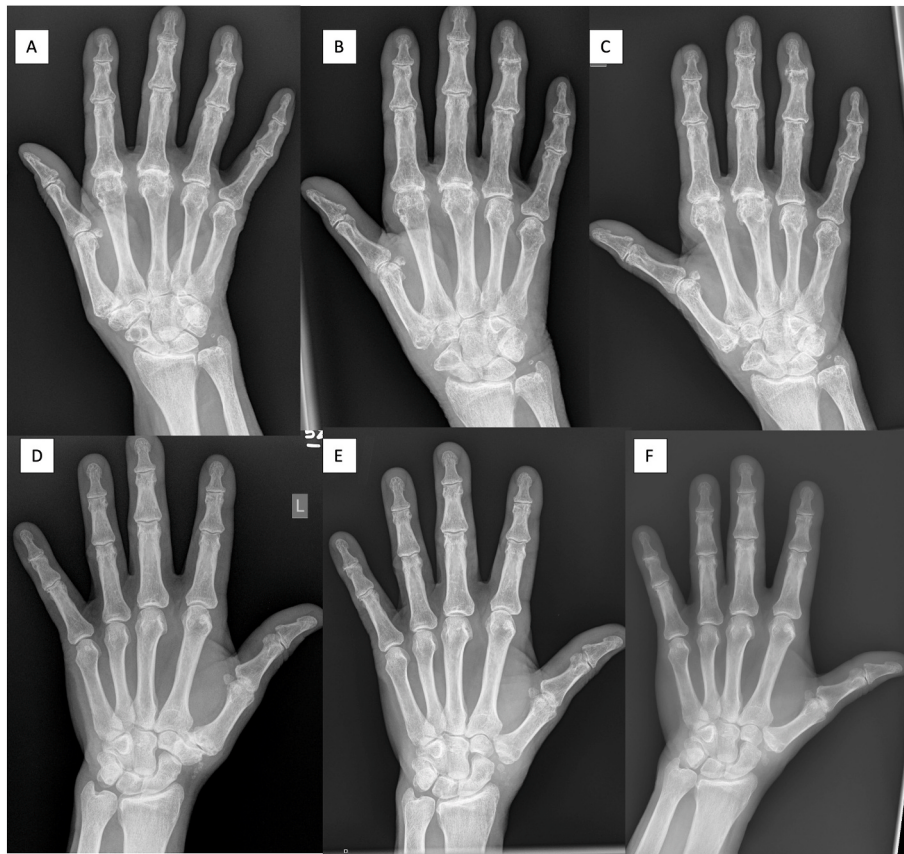


Fig. 6. Comparison radiographs between LRTI + IS vs Standard LRTI. A. Preoperative radiograph Standard LRTI. B. Immediate postoperative radiograph Standard LRTI. C. 2-year follow-up postoperative radiograph Standard LRTI. D. Preoperative radiograph LRTI + IS. E. Immediate postoperative radiograph LRTI + IS. F. 2-year follow-up postoperative radiograph LRTI + IS.

score and pain relief between isolated trapeziectomy and LRTI. However, there is a significant increase in the grip and tip pinch strength in LRTI group.

To our knowledge only three studies have described the use of an interference screw in the LRTI procedure.^{16–18} Wysocki et al.¹⁶ retrospectively analyzed 29 patients treated with LRTI + IS, outcomes were comparable to our results with no reported revision surgeries, the only statistically significant difference was decreased lateral key pinch strength compared with the contralateral side. Additionally, Brunton et al.¹⁷ reported the surgical technique in 2011 with no clinical results, nevertheless, in this paper they mentioned a non-published report by Jackson et al., in 2008 of cadaveric comparison of thumb CMC arthroplasty biomechanics performing an abductor pollicis longus suspensionplasty fixated with interference screw versus pulvertaft tendon suture technique, obtaining lower subsidence results in the interference screw group. Furthermore, Muramatsu et al.¹⁸ reported a study of 26 patients with a follow up of 12–48 months with good outcomes using a similar technique fixed with interference screw in the context of partial trapeziectomy instead of a complete one. Unfortunately, this was a retrospective study and there is no comparison with a standard LRTI technique.

There are some limitations in this research. This was a planned pilot study with a small size sample to be completed in a future randomized control trial, limiting our whole picture of definitive outcomes, although equivalence of both groups of treatment was achieved. Even though, current studies are focused on identifying whether an isolated trapeziectomy could be a better treatment than a LRTI, in this investigation we present a safe and reliable fixation technique with interference screw that has equivalent outcomes in a long-term follow-up. Trapezial height was measured confirming no statistically significant difference between

both groups, although standardization of imaging evaluation was found to be a minor issue during the pilot phase, a recent systematic review¹⁹ has revealed that preservation of the scaphometacarpal space postoperatively is not associated with bad postoperative outcomes. Furthermore, Yang et al.²⁰ reported in their study about standard LRTI no differences in grip strength, tip pinch strength, thumb range of motion, and VAS with postoperative mild, moderate or severe metacarpal subsidence. Moreover, subsidence does not seem to be a factor that in long term showed any difference in complications and clinical outcomes.¹³

5. Conclusion

Ligament reconstruction and tendon interposition with and without interference screw has shown equivalent results in a 2-year follow-up related to stability and functional outcomes. Interference screw is a safe and reliable technique with no difference in pain or complication rates.

Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Informed consent

Informed consent was obtained from all individual participants included in the study.

Institutional ethical committee approval

Capital Health Research Ethics board approved the publication of this study. NSHA REB File #: CDHA-RS/2015-239.

Authors contributorship

AT and DJ conceived the study. KT, MCP and RP researched literature and made the recruitment of patients and data analysis, EV performed statistical analysis and RP and EV made the development of first draft manuscript. All authors reviewed, edited and approved the final version of the manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jorep.2023.100208>.

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