A commentary by Peter J. Stern, MD, is linked to the online version of this article at jbjs.org.

A Prospective, Randomized Trial of Mobilization Protocols Following Ligament Reconstruction and Tendon Interposition

Douglas T. Hutchinson, MD, Stephanie Sueoka, MPT, DPT, CHT, Angela A. Wang, MD, Andrew R. Tyser, MD, Kathleen Papi-Baker, MOT, OTR/L, CHT, and Nikolas H. Kazmers, MD, MSE

Investigation performed at the Department of Orthopaedics, University of Utah, Salt Lake City, Utah

Background: The purpose of this study was to evaluate the hypothesis that an increased duration of immobilization following trapeziectomy with ligament reconstruction and tendon interposition (LRTI) leads to improved patient-reported outcomes compared with an early mobilization protocol.

Methods: At 2 institutions, we prospectively randomized 223 patients (238 thumbs) undergoing LRTI to receive 1 of 2 postoperative rehabilitation protocols. The immobilization protocol consisted of use of a postoperative forearm-based thumb-spica splint for 7 days followed by a forearm-based thumb-spica cast for 5 weeks and then by a custom forearm-based thermoplastic thumb-spica splint for an additional 6 weeks. An active range of motion (ROM) was started 6 weeks postoperatively. The early mobilization protocol consisted of the same postoperative splint for 7 days followed by use of a forearm-based thermoplastic thumb-spica splint for 3 weeks and then by a hand-based thumb-spica splint for 4 weeks. An active ROM was started 4 weeks postoperatively. The outcome measures included the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire; pinch and grip strength; 9-hole peg test (NHP); visual analog scale (VAS) for pain; VAS for patient satisfaction; and wrist and thumb ROM. These were measured preoperatively and at 6, 12, 26, 52, and 104 weeks postoperatively. Differences in continuous and categorical variables were assessed with use of Tukey multiple comparisons following 1-way analysis of variance and Fisher exact tests, respectively.

Results: A minimum follow-up of 1 year (mean, 1.7 years) was achieved for 71% (169) of the 238 randomized thumbs (157 of the 223 patients): 74 patients (80 thumbs) treated with the immobilization protocol and 83 patients (89 thumbs) treated with the early mobilization protocol. DASH scores, VAS pain scores, VAS patient satisfaction scores, and strength all improved similarly with no significant differences between groups at any time point. Wrist and thumb ROM and NHP outcomes were significantly worse for the immobilization group at 6 weeks postoperatively, with no differences observed between groups at 12 weeks and beyond.

Conclusions: A conservative immobilization protocol does not improve functional outcomes, satisfaction, strength, or ROM following LRTI compared with an early mobilization protocol.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

Trapeziectomy with ligament reconstruction and tendon interposition (LRTI) for the treatment of thumb carpometacarpal arthritis has been widely used since its introduction in 1986[1]. It is one of the more common procedures performed by hand surgeons worldwide and has been demonstrated to be highly successful in improving patient-reported outcomes[2]. Trapeziectomy without LRTI has also shown good results[2,3].

Despite the well-documented success rates of LRTI, the time for recovery following the procedure and the resulting time

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that patients need to take off from work remain important factors in the decision-making process for many patients. There is no current consensus regarding the optimal duration or type of immobilization needed to reliably achieve favorable outcomes following the procedure. Burton and Pellegrini recommended 4 weeks of forearm-based thumb-spica cast immobilization followed by use of a splint for 4 to 6 weeks[1]. The *Rehabilitation of the Hand and Upper Extremity* textbook suggests the use of a cast or splint for up to 13 weeks[4], and the Indiana Hand to Shoulder Center Protocols recommend 8 to 10 weeks of thumb support[5]. Although several studies have compared different postoperative rehabilitation protocols for LRTI, current evidence is limited. In a 2014 systematic review, Wolfe et al. concluded that multicenter studies that compare different postoperative immobilization and therapy protocols following LRTI are needed[6].

The purpose of this 2-center, prospective, randomized trial was to evaluate the hypothesis that a postoperative protocol with an increased duration of immobilization following LRTI leads to improved patient-reported outcomes at 1 year compared with an early mobilization protocol.

Materials and Methods

After obtaining institutional review board approval and registering with ClinicalTrials.gov (NCT01425034), we prospectively randomized patients undergoing LRTI at 2 institutions to receive 1 of 2 postoperative rehabilitation protocols over a 5-year period (from August 2011 through June 2016). On the day of consent, patients were randomized by opening an opaque envelope that had an equal likelihood of assignment to either rehabilitation group. We excluded patients <40 years old, those who had a prior thumb carpometacarpal procedure, and those with a diagnosis of rheumatoid arthritis. Concomitant surgery such as metacarpophalangeal joint stabilization (including volar plate capsulodesis, arthrodesis, or temporary pinning), carpal tunnel release, or trigger finger release was not grounds for exclusion.

The immobilization protocol included the use of a forearm-based thumb-spica plaster splint for 7 days postoperatively followed by a forearm-based thumb-spica cast for 5 weeks. An active range of motion (ROM) was started at 6 weeks postoperatively, but support was continued with use of a custom forearm-based thermoplastic thumb-spica splint for an additional 6 weeks. At 12 weeks postoperatively, immobilization was discontinued.

The early mobilization protocol included the use of a forearm-based thumb-spica plaster splint for 7 days postoperatively followed by a forearm-based thermoplastic thumb-spica splint for 3 weeks. An active ROM was started at 4 weeks postoperatively and was supplemented with a hand-based thumb-spica splint until 8 weeks postoperatively, when immobilization was discontinued.

Resistive wrist strengthening, and thumb strengthening with putty, were initiated at 12 weeks postoperatively in the immobilization group and at 8 weeks in the early mobilization group. Modalities including ice, elastic garments, and on occasion electrical stimulation were initiated as needed for edema control at the first postoperative visit.

All procedures were performed under general and/or regional anesthesia with a technique similar to that described by Varitimidis et al. that utilizes the whole width of the flexor carpi radialis tendon, with the exceptions of the retention of the thumb metacarpal base and the use of either Wagner or dorsal approaches to the carpometacarpal joint, based on the preference of the surgeon[7]. A complete trapeziectomy with LRTI involving the entire flexor carpi radialis tendon was performed. No pins were utilized. A total of 6 hand-fellowship-trained orthopaedic surgeons performed the procedures.

The primary outcome measure was the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Secondary outcomes included the 9-hole peg test (NHP), visual analog scale (VAS) for pain, VAS for patient satisfaction, ROM (of the wrist and thumb as described by Kapandji[8]), grip strength, and pinch strength (2-point pinch, 3-point [chuck] pinch, and lateral pinch). These metrics were measured preoperatively and at 6, 12, 26, 52, and 104 weeks postoperatively, with the exception of pinch and grip strength, which were not evaluated at the 6-week postoperative time point. Two principal certified hand therapists—1 at each participating center—and 3 additional certified hand therapists performed or facilitated these outcome measurements. The number of therapy visits, complications, and simultaneous additional procedures were recorded.

Basic descriptive statistics were calculated. With the exception of age which was compared using the Student t-test, differences in continuous variables were evaluated with use of Tukey confidence intervals (CIs) following 1-way analysis of variance (ANOVA) with an overall CI of 95%. Box-Cox transformation

TABLE I Baseline Patient Characteristics for Each Group

Factor	No. (%)*		P Value
	Immobilization Group (N = 80)	Early Mobilization Group (N = 89)	
Age *(yr)*	62.5 ± 7.8	62.0 ± 6.9	0.61
Female	62 (78%)	70 (79%)	0.99
Dominant hand involvement	42 (53%)	49 (55%)	0.76
Bilateral staged LRTI	12 (15%)	12 (13%)	0.84

*Except for age, which is given as the mean and standard deviation. Values were calculated per thumb, rather than per patient, given that each group included 6 patients with staged bilateral LRTI.

TABLE II Additional Simultaneous Surgical Procedures in Each Group

Factor	No. (%)*		P Value†
	Immobilization Group (N = 80)	Early Mobilization Group (N = 89)	
Carpal tunnel release	19 (24%)	16 (18%)	0.45
Metacarpophalangeal joint procedure‡	9 (11%)	10 (11%)	>0.99
Other simultaneous procedure	15 (19%)	10 (11%)	0.29
Cyst/mass excision	6 (8%)	6 (7%)	—
De Quervain tendinopathy release	1 (1%)	0 (0%)	—
Injection	2 (3%)	2 (2%)	—
Joint arthrodesis (non-thumb)	1 (1%)	2 (2%)	—
Trigger digit release	5 (6%)	2 (2%)	—
Radial artery dorsal branch repair	1 (1%)	0 (0%)	—
Other	1 (1%)	1 (1%)	—
Totals			
Isolated LRTI (no simultaneous metacarpophalangeal or other procedures)	50 (63%)	65 (73%)	0.10
LRTI with ≥1 additional procedure			
Not including metacarpophalangeal joint procedures	25 (31%)	19 (21%)	0.20
Including metacarpophalangeal joint procedures	30 (38%)	24 (27%)	0.10

*Values were calculated per thumb, rather than per patient, given that each group included 6 patients with staged bilateral LRTI. The sum of subcategories may exceed the total as some patients had ≥1 additional procedure. †Significance was evaluated with use of the Fisher exact test. ‡Includes arthrodesis, volar plate capsulodesis, and temporary pinning.

was utilized as needed prior to 1-way ANOVA for data displaying non-constant intergroup variance or skewness. General linear modeling was utilized to evaluate for an effect of simultaneous surgical procedures (in addition to LRTI) on the primary outcome (DASH score) while including treatment group and postoperative time point. Differences in categorical variables were determined with use of the Fisher exact test. A 95% CI ($\alpha = 0.05$) was chosen. A priori power analysis revealed that a total of 105 subjects were required to achieve 95% power to test a difference equal to half of a standard deviation (SD) for the DASH score with a 95% CI.

Results

A minimum follow-up of 1 year was obtained for 169 (71%) of the 238 thumbs (157 of the 223 patients), with a mean follow-up of 1.7 years (see Appendix, Fig. E-1). No significant differences were detected in age, sex, dominant hand involvement, or rates of bilateral surgery between groups (Table I). No significant differences in follow-up rate were detected between study sites (66% and 79%; $p = 0.41$) or between treatment groups (73% for immobilization and 69% for early mobilization; $p = 0.76$). Additional simultaneous operative procedures performed with LRTI are summarized in Table II. No significant differences were observed between treatment groups in terms of the percentages who underwent metacarpophalangeal joint procedures ($p > 0.99$), carpal tunnel release ($p = 0.45$), or other simultaneous procedures ($p = 0.29$). There were no significant differences between groups in terms of the percentages of patients who underwent ≥1 additional surgical procedures, with 63% and 73% having an isolated LRTI in the immobilization and early mobilization groups, respectively ($p = 0.10$).

No significant differences were detected in the DASH, VAS pain, or VAS satisfaction scores between groups at any time

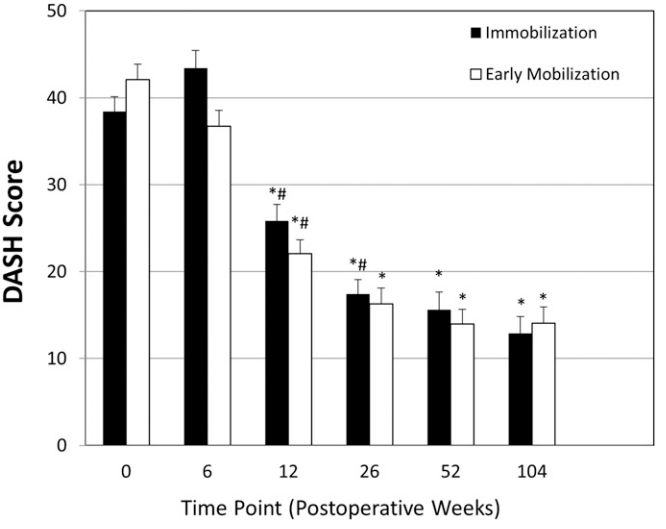

Fig. 1

Graph showing DASH scores at postoperative time points. Data are shown as the mean and the standard error of the mean. * = $p < 0.05$ when compared with the respective preoperative value, and # = $p < 0.05$ when compared with the prior time point, as determined with use of Tukey multiple comparisons.

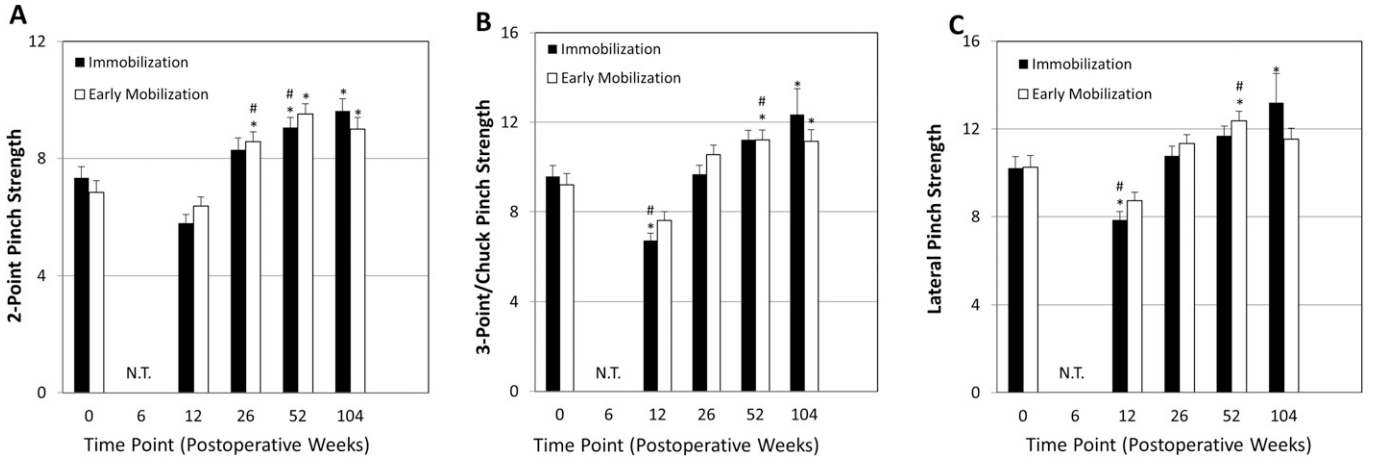

Fig. 2

Pinch strength metrics including 2-point pinch (**Fig. 2-A**), 3-point (chuck) pinch (**Fig. 2-B**), and lateral pinch (**Fig. 2-C**). Data are shown as the mean and standard error of the mean. All measurements are in pounds. * = $p < 0.05$ when compared with the respective preoperative value, and # = $p < 0.05$ when compared with the prior time point, as determined with use of Tukey multiple comparisons. N.T. = not tested.

point ($p > 0.05$ for each individual comparison based on Tukey multiple comparisons). DASH (Fig. 1), VAS pain (see Appendix, Fig. E-2), and VAS patient satisfaction scores (see Appendix, Fig. E-3) improved in both groups after surgery. The DASH patient satisfaction scores continued to improve significantly through the 26th postoperative week in the immobilization group and through the 12th postoperative week in the early mobilization group. The maximum improvement in the DASH score was achieved by 26 and 12 weeks postoperatively for the immobilization and early mobilization groups, respectively. The maximum improvement in the VAS patient satisfaction score was achieved by 12 and 6 weeks for the immobilization and early mobilization groups, respectively. There were no significant differences in pinch strength between groups at any time point (Fig. 2). At 6 weeks postoperatively, the early mobilization group demonstrated better NHP times, thumb ROM, and wrist ROM than the immobilization group, but these metrics as well as grip strength did not differ between groups at any other time points (see Appendix, Figs. E-3 through E-6).

Complications are reported in Table III. No revision surgery was performed. The number of therapy visits significantly differed between groups, with an average and SD of 3.8 ± 2.0 visits for the immobilization group and 4.5 ± 2.3 visits for the early mobilization group ($p = 0.02$). However, the total number of visits (therapy plus physician visits) was similar between groups (6.6 ± 2.3 visits for the immobilization group and 7.0 ± 2.9 visits for the early mobilization group; $p = 0.23$).

Post-hoc power analysis revealed a power of >0.99 for detecting a difference of 10 points (an estimate of the minimum clinically important difference[9]) in DASH scores at 1 year postoperatively. General linear modeling showed that the primary outcome (DASH score) was not significantly affected by the

TABLE III Complications in Each Group

Complication	No. (%)*		P Value†
	Immobilization Group (N = 80)	Early Mobilization Group (N = 89)	
Complex regional pain syndrome	1 (1%)	0 (0%)	—
Extrusion of the "anchovy"	0 (0%)	0 (0%)	—
Contracture of 1st web space	1 (1%)	0 (0%)	—
Radial artery injury	1 (1%)	0 (0%)	—
Revision surgery	0 (0%)	0 (0%)	—
Superficial radial paresthesias	1 (1%)	4 (4%)	—
Symptomatic subsidence or "anchovy" extrusion	0 (0%)	0 (0%)	—
Total	4 (5%)	4 (4%)	>0.99

*Values were calculated per thumb, rather than per patient, given that each group included 6 patients with staged bilateral LRTI. †A Fisher exact test was performed with use of a 2 × 2 contingency table to compare the overall rate of complications between groups.

performance of surgical procedures in addition to the LRTI, regardless of whether the additional procedures included ($p = 0.63$) or excluded ($p = 0.30$) metacarpophalangeal procedures. In this model, treatment group and postoperative time point remained significant ($p < 0.001$).

Discussion

This was a large, prospective, randomized clinical trial performed at 2 independent medical centers to evaluate 2 postoperative rehabilitation protocols after LRTI with a minimum follow-up of 1 year and a mean follow-up of 1.7 years. The main finding of this study is that a more conservative postoperative cast immobilization rehabilitation regimen did not outperform (in terms of our primary and secondary outcome metrics) an earlier-mobilization protocol that utilized splints only.

Despite a wide variation in rehabilitation protocols in clinical studies investigating different operative techniques for thumb carpometacarpal joint osteoarthritis[1,2,10-12], few have addressed the effect of different postoperative rehabilitation regimens on outcomes following LRTI surgery for thumb basal joint osteoarthritis. In a randomized, prospective report with a median clinical follow-up of 6 months, Horlock and Belcher compared early and late mobilization protocols following simple trapeziectomy[11]. The early mobilization protocol included 1 week in a postoperative dressing followed by the application of a removable splint; patients were instructed to remove the splint during the day to allow light use of the hand and to wear the splint for more strenuous activities and at night for 6 weeks postoperatively. The late mobilization protocol included the use of a splint full time until 6 weeks postoperatively followed by use of the hand as tolerated. Both groups were allowed to use the splint as needed. Horlock and Belcher did not detect any significant differences between these groups; however, only 39 patients were studied and no power analysis was reported.

In a similar study, published in 2014, Wu et al. reported on 40 patients who had undergone LRTI[12]. This retrospective study compared 6 weeks of thumb-spica cast immobilization with mobilization at 1 week postoperatively followed by supportive splinting. The authors did not detect any significant differences in any measured outcome after a minimum of 18 months of follow-up. However, the final analysis included only 15 patients in each group and no power analysis was reported; therefore, we believe that these findings should be interpreted with caution because they may be subject to type-II statistical error.

The present study expands on the investigations that have been published to date. The strengths of the study include the prospective, randomized, 2-center format; a large cohort; and a comprehensive assessment at a minimum of 1 year postoperatively that included both patient-reported and measured functional outcomes. However, there were limitations to this study. It was not possible to blind the patient to the assigned rehabilitation protocol or to blind the evaluator prior to 12 weeks postoperatively. Beyond 12 weeks postoperatively, it is possible that the evaluators had some memory of the patient group designation. It is unclear whether the 30% of patients lost to follow-up systematically differ from those included in the study or how their inclusion would change the findings of the study. Although complication and revision rates could change over a longer follow-up period, we would expect that failures attributed to inadequate immobilization, such as painful subsidence or interposed tendon extrusion, would have been identified within the time frame of our study follow-up. The limited number of complications precluded meaningful statistical comparison between groups. Specifically, with only 1 case of complex regional pain syndrome, which occurred in the immobilization group, we are unable to conclude whether early mobilization would reduce the prevalence of this complication. We also advise caution about generalizing our results to postoperative rehabilitation protocols that differ from the specific study protocols or that follow other surgical methods. In addition, we did not attempt to assess return to work because of heterogeneity in work requirements and because many study patients were retired. Therefore, we cannot draw conclusions regarding the time required to return to work. We also did not assess return to preoperative activities.

Although there was no apparent downside to an early mobilization protocol in this trial, it is also worth noting that the study did not demonstrate any quantitative, patient-reported benefit to early mobilization. Even though maximum improvement in DASH and VAS patient satisfaction scores occurred sooner in the early mobilization protocol compared with the immobilization protocol, there were no significant differences in patient-reported VAS satisfaction, VAS pain, or DASH scores between the 2 cohorts at any of the measured postoperative time points. While it is our assumption that less immobilization, no cast immobilization, and earlier motion may lead to an improved patient experience, this study did not address this issue.

Appendix

(eA) Figures showing the CONSORT (Consolidated Standards of Reporting Trials) flow diagram and graphs representing VAS pain and satisfaction scores, results of the NHP, thumb opposition, wrist ROM, and grip strength are available with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/E780). ■

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Douglas T. Hutchinson, MD[1]
Stephanie Sueoka, MPT, DPT, CHT[1]
Angela A. Wang, MD[1]
Andrew R. Tyser, MD[1]
Kathleen Papi-Baker, MOT, OTR/L, CHT[2]
Nikolas H. Kazmers, MD, MSE[1]

[1]Department of Orthopaedics, University of Utah, Salt Lake City, Utah

[2]Physical Therapy, Intermountain Park City Hospital, Park City, Utah

E-mail address for N.H. Kazmers: nkazmers@gmail.com

ORCID iD for D.T. Hutchinson: 0000-0002-4156-1520
ORCID iD for S. Sueoka: 0000-0002-7288-1893
ORCID iD for A.A. Wang: 0000-0001-8539-5926
ORCID iD for A.R. Tyser: 0000-0003-1580-1428
ORCID iD for K. Papi-Baker: 0000-0001-8676-1019
ORCID iD for N.H. Kazmers: 0000-0002-3685-1662

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