Comparison of 2 Postoperative Therapy Regimens After Trapeziectomy Due to Osteoarthritis: A Randomized, Controlled Trial

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Purpose The main aim of the present study was to evaluate whether early mobilization after trapeziectomy in the first carpometacarpal joint is noninferior to a postoperative regimen comprising the use of a rigid orthosis and mobilization after 6 weeks, with regards to patient-reported activity performance and the effect of surgery in patients with first carpometacarpal osteoarthritis.

Methods In this prospective, randomized, controlled noninferiority trial, participants were assessed at baseline (before group allocation) and at 3, 6, and 12 months after surgery. The primary outcomes were activity performance, measured using the Canadian Occupational Performance Measure (1-10), where 1 = unable to perform), and the patient-reported effect of surgery on a 6-point scale ranging from "much worse" to "completely recovered." A change of 2.0 points in the Canadian Occupational Performance Measure was used as a noninferiority margin. Secondary outcomes included hand function (patient-reported in the Measure of Activity Performance of the Hand questionnaire), pain on a numeric rating scale, grip and pinch strengths, and joint mobility. We performed both intention-to-treat and per-protocol analyses.

Results Of the 59 participants (88% women) with a mean age of 65 years, 55 (93%) completed all assessments. We found no differences between the groups in primary or secondary outcomes at any time point, except for more decreased pain at rest in the intervention group (n = 28) compared with the control group (n = 27) after 12 months. The per-protocol analyses did not change these results. Fifteen participants experienced 1 or more adverse events during the first 3 months, but the types and frequencies of adverse events were similar between the 2 groups.

Conclusions A postoperative regimen with early mobilization after trapeziectomy is as safe and effective as a postoperative regimen with longer immobilization in patients with first carpometacarpal osteoarthritis. (*J Hand Surg Am. 2022;47(2):120–129. Copyright* © 2022 by the American Society for Surgery of the Hand. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).)

Type of study/level of evidence Therapeutic II.

Key words Activity performance, hand therapy, postoperative care, randomized controlled trial, trapeziectomy.

Additional Material at jhandsurg.org

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0363-5023/22/4702-0002 https://doi.org/10.1016/j.jhsa.2021.08.015 AND OSTEOARTHRITIS (HOA) IS among the most common joint conditions and is increasing in prevalence because of the aging of the population.¹ The symptoms and functional consequences include pain and stiffness, reduced grip strength and joint mobility, and impaired activity performance and quality of life.^{2–4} Thumb carpometacarpal osteoarthritis (CMC-OA) affects up to 11% of men and 33% of women in their 50s and 60s.⁵

Osteoarthritis (OA) of the first carpometacarpal (CMC1) joint usually presents with a combination of structural changes that typically involve reduced cartilage thickness, increased ligament laxity with resulting instability, subluxation of the trapezium, and adduction contracture, which in turn result in decreased thumb web space.⁶ Two systematic reviews comparing the effects of different surgical techniques in CMC1-OA concluded that no evidence is currently available regarding which surgical procedure is superior.^{7,8}

The outcomes of surgery have been suggested to be determined not only by the surgical procedure, but also by the postoperative treatment. In a review of postoperative rehabilitation following CMC1 surgery, the authors identified 3 phases of rehabilitation: an acute phase (0-6 weeks after surgery), an unloaded phase (1-12 weeks following surgery), and a functional phase (3-26 weeks after surgery). The contents of the 3 phases varied, with emphasis on the immobilization of the CMC1 and the first metacarpophalangeal joints and exercises that enhance joint mobility in the acute phase, introducing exercises to improve CMC1 palmar abduction and first metacarpophalangeal flexion in the unloaded phase and initiating progressive joint mobility and strengthening exercises in the functional phase. Based on the combined results of the 27 included studies, the authors concluded that early active recovery, including short immobilization and early initiation of exercise, seems to provide positive outcomes for pain, grip strength, and activity performance but that high-quality studies comparing different postoperative treatments are lacking.⁹ A postoperative regime with mobilization starting 6 weeks after surgery has been the standard at our hospital for decades but has been increasingly debated upon among surgeons and therapists.

The main aim of the present study was therefore to evaluate whether early mobilization after trapeziectomy in the CMC1 joint is noninferior to a postoperative regimen with longer immobilization with regards to activity performance and patientreported effects of surgery after 12 months.

MATERIALS AND METHODS

Study design

This randomized, controlled, noninferiority trial was designed according to the Consolidated Standards of Reporting Trials guidelines.¹⁰ Participants were assessed at baseline and after 3, 6, and 12 months. As part of postoperative treatment, they were also seen for clinical evaluations at 3 and 6 weeks after surgery. A patient representative with CMC1-OA who had undergone trapeziectomy participated in planning the study, including discussing research questions and outcomes and ensuring a patient-friendly design.¹¹ The study is registered with the International Standard Randomised Controlled Trial Number (ISRCTN), Identifier NCT01679717 and was approved by the Regional Committee for Medical Research Ethics (2012/313). All participants received oral and written information about the study and provided informed consent.

Participant recruitment

From June 2012 to September 2016, patients scheduled for CMC1 surgery because of OA at Diakonhjemmet Hospital in Oslo, Norway, were screened for eligibility by a consulting surgeon and invited to participate in the study. The exclusion criteria were surgery involving other joints of the hand, previous surgery on the same thumb, other diseases or injuries that may influence hand function, inability to communicate in Norwegian, and mental or cognitive deficits.

Three occupational therapists (M.H-E., T.N., and Å.H.), all certified by the Norwegian Occupational Therapist Association as specialists in rheumatological and orthopedic care, contacted the eligible participants and informed them about the study. Those who agreed to participate received a letter with a baseline appointment, an informed consent form, and a questionnaire that they were encouraged to complete and bring to the appointment, which occurred within the 2 weeks prior to surgery. Upon arrival at the department, the occupational therapist discussed the study with the participants and obtained their written informed consent prior to assessment and randomization.

Randomization and allocation concealment

Participants were randomly assigned to the control group (standard care) or the intervention group (early mobilization). A statistician created a computergenerated randomization list with a block size of 10. Concealed envelopes prepared by a secretary were opened by the occupational therapist after the baseline assessment to allocate the participant to either the control group or the intervention group. After randomization, each participant was informed of the content of the intervention that they would receive, but not whether it was standard care or the new regimen. Thus, in this trial, the occupational therapist delivering the postoperative intervention was aware of the group allocation, but the surgeons and participants were not. Furthermore, the assessors performing the clinical examination at follow-up visits were not involved in the baseline assessments or the interventions and were blinded to the participant's group allocation, as was the statistician who performed the main statistical analyses.

Baseline and outcome measures

The demographic variables consisted of age, sex, marital status, level of education, and work status. The primary outcome, activity performance, was recorded using the Canadian Occupational Performance Measure (COPM), starting with an interview addressing hand-related activity limitations.¹² At the end of the interview, the patient rated up to 5 of the most important activities for performance on a scale of 1-10, with higher scores reflecting better performance. A mean score is calculated of the most important activities identified by the patients. The Norwegian version of COPM has been tested for psychometric properties and has demonstrated good ability to detect functional changes in HOA.¹³ In the COPM manual, a change of 2.0 points in the mean score is suggested as a minimal important change $(MIC).^{12}$

To capture the patient perspective, participants also rated their experienced effect of the operation on a 6-point scale ranging from "much worse" to "completely recovered" at 3, 6, and 12 months.

Hand function was self-reported using the Measure of Activity Performance of the Hand, which contains 18 standardized activities scored from 1 to 4, where 1 indicates no limitations. The Measure of Activity Performance of the Hand has been tested for validity, reliability, and responsiveness in patients with HOA and CMC1-OA, with good results.^{14–16} A mean score was calculated based on scores of at least 15 activities. The MIC for Measure of Activity Performance of the Hand has not previously been reported, but a smallest detectable change of 0.60 has been estimated in a sample of patients with CMC1-OA.¹⁵

Disease variables collected from patients' medical records consisted of the hand for which the patient was referred for surgical consultation and the surgical procedure. The degree of HOA was assessed at baseline based on conventional radiography (posteroanterior view) of the surgical hand using a modified Kellgren-Lawrence grade scale (grade 0-4, where 0 = no OA), where OA is defined as a Kellgren-Lawrence grade of $\geq 2.^{17}$ The scaphotrapeziotrapeziodal joint was graded using the same scale. Malalignment (subluxation) of the CMC1 joint was scored as absent/present according to the Osteoarthritis Research Society International atlas.¹⁸ The images were graded by an experienced physician (I.K.H.) who was blinded to group allocation and clinical findings.

Maximal grip and pinch strengths were measured using Grippit (Catell) following published testing procedures.¹⁹ Normative values are available.²⁰ The MIC for Grippit has not previously been reported. However, the MIC for a similar instrument (Jamar) is estimated to be a change of approximately 20%.²¹ Active palmar abduction of the thumb was measured using Pollexograph (Erasmus University Medical Center) according to published procedures.²² Pain following the measurement of grip and pinch strengths in the operated hand was self-reported by patients using a numeric rating scale (0–10, where 0 = no pain). A score change of 33% represents an MIC in patients with chronic musculoskeletal conditions.²³

Interventions

The surgical procedure comprised the removal of the trapezium and, for some patients, tendon ligament reconstruction with tendon interposition as well.²⁴ The postoperative interventions delivered to each group are described in Table 1 and Appendix E1 (available online on the *Journal*'s website at www.jhandsurg.org).

Exercise sessions were recorded by patients during the postoperative period in separate treatment diaries for joint mobility and hand strength. Acceptable treatment adherence was defined as performing 5 exercise sessions for joint mobility per week for a minimum of 3 weeks and 2 exercise sessions for hand strength per week for a minimum of 3 weeks.

Adverse events related to the surgery or postoperative regimen that occurred within 3 months after surgery were recorded at the visits.

Sample size

The COPM allows patients to list and score activities that are important but difficult for them to perform; thus, we expected it to be more responsive than the standardized measures in capturing changes in activity performance after CMC1 surgery. The smallest detectable change in COPM performance scores has been

Phase	Intervention Group (Early Mobilization)	Control Group (Usual Postoperative Care)		
Acute phase	0–2 weeks: Cast that immobilizes the wrist and thumb. Exercise for joint mobility in 2–5 fingers, elbow, and shoulder. Encourage normal use of operated hand in light daily activities, keeping it elevated when resting.			
Unloaded phase	Week 3: Remove sutures and cast. Encourage normal use of operated hand in daily activities except for heavy activities, keeping it elevated when resting.			
	Week 3: Start using a soft neoprene orthosis (comfort cool) supporting the wrist, CMC1, and MCP1 joints (Appendix E1).Three exercises for joint mobility, including thumb (Appendix E1) for 4 weeks.	 Week 3: Start using a rigid orthosis (custom made thermoplastic) immobilizing the CMC1 and MCP1 joints (Appendix E1). Daily wrist exercise going through full range of motion (Appendix E1). 		
	Week 3.5: Follow-up by phone call. If needed, the patient meets at the department for adjustment of the orthosis and exercise regimen.			
Functional phase	Week 6: Gradually stop using the orthosis except for in heavy activities if needed.			
	Continue performing exercises to maintain joint mobility.	Start performing 3 exercises for joint mobility, including the thumb (Appendix E1), for 4 weeks.		
	Week 12: Two exercises for hand strength for 4 weeks (Appendix E1).			

TABLE 1. Description of the Interventions in a Postoperative Regimen With Early Mobilization After Trapeziectomy*

*Data are from the CMC1 joint (intervention group) and a standard postoperative regimen with longer immobilization (control group).

reported to be 1.47.²⁵ In the COPM manual, a change of 2.0 points is suggested to be an MIC and was used as a noninferiority margin.¹² Assuming an SD of the COPM performance score of 1.59 in both the groups, we calculated that 56 patients (28 in each group) were required to detect a mean difference of 2 points with a significance level of 0.05 and a power of 80.¹³ With an expected 20% loss to follow-up at 12 months after surgery, the total sample was set to 70 participants.

Statistical analyses

We performed both intention-to-treat analyses (comparing patients from the groups into which they were randomized) and per-protocol analyses (removing data from patients who did not comply with the protocol). Participants who did not return their treatment diary were categorized as noncompliant. All quantitative outcomes, including the primary endpoint, were analyzed using a linear mixed model. Each outcome was estimated by adjusting for the baseline assessment of the outcome, treating the study group and time as categorical variables. Both the baseline adjustment and the grouping variable were entered in the model as interactions with time (categorical). Subject-specific random intercepts were used in each model.

The experienced effect of the operation was dichotomized into "significantly improved" (completely recovered or much better) or "no improvement" (a little better to much worse). The analysis was based on complete cases only, and a 95% CI is given for the difference in the proportion of significantly improved individuals. The linear mixed model does not require imputation for missing data; therefore, no imputation was done.

RESULTS

Sixty-seven patients were invited to participate in this study; 58 met the inclusion criteria, agreed to participate, and were randomly assigned to the control group (n = 29) or the intervention group (n = 29; Fig. 1). One patient in the control group withdrew before surgery because of another serious illness. Fifty-five patients completed the follow-up at 12 months and were included in the intention-to-treat analysis, whereas 16 patients (55%) in the intervention group were classified as adhering to the intervention and were included in the per-protocol analyses. As the drop-out rate was much lower than expected, inclusion was stopped earlier than originally planned.

The baseline characteristics of the participants were well matched between the 2 groups, except for a younger age in the control group and a larger proportion with scaphotrapeziotrapeziodal-OA in the intervention group (Table 2).

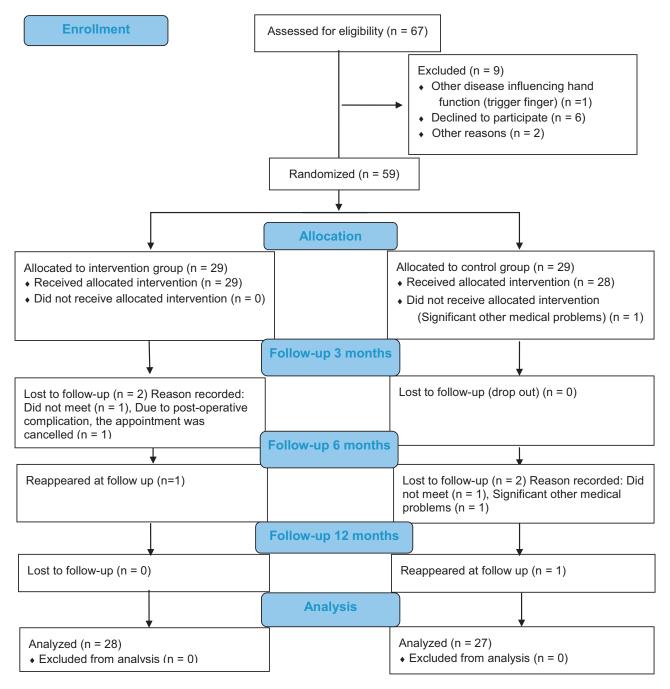


FIGURE 1: Flow diagram of study inclusion.

The number of patients operated upon in their left and right thumbs was 12 and 16, respectively, in the control group and 12 and 17, respectively, in the intervention group. A total of 18 patients (62%) in the intervention group and 16 (57%) in the control group were operated upon in their dominant hand. In addition to trapeziectomy, 3 patients in each group had tendon interposition.

At 3 months, a total of 7 (25%) patients in the control group and 16 (59%) patients in the intervention group reported that they were still using the orthosis, primarily

because it gave them pain relief during heavy activities (P < .05). Nineteen (68%) and 17 (61%) participants in the control group and 27 (93%) and 20 (69%) in the intervention group returned the treatment diary for joint mobility and strength, respectively, after 3 months.

Efficacy and safety of the postoperative treatment regimens

We found no significant differences between the 2 groups in any primary or secondary outcome at 12 months, except for a larger reduction in pain at rest in

Characteristics	All Patients, n = 57	Intervention Group, n = 29	Control Group, n = 28
	$\mathbf{n} = 57$	$\Pi = 29$	$n = 2\delta$
Personal factors			
Age, y, mean (SD)	64.5 (7.4)	66.7 (6.6)	62.1 (7.6)
Female, n (%)	50 (87.7%)	25 (86.2%)	25 (89.3%)
Living alone, n (%)	17 (29.8%)	10 (34.5%)	7 (25.0%)
Education > 12 y, n (%)	15 (26.8%)	8 (28.6%)	7 (25.0%)
Working, n (%)	26 (45.6%)	10 (34.5%)	16 (57.1%)
Body structures [†]			
Numbers of joint with OA changes, mean (SD)	4.7 (3.0)	5.2 (3.0)	4.1 (3.0)
CMC1 KLG grade 2-4, n (%)	59 (100%)	29 (100%)	28 (100%)
Malalignment CMC present, n (%)	44 (75.9%)	21(72.4%)	23 (79.3%)
STT-OA present, n (%)	28 (49.1%)	18 (62.1%)	10 (35.7%)
Body functions			
Thumb pain, median (range)‡	7 (2-10)	7 (2-10)	7 (4-10)
Joint mobility, mean (SD)‡	4.8 (2.7)	4.8 (2.7)	4.8 (2.7)
Grip strength max, median (range)	140 (18-496)	145 (18-477)	134 (32-496)
Pinch strength max, median (range)	17 (0-68)	16 (0-42)	17.5 (0-68)
Pain after grip strength, mean (SD)‡	3.9 (2.9)	3.6 (2.9)	4.2 (3.0)
Pain after pinch strength, mean (SD)‡	4.2 (3.0)	4.7 (2.9)	3.7 (3.1)
Palmar abduction, degrees, mean (SD)	45.0 (9.5)	45.2 (10.0)	44.8 (9.2)
Activity and participation			
MAP-Hand standard, mean (SD)§	2.3 (0.5)	2.3 (0.5)	2.2 (0.5)
COPM performance, mean (SD)	4.1 (1.4)	4.0 (1.5)	4.1 (1.3)

KLG, Kellgren-Lawrence grade; MAP-Hand, Measure of Activity Performance of the Hand; STT, scaphotrapeziotrapeziodal.

*Participants were randomized to a postoperative regimen with early mobilization after trapeziectomy (intervention group) or a standard postoperative regimen with longer immobilization (control group).

†Radiographic carpometacarpal and scaphotrapeziotrapeziodal joint osteoarthritis severity were classified using a modified Kellgren and Lawrence grade scale of 0–4, where 0 indicates no CMC1-OA or scaphotrapeziotrapeziodal-OA.

 \ddagger Pain is self-reported using a numeric rating scale (0-10, where 0 = no pain).

A trivity performance was measured using the mean score of MAP-Hand (0-3, where 0 = no activity problems).

||The COPM is a mean performance score (1-10), where 1 = 1 not able to perform).

the intervention group compared to the control group (P < .05; Table 3).

Twenty (74%) patients in the control group and 22 (79%) in the intervention group reported that their function in the operated thumb was significantly improved 12 months after surgery (P = .22). In general, both groups reported significant and clinically relevant improvement in most outcomes over the 12-month period, except for joint mobility in the first interphalangeal joint and palmar abduction of the thumb, where mobility was stable over the 1-year period. However, we found no differences between the 2 groups (Table 3; Fig. 2).

The per-protocol analyses (n = 29) did not reveal any significant between-group differences in any outcome. Thirteen patients experienced 1 or more adverse events during the first 3 months. The groups were similar regarding the types and frequencies of adverse events (Table 4).

DISCUSSION

Even if clinical experience supports early activity, there is little high-quality research examining its safety. In this randomized controlled trial, we therefore evaluated whether early mobilization after trapeziectomy in the CMC1 joint was noninferior to a more restrictive postoperative regimen with regard to pain and hand function. After 12 months, we found no significant differences between the 2 groups in any measure, except for significantly less thumb pain at rest in the early mobilization group (P < .05). Our

TABLE 3. Comparison of the Effect of a Postoperative Regimen With Early Mobilization After Trapeziectomy (Intervention Group) and a Standard Postoperative Regimen With Longer Immobilization (Control Group)*

Characteristic	Time Point	Intervention, n = 28	Control, n = 27	Treatment Difference	P Value
Activity	Baseline	4.0 (1.5)	4.1 (1.3)	0.11 (-0.6 to 0.9)	.79
performance [†]	3 mo	6.7 (1.9)	6.1 (2.6)	0.06 (-1.3 to 1.2)	.75
•	5 mo 6 mo	6.6 (2.5)	6.5 (2.4)	0.05 (-1.4 to 1.3)	.73
	12 mo	7.2 (1.8)	7.2 (2.3)	-0.08 (-1.0 to 1.2)	.94
Experienced effect	3 mo	18 (67%)	14 (50%)	-0.08 (-1.0 to 1.2) 4 (-0.1 to 0.4)	.24
of the surgery‡	5 mo 6 mo	20 (71%)	18 (72%)	2 (-0.3 to 0.2)	.24
	12 mo			-2 (-0.1 to 0.5)	.00
Hand function§	Baseline	20 (91%) 2.3 (0.5)	22 (85%) 2.2 (0.5)	-2 (-0.1 to 0.3) 0.1 (-0.2 to 0.4)	.22
Hallu fullcuolig					
	3 mo 6 mo	1.9 (0.5)	1.9 (0.7)	-0.01 (-0.3 to 0.3)	.96 76
		1.7 (0.5)	1.7 (0.5)	0.04 (-0.2 to 0.3)	.76
Thursday	12 mo	1.7 (0.5)	1.6 (0.5)	0.1 (-0.2 to 0.4)	.42
Thumb pain	Baseline	7.4 (2.0)	7.8 (1.9)	-0.3 (-1.6 to 0.8)	.55
	3 mo	5.1 (2.8)	5.4 (2.5)	-0.2 (-1.4 to 1.0)	.71
	6 mo	3.9 (2.6)	3.9 (2.5)	-0.1 (-1.3 to 1.6)	.87
	12 mo	3.6 (2.2)	3.4 (2.2)	0.2 (-1.0 to 1.5)	.73
Grip force, max, N	Baseline	145.2 (110.5)	134.3 (96.4)	10.9 (-43.8 to 65.8)	.69
	3 mo	137.8 (82.5)	141.0 (100.1)	9.9 (-45.1 to 64.9)	.72
	6 mo	160.9 (84.2)	175.1 (104.9)	5.3 (-49.9 to 60.7)	.85
	12 mo	171.6 (97.4)	179.8 (123.2)	3.1 (-51.8 to 58.1)	.91
Pinch force, max, N	Baseline	19.2 (11.7)	19.6 (12.6)	-0.3 (-10.2 to 9.4)	.94
	3 mo	23.5 (14.4)	22.5 (16.8)	1.3 (-8.6 to 11.2)	.79
	6 mo	29.2 (16.9)	33.7 (18.8)	-2.7 (-12.8 to 7.4)	.60
	12 mo	31.4 (14.3)	37.5 (35.7)	-5.7 (-15.7 to 4.2)	.26
Joint mobility IP1, $^\circ$	Baseline	64.6 (12.7)	66.6 (13.4)	-2.0 (-9.52 to 5.5)	.59
	3 mo	66.0 (13.4)	64.1 (17)	1.58 (-6.0 to 9.2)	.68
	6 mo	65.8 (14.6)	67.5 (13.8)	-2.1 (-9.9 to 5.6)	.58
	12 mo	67.6 (14.1)	67.2 (16.4)	0.3 (-7.3 to 7.9)	.93
Joint mobility	Baseline	50.6 (13.8)	50.7 (14.1)	0.2 (-7.4 to 7.9)	.95
MCP1, $^{\circ}$	3 mo	45 (15.2)	41.8 (18.8)	2.9 (-4.8 to 10.6)	.46
	6 mo	41 (15)	39.5 (13.9)	0.9 (-6.9 to 8.7)	.82
	12 mo	44.6 (13.4)	39.7 (13.2)	4.1 (-3.6 to 11.9)	.29
Palmar abduction of	Baseline	45.2 (10)	44.9 (9.2)	0.3 (-4.7 to 5.3)	.90
the thumb, $^{\circ}$	3 mo	44.9 (9)	41.4 (9.6)	3.3 (-1.7 to 8.4)	.19
	6 mo	45.6 (10)	47.5 (9.4)	-1.9 (-7.1 to 3.2)	.46
	12 mo	45.5 (8.4)	44.9 (11.5)	0.6 (-4.4 to 5.8)	.79
Pain after grip force	Baseline	4.7 (2.8)	5.7 (3.2)	-0.9 (-2.2 to 0.3)	.13
	3 mo	2 (2.4)	2 (2.2)	0.02 (-1.3 to 1.3)	.97
	6 mo	1.7 (1.9)	2.4 (2.2)	-0.8 (-2.0 to 0.5)	.24
	12 mo	1.7 (2.6)	2.1 (2.1)	-0.4 (-1.7 to 0.8)	.51
					(Continued)

TABLE 3. Comparison of the Effect of a Postoperative Regimen With Early Mobilization After Trapeziectomy (Intervention Group) and a Standard Postoperative Regimen With Longer Immobilization (Control Group)* (Continued)

Characteristic	Time Point	Intervention, n = 28	Control, $n = 27$	Treatment Difference	P Value
Pain after pinch force	Baseline	5.6 (2.7)	5.2 (3.2)	0.4 (-1.0 to 1.8)	.57
	3 mo	2.1 (2.6)	2.1 (2.2)	-0.07 (-1.5 to 1.4)	.92
	6 mo	3.5 (2.6)	4.3 (3.2)	-0.8 (-2.3 to 0.7)	.28
	12 mo	1.5 (2.7)	2.6 (2.7)	-1.1 (-2.6 to 0.4)	.15

IP1, first interphalangeal joint; MCP1, first metacarpophalangeal.

*All variables are on the operated hand and are given as means (SDs) for treatment groups. The treatment difference (Intervention - Control) is given with the 95% CI computed via a linear mixed model.

†The COPM is a mean performance score (1-10), where 1 = not able to perform) and satisfaction score (1-10), where 1 = not satisfied at all). ‡Significantly improved was answered as "yes."

Activity performance was measured with the mean score on the MAP-Hand (0-3, where 0 = no activity problems).

||Pain is self-reported using numeric rating scale (0-10), where 0 = n0 pain).

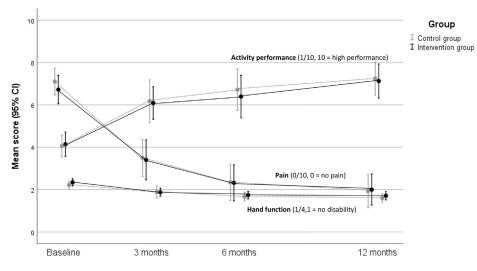


FIGURE 2: Pain, hand function, and activity performance scores from baseline to 12 months in patients receiving a postoperative regimen with early mobilization after trapeziectomy (intervention group) or a standard postoperative regimen with longer immobilization (control group).

results are in line with those of 3 previous comparative studies that concluded that early active recovery does not lead to worse outcomes or more complications.^{26–28} The results indicate that early mobilization after trapeziectomy is as safe and effective as longer periods of immobilization and should be implemented as a routine clinical practice.

A well-known consequence of trapeziectomy is thumb shortening and muscular instability, which may affect grip strength.^{29,30} Therefore, when discussing surgery with patients, they are usually informed that their grip strength is not expected to improve. However, in a recent study, preoperative strength was recovered after 6 months and significantly improved after 12 months.³¹ This finding is in line with the results from our trial, where patients in both groups significantly increased their grip and pinch strengths after 6 and 12 months. Whether this result is caused by improved stability, decreased pain, or other factors should be explored in future studies.

Approximately half of the participants did not adhere to the intervention. Nonadherence is a wellknown challenge, and a recent review showed that 30%-80% of people with rheumatic and musculoskeletal diseases do not adhere to treatment at some point in their disease course.³² Therefore, studies investigating patients' experiences regarding barriers and facilitators for adherence are warranted.

We found no improvement in palmar abduction from baseline to the 1-year follow-up. In our study,

Adverse Event	Intervention Group, $n = 28$	Control Group, $n = 27$
Scarring	Number of patients: 0	Number of patients: 2 - Delayed wound healing (n = 2)
- Severe pain	 Number of patients: 4 Tenosynovitis in FCR (n = 1) de Quervain (n = 1) Pain due to early use in heavy activities (n = 1) 	 Number of patients: 4 CRPS (n = 1) Pain due to early use in heavy activities (n = 1) Wrist radiocarpal arthritis (n = 1)
Sensibilizatio	 Number of patients: 2 Hyperesthesia on the dorsal side of the thumb (n = 1) Decreased sensibility (n = 1)* 	 Number of patients: 3 Hyperesthesia on the dorsal side of the thumb (n = 1) Decreased sensibility (n = 2)*

TABLE 4.	Adverse Events After a	Postoperative Regimen	With Early Mobilization After	r Trapeziectomy
(Interventi	on Group) or a Standar	d Postoperative Regime	n With Longer Immobilization	(Control Group)*

CRPS, complex regional pain syndrome; FCR, flexor carpi radialis.

*Decreased sensibility was temporary, on the dorsal side of the thumb, and related to the cicatrice.

patients were instructed to wear the orthosis until 6 weeks after surgery, which may have been too short for the orthosis to stretch the thenar muscles. Including specific stretching exercises in the postoperative exercise program should therefore be considered.

As with most nonpharmacological treatments, a limitation of our study is that it was impossible to conduct a double-blind study because the occupational therapists delivering the intervention were aware of the assigned treatment. However, the baseline assessment was performed before randomization, and both assessors at follow-up and most patients were blinded to the group allocation. Furthermore, the primary outcomes were selfreported, reducing the chance of results being greatly affected by an observer bias.

According to the power calculation, 28 participants in each group were needed to have a sufficient sample size. With a total of 28 participants in the intervention group and 27 participants in the control group included in the analysis at 12 months, the sample is slightly underpowered. Even if this is unlikely to change the qualitative nature of the conclusion, there is a small probability that there was a difference that the sample was not large enough to identify (a type II error). Further, use of patient-reported outcomes, such as the Michigan Hand Outcomes Questionnaire or Patient-Rated Wrist and Hand evaluation, would have allowed for comparisons with other studies.^{33,34}

In conclusion, the results of this trial support trapeziectomy as reducing pain and improving activity performance and function in patients with CMC1-OA and indicate that early mobilization is as safe and effective as a more restrictive regimen.

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APPENDIX E1. Hand exercises in postoperative regimens after trapeziectomy

HAND EXERCISE PROGRAM: JOINT MOBILITY

Before you do the hand exercises, your hands should be warmed up. Use a hand cream and massage your hands for about 2-3 minutes to make them more limber. It is important when you do these exercises that you are sitting comfortably on a chair with your forearm resting on a table. We recommend that you perform the exercises 1 hand at a time, 3 times a week, for the next 4 weeks. **Exercise 1:**

Start the exercise by shaping the hand as if grabbing a bottle. Keep the thumb in a C-shape. Slowly move the thumb and index finger toward each other. Open the hand fully to stretch all the fingers after fingertip touching. Repeat with the other fingers. Make sure that all finger joints are slightly bent when touching. Perform 2 repetitions.

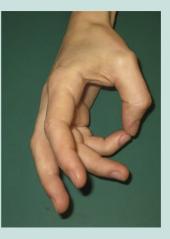






(Continued)

APPENDIX E1. Hand exercises in postoperative regimens after trapeziectomy (Continued)



Exercise 2:

Place your hand on a table for support. The little finger should be resting on the table. Move the thumb parallel to the table top as if you were grabbing a bottle. Relax and then touch the thumb against the index finger. Perform 5 repetitions.





Exercise 3:

Rest your hand on a table with the little finger resting on the table. Stabilize the operated joint and bend the two distal joints, holding the position for 5 seconds, and then relax. Perform 5 repetitions.



APPENDIX E1. Hand exercises in postoperative regimens after trapeziectomy (Continued)



Exercise 4:

Rest your forearm on a table. Lift and bend your wrist as shown in the picture. Perform 5 repetitions.





STRENGTHENING

Three months after your thumb surgery is the time for strengthening exercises. Before you begin, your hands should be warmed up. Use a hand cream and massage your hands for about 2-3 minutes to make them more limber. It is important when you do these exercises that you are sitting comfortably on a chair with your forearm resting on a table. We recommend that you perform the exercises 3 times a week for 4 weeks.

Exercise 1:

For this exercise you will need a rubber band. Rest the hand on a table. Place the band in a figure of 8 around the thumb and fingers. Move the thumb away from the index finger. Hold the top position for 5 seconds, and keep the tension on the way back. Perform 4 repetitions in the right hand, and then 4 in the left hand. Repeat 3 times, for a total of 12 repetitions in each hand.



(Continued)

APPENDIX E1. Hand exercises in postoperative regimens after trapeziectomy (Continued)



Exercise 2:

In this exercise you will need a cylinder. Rest the arm on a table. Make sure you get a good grip on the cylinder with your full hand, including your thumb. Squeeze as hard as you can for 5 seconds. Make sure that all your finger joints are bent.Perform 4 repetitions in the right hand, and then 4 in the left hand. Repeat 3 times, for a total of 12 repetitions in each hand.

