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Original Research

Orthosis Followed by Trapeziectomy for Thumb Base Osteoarthritis: A Cohort Pilot Study on Pain and Function

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Purpose: This study aimed to assess how much symptoms resolve during a 6-week continued nonsurgical treatment with an orthosis and after trapeziectomy in people with thumb carpometacarpal joint osteoarthritis (CMC-1 OA) referred for surgical consultation. The data on symptom resolution magnitude and trajectory can help inform patients about postsurgical recovery and assist researchers in designing clinical trials to evaluate surgery's effectiveness for CMC-1 OA.
Methods: We recruited 52 patients with CMC-1 OA referred for surgical consultation. All eligible and willing patients underwent a 6-week treatment period with an orthosis before trapeziectomy. We collected outcome measures at the time of recruitment, after 6-week use of an orthosis (time of surgery), and at 3, 6, 9, and 12 months following the surgery. The Patient-Rated Wrist/Hand Evaluation questionnaire was the primary outcome measure. We used a repeated measures mixed model to estimate the group mean values for continuous outcomes. We compared the estimates with known minimal clinically important difference values.
Results: A continued nonsurgical treatment with a 6-week use of an orthosis resulted in no relief from hand disability and pain. After trapeziectomy, a large and clinically important change occurred at 3 months, and a rapid decrease in symptoms continued until 6 months, at which point it was three times the minimal clinically important difference value for Patient-Rated Wrist/Hand Evaluation.
Conclusions: This study provides useful estimates for the trajectory and magnitude of the symptom resolution after trapeziectomy. A continued nonsurgical treatment with a 6-week use of an orthosis had a negligible impact on symptoms in patients who were referred for surgical consultation. In contrast, a large improvement can be expected after trapeziectomy. However, it remains unclear how much of this change is attributable to the surgery itself.
Type of study/level of evidence: Therapeutic IIb.

Thumb carpometacarpal (CMC-1) joint osteoarthritis (OA) is a common painful condition of the hand, with prevalence estimates ranging from 6% to 39% among individuals aged 50–80 years.[1] This condition affects most hand functions because action of the thumb is required in nearly all activities of daily living, such as lifting or carrying, turning a key, or handling small objects.[2,3]

The initial treatment of CMC-1 OA is nonsurgical, typically comprising pain medication, hand therapy, and the use of an orthosis.[4] Surgery, generally trapeziectomy, with or without ligament reconstruction and tendon interposition, is considered when nonsurgical treatments do not provide sufficient pain relief.

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However, it is unclear if surgery provides benefits over continuing nonsurgical treatment because the evidence on the efficacy of surgery predominantly comes from observational studies.[5] Furthermore, many people improve and remain improved for years after hand therapy, implying that a considerable proportion of the improvement after surgery may not relate to surgery.[6] A rigorous trial is therefore needed to estimate the efficacy of trapeziectomy.

The objective of this pilot study was to assess the symptom resolution magnitude and trajectory following a continued nonsurgical treatment with a 6-week use of an orthosis and subsequent trapeziectomy in patients who were referred for surgical consultation. We will use these estimates to inform the design of an efficacy trial that uses a placebo-surgery comparator to assess the effect of trapeziectomy. This study also provides prognostic information for individuals considering surgery or continued conservative treatment with an orthosis.

Materials and Methods

Design

This is a prospective, pragmatic multicenter observational cohort study in which all participants first underwent a continued nonsurgical treatment with a 6-week period of orthosis use, followed by surgery (trapeziectomy), and a 12-month follow-up.

Setting

We recruited the participants between August 2017 and November 2018 from three secondary and tertiary referral centers. Highly experienced hand surgeon specialists screened, recruited, and operated on all participants.

The Institutional Review Board of the Helsinki University Hospital (HUS1525/2017) approved the study protocol. We conducted the study according to the Declaration of Helsinki and obtained informed consent from all participants.

Participants and recruitment

At each center, the hand surgeon screened all patients referred by primary care physicians for potential surgical treatment of CMC-1 OA that had not responded to nonsurgical treatments, including orthosis. If the referred patients were dissatisfied with their current symptoms, eligible for surgery, and accepted the associated risks, the hand surgeon scheduled a trapeziectomy. At this stage, we offered the participants a chance to take part in the study. Thus, participation in the study did not affect the treatment.

Inclusion criteria were age over 45 years, surgical treatment planned for a painful CMC-1 OA (grade II–IV), and a written informed consent.[7] Patients were excluded if the primary reason for pain was attributed to any condition other than CMC-1 OA, patient had systemic inflammatory disease or neurological disease compromising the function of symptomatic hand, any previous surgical treatment for same hand within the preceding 6 months, operative treatment planned for both CMC-1 joints, or zig-zag deformity (over 45° of thumb metacarpophalangeal (MP) joint hyperextension at rest).

Interventions

After recruitment, all participants received an orthosis (Actimove Rhizo Forte, Essity AB). The orthosis has an individually adjustable aluminum core, aiming to immobilize both the CMC-1 and MP joint of the thumb but leaving the motion of the wrist and other fingers free. The participants received instructions to continue nonsurgical treatment, using the orthosis continuously for the first 3 weeks, followed by daytime use for the next 3 weeks.

After a period of 6 weeks of orthosis use, all participants underwent a trapeziectomy. During the operation, the hand surgeon exposed and removed the trapezium bone. After carefully examining the space between the metacarpal and scaphoid, the surgeon closed the joint capsule. We did not use suspensionplasty or tendon interposition with ligament reconstruction. If the scaphotrapezio-trapezoid joint had severe arthritic changes, the surgeon also removed 3–4 mm from the proximal part of the trapezoid. After closing the skin, the surgeon immobilized the thumb with a cast in palmar abduction and opposition for 3 weeks.

At the 3-week postoperative visit, we removed the cast and referred the participants to a hand therapist for supervision of home exercises. The exercise program included range of motion and strengthening exercises. For the next 3 weeks, we instructed the participants to wear the previously provided orthosis during daily activities. After this period, the participants could continue using the orthosis if they felt it made using their hand easier.

Outcomes

At the initial clinical encounter, we collected the following baseline data: age, sex (female, male), handedness (left-handed or right-handed), duration of CMC-1 OA symptoms (months), radiological classification (Eaton and Glickel), height and weight, amount of physical exercise (hours per week), smoking (yes or no), education level, and occupation (1–7, 1 = heavy physical, 2 = physical varying, 3 = partly physical, 4 = partly office, 5 = office, 6 = unemployed, 7 = retired). In addition, the participants completed outcome measure questionnaires. Thereafter, we collected the outcome measures on the day of surgery (6 weeks after the initial encounter) and at 3, 6, 9, and 12 months after surgery.

The primary outcome was the Patient-Rated Wrist/Hand Evaluation (PRWHE) questionnaire total score (0–100, lower score indicates fewer symptoms). The PRWHE consists of five pain-related questions and ten questions of different functional tasks. The PRWHE questionnaire is valid and sensitive to change in individuals with CMC-1 OA.[8] The minimal clinically important difference (MCID) for Patient-Rated Wrist Evaluation is 14 points in patients undergoing nonsurgical treatment for tendon, joint, and nerve symptoms and 11.5 points in patients with distal radius fractures.[9,10]

The secondary outcomes were PRWHE pain (0–50, lower score indicating less pain) and function subscores (0–100, lower score indicates fewer symptoms), pain on daily tasks during the last week on a numeric rating scale (NRS; NRS pain, 0–10, lower score indicates less pain), thumb functional performance on a NRS (NRS function, 0–10, higher score indicates better function), and Patient Global Impression of Change (PGI-C) on a 5-step Likert scale (How is the condition of your thumb currently compared with its condition before the treatment? “Much worse” to “Much better”), and the use of pain medication (response options: daily, weekly, less than weekly, none). On the day of surgery, we recorded adherence to and reasons for not adhering to the use of orthosis (response options: yes or no; if no, the reason). In addition, we recorded duration of sick leave after surgery and reasons for deteriorating in PGI-C (4 or 5 on a 5-step Likert scale).

Statistical methods

Because of the nature of the study (a pilot), we did not perform a formal sample size calculation. For the continuous outcomes, we estimated the mean value at each time point using a repeated

Table 1
Descriptive Characteristics and Baseline Variables

Characteristic	n	%
Participants, n (% female)	52	75
Handedness		
Left	6	11
Right	43	83
Ambidextrous	3	6
Affected side		
Left	25	48
Right	22	42
Bilateral*	5	10
Dominant is symptomatic	27	52
Pain medication		
Daily	14	27
Weekly	14	27
Less frequently	18	35
None	6	11
Eaton-Littler classification		
II	9	17
III	20	39
IV	22	42
Education		
Primary education	18	35
Lower secondary	12	23
Upper secondary	16	31
Tertiary education	6	11
Work		
Heavy physical	2	4
Physical varying	20	39
Partly physical	2	4
Partly office	2	4
Office	6	11
Unemployed	2	4
Retired	18	35
Sick leave before intervention		
No sick leave	22	42
Less than 2 wk	5	10
2 wk to 3 mo	5	10
Over 3 mo	2	4
Retired	18	35
STT resection	20	39
Current smoker	11	21
	Mean	SD
Age	62	8
BMI	28	4
Physical exercise (h/wk)	4	2
PRWHE total score	64	13
Pain subscale	34	7
Function subscale	60	16
NRS pain	7	2
NRS function	5	2
	Median	Q1–Q3
Duration of symptoms (mo)	30	12–48

BMI, body mass index; STT, scaphotrapeziotrapezoid joint.
* Excluded only if both thumbs were to be operated on.

measures mixed model including patient identification code as a random factor, time point as a fixed factor, and baseline value as a covariate. We reported the marginal mean values from the model as means with 95% CIs. For the PGI-C and pain medication use, we reported the crude data.

Results

We recruited 52 participants. Two participants were not available for any of the follow-ups. Most of the participants were female with Eaton-Littler grade III–IV OA and symptom duration between 1 and 4 years (Table 1).

Forty-six participants adhered to the planned orthosis protocol. One participant used his own orthosis supporting the wrist in addition to the thumb CMC-1 and MP joints. Six participants only partially adhered to our orthosis protocol over the 6-week period due to an increase in pain (n = 3), abrasion (n = 2), and inconvenience (n = 1). In addition, four participants reported minor harms during the period of orthosis use, such as abrasion (n = 1), pain in other parts of the hand (n = 1), and inconvenience at work (n = 2).

The mean PRWHE total score did not improve during the continued nonsurgical treatment with a 6-week use of an orthosis. After trapeziectomy, the symptoms improved considerably during the first 6 months, with gradual improvement continuing until 12 months (Fig. 1). The PRWHE pain and function subscores, as well as the NRS for pain and function, aligned with the primary outcome (Fig. 1 and Table S1). No adverse events occurred during or after surgery.

According to the PGI-C, only 14 participants (27%) improved (somewhat better or much better) with the continued nonsurgical treatment with orthosis, whereas 50 participants (94%) had improved 12 months after surgery (Fig. 2). The reasons for deterioration in PGI-C scores are reported in Table S2. Despite some participants having improved with continued nonsurgical treatment, they were still not satisfied with their current state and wanted to proceed with surgical treatment. Over half of the participants used pain medications daily or weekly at baseline. One year after surgical treatment, 80% of participants did not use any pain medications (Fig. 3). The median (quartiles 1–3) duration of sick leave after surgery was 90 (56–130) days.

Discussion

Trapeziectomy with or without ligament reconstruction and tendon interposition has never been compared with nonsurgical treatment or placebo.[11] The purpose of our pilot study was to estimate the magnitude and trajectory of change in hand function and pain after a continued nonsurgical treatment with a 6-week use of an orthosis and subsequent trapeziectomy in patients with CMC-1 OA. These data help to inform the design of our upcoming placebo-surgery controlled trial on the efficacy of trapeziectomy and to provide prognostic information for patients considering surgery or continued conservative treatment.

Our findings showed no improvement in hand function and pain during the continued nonsurgical treatment with a 6-week use of an orthosis (Fig. 1). This is consistent with the findings of a systematic review and meta-analysis, showing that the use of an orthosis has little or no effect on hand function or pain in the short term.[12]

Previous studies on trapeziectomy have reported the improvements in pain after surgery ranging from 42% to 76% and from 37% to 57% in function (measured by various patient-reported outcome measures) at 12 months.[13–15] This aligns well with the findings of our study, in which the reduction in PRWHE total score was 52%, 65%, 76%, and 79% at 3, 6, 9, and 12 months, respectively. The magnitude and trajectory of change were highly similar across all secondary outcomes used in this study (Table S1). Most of the improvement in both pain and function was evident already at 6 months, with a gradual but clearly slower trajectory of improvement thereafter (Fig. 1). This supports setting the 6-month follow-up as the primary outcome assessment time point for randomized controlled trials assessing the effect of trapeziectomy.

Relating the changes observed in our study to previously reported estimates for MCID (MCID = 11.5–14 points), we found the change in PRWHE score to be approximately 2.5 times the MCID at 3 months and around three times the MCID at 6 months.[9,10] This indicates a clinically important effect for surgery.

The efficacy of surgery, however, may differ from what we can infer from this study for the following reasons. First, we cannot determine how much participants would have improved

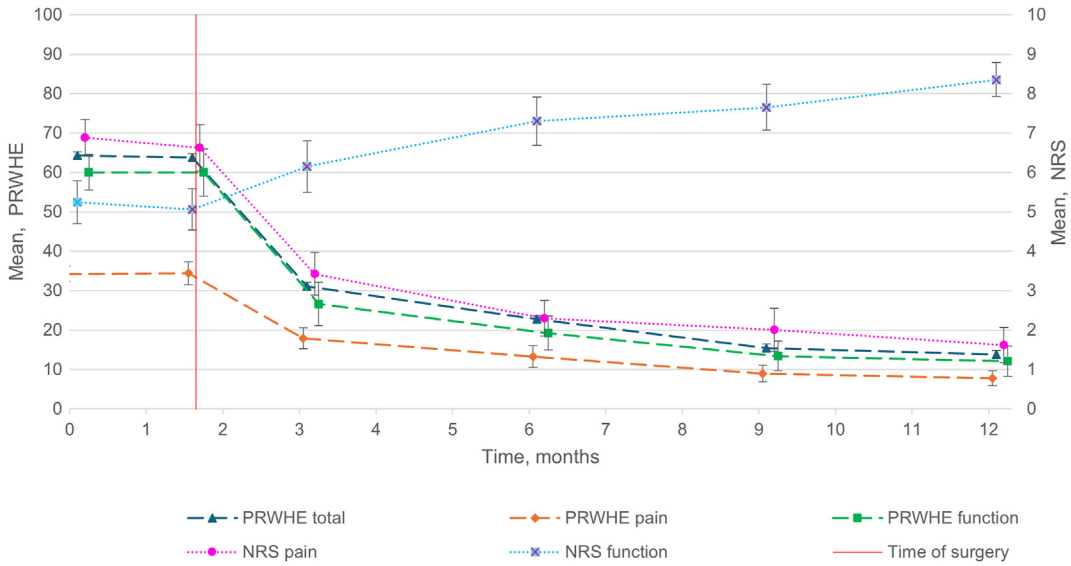

Figure 1. Change in hand function and pain. Marginal means and CIs of outcomes after 6-week use of orthosis and 3, 6, 9, and 12 months after trapeziectomy.

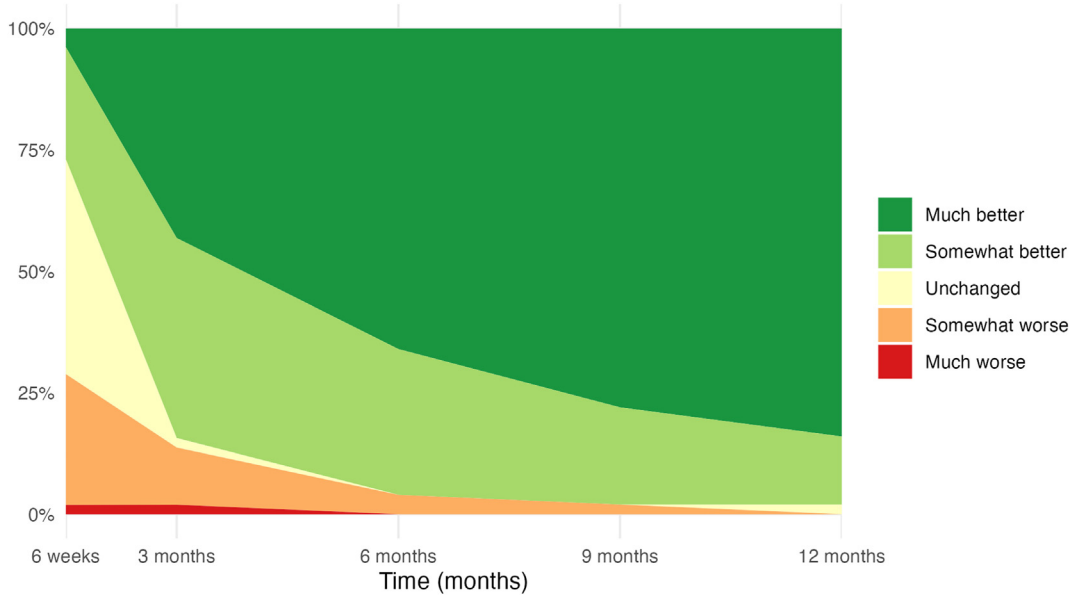

Figure 2. Patient Global Impression of Change from the end of treatment with orthosis (6 weeks) to 12 months after trapeziectomy.

without surgery. Evidence suggests that a longer follow-up may result in substantial improvement without surgical treatment.[6,12] Second, CMC-1 OA is irreversible, and radiographic progression is evident in 20% to 70% of people, depending on follow-up length and scoring system used.[16] Radiographic, but asymptomatic hand OA progresses to symptomatic disease in 13% to 28% depending on the population and type of OA suggesting that sometimes symptoms worsen during follow-up.[17,18] This would suggest that the long-term effect could, in theory, be larger than the observed change in this study. Third, and most importantly, the participants in our pilot study were not blinded to the treatment they received. According to conventional wisdom, self-reported outcomes are susceptible to detection bias, that is, measurements can be affected, either intentionally or unintentionally, when the assessor is aware of the received treatment.[19] However, recent evidence suggests that this kind of bias may not be as large in surgical trials as is commonly assumed.[20,21] Instead, other nonspecific effects account for the change after ineffective or placebo surgery when patient-rated pain and function are used as an outcome.[20]

In this pilot study, continued nonsurgical treatment with a 6-week use of an orthosis seems to result in, at best, marginal change in symptoms in individuals referred for surgical treatment of CMC-1 OA. After trapeziectomy, we observed substantial change in both hand function and pain. Still, due to the aforementioned limitations, the efficacy of trapeziectomy should be evaluated in a blinded randomized controlled trial. The observed change likely applies to other surgical techniques for CMC-1 OA because evidence consistently shows that adding procedures such as ligament reconstruction and tendon interposition to conventional trapeziectomy does not provide additional benefits.[5] We interpret our results to support selecting the 6-month postsurgery time point as the primary time point for assessing efficacy of trapeziectomy.

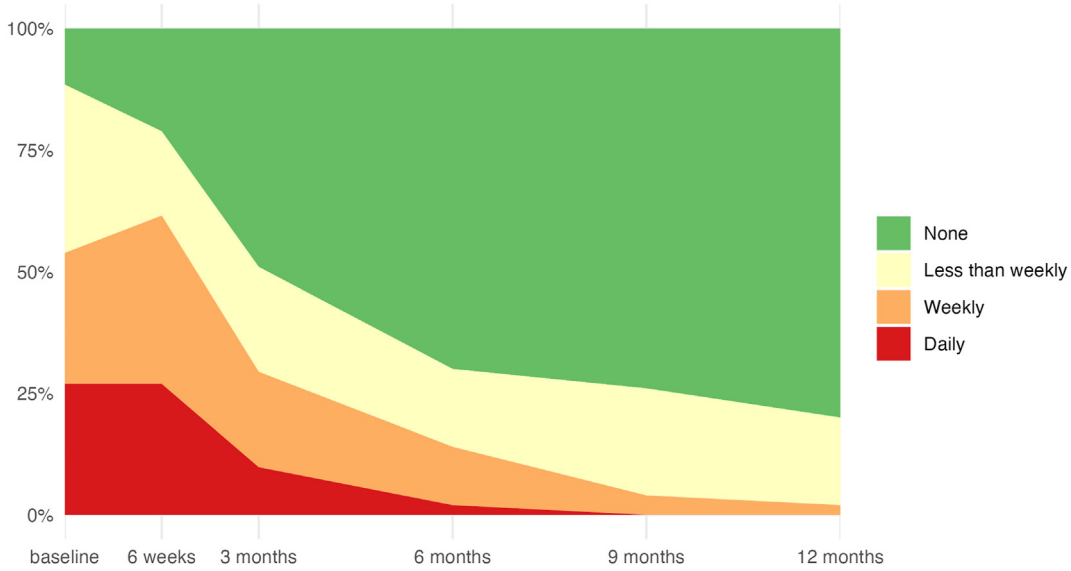

Figure 3. Pain medication. Observed change in use of pain medication during follow-up.

Conflicts of Interest

No benefits in any form have been received or will be received related directly to this article.

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