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# Total joint arthroplasty versus trapeziectomy in the treatment of trapeziometacarpal joint arthritis: a randomized controlled trial

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## Abstract

The aim of this double anonymized, randomized controlled trial was to determine whether total joint arthroplasty has superior outcomes than trapeziectomy 1 year after surgery for trapeziometacarpal osteoarthritis. A total of 62 women aged 40 years and older, scheduled for surgery for stage II or III osteoarthritis of the trapeziometacarpal joint, were included and randomized to trapeziectomy or total joint arthroplasty. The primary outcome was the total score of the Michigan Hand Outcomes Questionnaire. Secondary outcomes were the Michigan Hand Outcomes Questionnaire subscale scores, Disability of the Arm, Shoulder and Hand Questionnaire, active range of motion, strength, return to work, patient satisfaction and complications. Data were collected at baseline and at 3 and 12 months. At 1 year, we found no superiority of total joint arthroplasty over trapeziectomy regarding the total score of the Michigan Hand Outcomes Questionnaire. The total joint arthroplasty did show a significant advantage in strength and range of motion.

**Level of evidence:** I

## Keywords

Thumb, trapeziometacarpal arthritis, osteoarthritis, total joint replacement, arthroplasty, trapeziectomy

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## Introduction

Trapeziometacarpal joint (TMJ) osteoarthritis (OA) is a common cause of pain and disability of the hands in postmenopausal women (Dahaghin et al., 2005; Gabay and Gabay, 2013; Gillis et al., 2011; Pellegrini, 2001). Its prevalence in the Dutch population is in the range of 15% to 52% for women and it is positively correlated with age (Teunissen et al., 2022). Numerous surgical techniques have been described for treatment of TMJ OA, including trapeziectomy, trapeziectomy with ligament reconstruction with or without tendon interposition, arthrodesis and total joint arthroplasty (TJA).

All surgical procedures are effective in reducing preoperative complaints (Davis et al., 2004; Holme et al., 2021; Pomares et al., 2016; van Laarhoven et al., 2019; Wolf et al., 2021). However, trapeziectomy

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can lead to thumb shortening owing to a collapse of the thumb metacarpal, causing pain by abutment to adjacent structures, or may lead to a Z-deformity of the thumb (DeGeorge et al., 2018) requiring secondary surgery. TJA is only feasible in patients without scaphotrapeziotrapezoid (STT) OA but may be complicated by implant loosening or dislocation (Holme et al., 2021). An advantage of trapeziectomy is the low cost of the intervention. A prosthesis is more costly. However, it has been found to be the best way to restore the normal anatomy, potentially leading to better function, faster recovery and preventing Z-deformity (DeGeorge et al., 2018).

The current evidence is of a low level and shows no superiority of one specific technique in outcomes such as pain, physical functioning and complications (Huang et al., 2015; Vermeulen et al., 2011; Wajon et al., 2015). Although many cohort studies have been published, high-level evidence comparing TJA with trapeziectomy is lacking.

The aim of this randomized controlled trial (RCT) was to determine whether TJA has better functional outcomes than trapeziectomy 1 year after treatment for stage II to III TMJ OA.

## Methods

### *Trial design*

A double anonymized RCT was conducted at our centre. Participants were preoperatively assigned randomly to a group receiving either TJA or trapeziectomy. This 1-year outcomes study is part of an ongoing RCT with a 5-year follow-up. Recruitment started in January 2014 and ended in November 2018. The local medical ethical review board approved the study (NL47755.075.14). The clinical trial registration number is NCT02204488 ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines for RCTs (Schulz et al., 2010).

### *Participants*

Based on clinical and radiological findings, all participants were diagnosed with TMJ OA by a level 4 certified hand surgeon (Tang and Giddins, 2016) at the outpatient clinic. When surgical treatment was indicated and agreed upon, and the patient met the inclusion criteria, patients were asked to consider participation in the study.

Women aged 40 years and older with symptomatic Eaton–Glickel (Eaton and Glickel, 1987) stage II or III OA were included in this study. The exclusion criteria were previous operations for TMJ OA on the same hand or secondary TMJ OA as result of trauma, rheumatoid arthritis, systemic lupus erythematosus or

gout, clinical signs of STT arthritis, symptomatic carpal tunnel syndrome or de Quervain's tenosynovitis in the affected hand. Patients with neurological or other disorders of the affected hand that could influence postoperative recovery or who had insufficient knowledge of the Dutch language were also excluded. Participants provided written informed consent before participating in the study.

### *Surgical interventions*

The surgical procedure of implantation of the uncemented semi-constrained (single mobility) Maia prosthesis (Groupe Lepine, Genay, France) was carried out under general or regional anaesthesia by experienced (level 4) surgeons. Prophylactic intravenous cefazolin (Mylan B.V., Bunschoten, The Netherlands) was administered preoperatively. A longitudinal incision was made dorsally over the TMJ. After identification of the joint, a dorsal capsulotomy was carried out. After resection of approximately 5 mm of the proximal end of the thumb metacarpal, the bone was progressively reamed to allow fitting of the metacarpal component. Osteophytes were removed. The central point of the trapezium was determined visually and marked with an awl, after which reaming for the spherical cup was carried out. The definitive 9 mm cup was put in place, after which the neck length was determined using various trial neck lengths. Alignment of the head with the cup could be adjusted by choosing a straight or offset neck. After placement of the definitive metacarpal, trapezium and neck components, the capsule and skin were closed.

The trapeziectomies were carried out under general or regional anaesthesia by experienced (level 4) surgeons. A dorsal approach was used to obtain the same scar as in the prosthesis group. A dorsal capsulotomy was carried out. After raising capsular and periosteal flaps from the trapezium, the trapezium was removed, after which the capsule and skin were closed. No specific capsular interpositions were done.

Postoperative care was the same in both groups; the thumb was immobilized in a plaster reinforced forearm bandage with the thumb in abduction, slight metacarpophalangeal (MCP) joint flexion and wrist extension. After 1 week, the bandage was replaced with a circular forearm and thumb plaster cast for another 3 weeks (Figure 1). Immediately after cast removal, patients were referred to the department of hand therapy. Patients were seen by the hand therapist for supervised rehabilitation once a week in weeks 5 to 8 and once every 2 weeks in the following 4 weeks. This treatment was carried out by all-round certified hand therapists with more than 5 years of



**Figure 1.** Cast immobilization.

clinical experience using a standard protocol (Appendix SI, available online).

### Outcomes

Preoperative measurements and assessments were conducted by one of three experienced certified hand therapists. They also informed the patients about the surgical procedures and postoperative rehabilitation. The assessors were certified hand therapists with more than 10 years of clinical experience, and they were unaware of the surgical procedure that had been done. Before the first measurement, a validation session took place to ensure the assessors made the measurements in the same way, according to a strict measurement protocol (American Society of Hand Therapists, 2015) to increase the reliability of the assessments (Pratt et al., 2004). Throughout the study, patients were measured by the same assessor to avoid potential measurement bias.

At baseline, sociodemographic characteristics were recorded. The primary outcome was hand function 1 year postoperatively, assessed by the total score of the Michigan Hand Outcomes Questionnaire, Dutch Language Version (MHOQ-DLV; 0–100) (Chung et al., 1998; Huijsmans et al., 2001; Marks et al., 2014). Secondary outcomes were the MHOQ subscale scores, the Dutch language version of the Disability of the Arm, Shoulder and Hand Questionnaire (DASH-DLV), active range of motion, and grip and key pinch strengths (a mean of three measurements, taken at maximum efforts) in the involved hand. Return to work was assessed in weeks, with a self-designed questionnaire containing five questions: whether the

patient did paid work; if not, was this because of the hand problem; how many hours a week the patient did paid work; the number of weeks to return to work after surgery; and the number of weeks until being fully employable again.

Satisfaction with the outcome and willingness to undergo the same procedure again was assessed using two questions scored on a numeric rating scale (NRS; 0 to 10). The number of patients with complications was recorded as well as the number requiring any revision surgery, such as prosthesis revisions or secondary suspension tendonplasty after trapeziectomy. Complications requiring additional surgical procedures for de Quervain's tenovaginitis or carpal tunnel syndrome were recorded separately.

Follow-up data were collected at 3 and 12 months after surgery. Radiological follow-up took place after 1 week and 1 year to examine the prosthesis position or any metacarpal bone collapse after trapeziectomy. Radiographs were examined for dislocation, osteolysis, prosthesis component displacement and STT OA in the TJA group, and abutment and scaphotrapezoidal (ST) OA in the trapeziectomy group.

### Sample size calculation

The sample size calculation was based on equal numbers in each group with an alpha error of 0.05 and power of 0.90 to detect a difference of 15 points on the MHOQ total score. These assumptions resulted in 25 participants per study arm. When adding 10% for non-parametric analysis ( $n=27.5$ ) and 10% extra patients taking potential loss to follow-up into account, the calculation resulted in 31 patients in each group.

### Randomization

An online randomization tool ([www.randomization.com](http://www.randomization.com)) was used to develop a randomization scheme in a 1:1 ratio, in blocks of four and stratified for the surgeon. Allocation concealment was guaranteed by converting this randomization scheme to consecutive sealed opaque envelopes. For each new participant, an independent secretary opened the next envelope and scheduled the surgery after baseline assessments had been done.

Patients and the hand therapists making measurements and those involved in rehabilitation, were unaware of the randomization and not allowed access to the electronic patient files. To avoid measurement bias, hand therapists involved in the pre- and postoperative assessments were not involved in the postoperative rehabilitation. The study group allocation was disclosed 1 year after surgery, or earlier in the case of complications.

### Statistical methods

Researchmanager<sup>®</sup> was used for data storage. This is a database that comprises the guidelines of Good Clinical Practice. Data were checked for errors, outliers and missing data. All variables were analysed for normal distribution by assessing the differences between mean, median and standard deviations (SD), histograms and boxplots. For the MHOQ, the data for the affected side was analysed as a continuous variable. Normally distributed continuous variables are presented as means with SD and as medians with interquartile ranges (IQR) if the distribution was non-parametric. Dichotomous and categorical data are described as frequencies with percentages.

An analysis of missing data was conducted by an inspection of matrix plots to identify the amount of and the patterns of missing values and determined whether data were missing (completely) at random (MCAR). Little's MCAR test was used to check whether there was a relation between missing questionnaires and other variables.

To verify equal randomization for baseline variables in both groups, between-group differences were examined using the Fisher exact test (for binary data), and the unpaired *t*-test (for continuous data). An intention-to-treat analysis was carried out. To test the study hypothesis, a longitudinal covariance analysis with a generalized estimated equations (GEE) model was used for the primary outcome. Under the assumption that missing data are MCAR and not due to group allocation or treatment effect, this model estimates missing data values, thereby allowing the use of data from all participants, irrespective of whether they were measured at all time points. An exchangeable correlation structure is assumed. The overall effect of the model is reported

as well as the model for interaction of group and time to determine the efficacy of the intervention. Secondary outcomes were analysed between groups for the outcome at 1 year using unpaired *t*-tests with a Bonferroni correction for multiple testing, Mann-Whitney U test or Fisher exact test, depending on the types of data. The threshold for significance was set at 0.05.

### Results

No significant or clinically relevant baseline differences were present between both groups (Table 1). The arthroplasty of two patients in the TJA group had to be converted to a trapeziectomy owing to fracturing of the trapezium during cup placement. According to the intention-to-treat principle, these patients were analysed in the TJA group. Another two patients in the TJA group did not return for follow-up assessment at 1 year. They returned later to have their contralateral TMJ OA treated. At that time, 14 to 18 months postoperatively, they stated that they had experienced no pain or limitations and had been satisfied with the results after 1 year. This information was retrieved from their medical files. Questionnaires were missing in 13% of the TJA group and in 10% of the trapeziectomy group. There was no relation between missing questionnaires and other variables. Little's MCAR test was not significant ( $p=0.34$ ), confirming that the missing data were MCAR. A flowchart of the study is presented in Figure 2.

#### Primary outcome

Raw MHOQ total (and sub) scores are presented in Table 2. Over time, the mean MHOQ total score in the TJA group was higher than in the trapeziectomy group

**Table 1.** Baseline characteristics.

Baseline characteristics	TJA ( $n=31$ )	Trapeziectomy ( $n=31$ )	<i>p</i> -value
Age (years)	59 (6.5)	61 (8.5)	0.16 <sup>a</sup>
Smoker	7	7	1 <sup>b</sup>
Diabetes mellitus present	2	2	1 <sup>b</sup>
Surgery on dominant hand	13	14	1 <sup>b</sup>
Eaton and Glickel stage			1 <sup>b</sup>
II	13	12	
III	18	19	
MHOQ total score <sup>c</sup>	49.9 (13.1)	44 (11.3)	0.065*

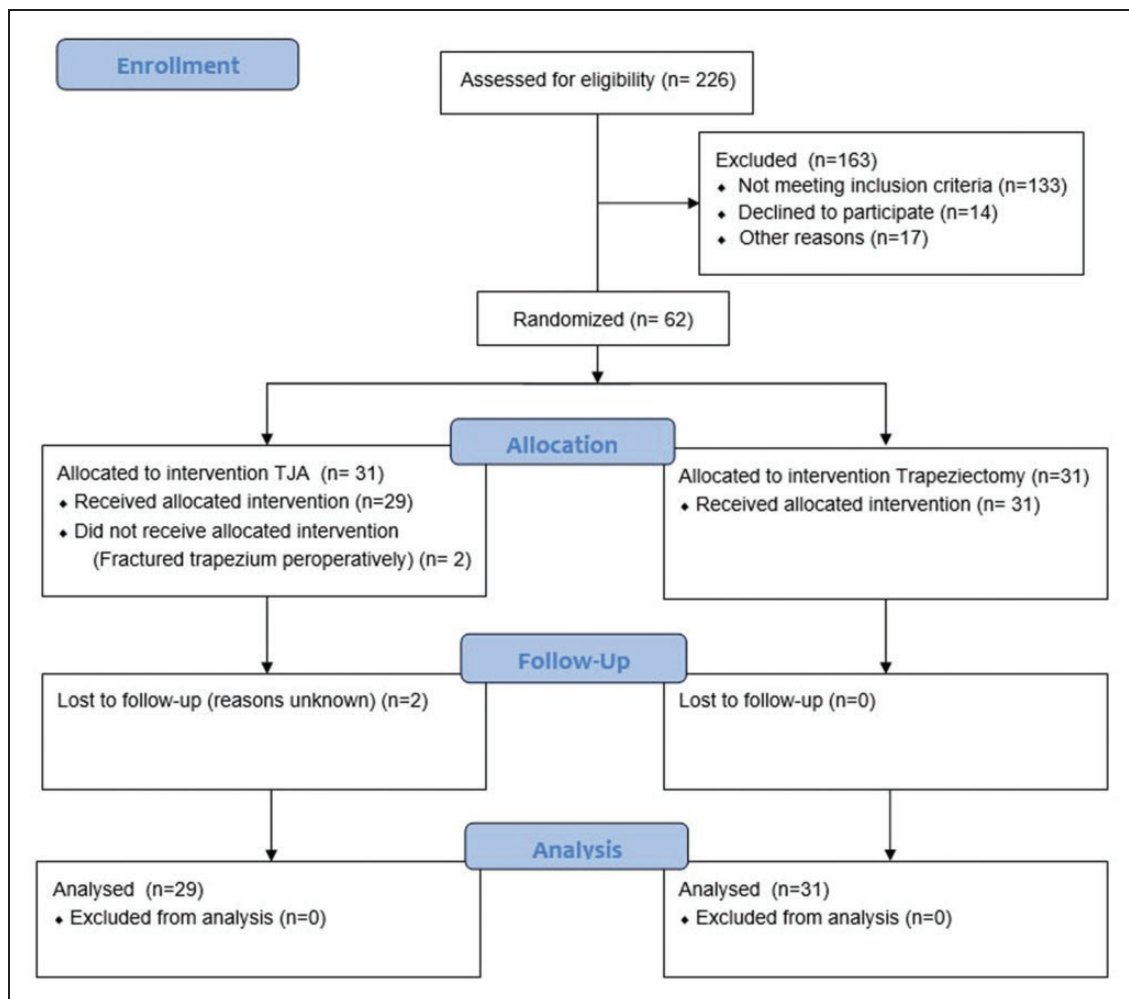
Data are presented as *n* or mean (SD).

<sup>a</sup>Unpaired *t*-test.

<sup>b</sup>Fisher exact test.

<sup>c</sup>MHOQ scores 0–100, a higher score represents a better hand function.

MHOQ: Michigan Hand Outcomes Questionnaire; TJA: total joint arthroplasty.



**Figure 2.** Consort flow diagram.

in the overall model (mean difference 8.5 points; 95% confidence interval [CI]:  $-1.6$  to  $15.3$ ;  $p=0.02$ ). In the model corrected for time, the differences were neither statistically significant nor clinically relevant (Table 3). The odds for reaching the minimum clinically important difference (MCID) for the MHOQ at 3 months was higher for the TJA group (odds ratio [OR] 5.3; 95% CI: 1.5 to 18.1;  $p=0.01$ ); however, at 1 year it was not significantly higher in the TJA group (OR 1.60; 95% CI: 0.50 to 5.13;  $p=0.56$ ). The odds to reach the patient acceptable symptom state (PASS) (Marks et al., 2019) of 70 points on the MHOQ score at 3 months were higher in the TJA group (OR 7.06; 95% CI: 1.37 to 36.40;  $p=0.019$ ). At 1 year, this difference diminished (OR 2.09; 95% CI: 0.68 to 6.43;  $p=0.26$ ).

### Secondary outcomes

Median DASH scores were significantly better in the TJA group at 3 months and 12 months when

compared to the trapeziectomy group (Table 4). A clinically relevant difference was only present at 3 months (median difference 18.3 points). MCP joint flexion of the operated thumb was significantly better in the TJA group at 3 months and at 12 months. MCP joint extension increased in the trapeziectomy group, with a median difference of  $5^\circ$  at 3 months to  $10^\circ$  at 12 months. No such change was observed in the TJA group. No statistically significant or clinically relevant differences were found for grip-strength, palmar abduction, opposition, interphalangeal (IP) flexion and IP extension.

Pinch strength showed clinically and statistically significant differences at 3 months in favour of the TJA group, which remained clinically relevant at 12 months.

A clinically relevant decrease in mean pinch strength was observed in the trapeziectomy group, which was not seen in the TJA group (Table 4). In addition, key-pinch strength was significantly higher in the TJA group at 3 months and at 12 months.

**Table 2.** Scores of the MHOQ total and subscales (0–100).

	TJA			Trapeziectomy		
	Baseline	3 months	1 year	Baseline	3 months	1 year
MHOQ-total	49.9 (13.1)	63.4 (16.1)	75.3 (16.7)	44.0 (11.3)	53.1 (17.8)	66.4 (20.2)
Function	53.0 (15.5)	57.2 (11.9)	68.7 (14.3)	47.7 (12.5)	51.9 (16.6)	60.7 (16.2)
ADL	55.8 (21.7)	72.6 (18.1)	81.0 (18.3)	47.7 (19.4)	60.5 (23.3)	73.5 (24.0)
Work	44.7 (24.1)	51.9 (26.6)	71.7 (29.6)	37.3 (19.8)	38.9 (24.9)	59.1 (29.7)
Pain	32.5 (16.9)	59.1 (21.6)	69.8 (23.0)	28.2 (9.7)	47.2 (20.8)	59.6 (22.7)
Aesthetics	77.1 (16.7)	80.8 (17.7)	88.4 (13.5)	76.4 (24.6)	77.5 (22.7)	84.0 (16.3)
Satisfaction	36.1 (22.7)	58.8 (29.5)	72.1 (24.9)	26.4 (20.4)	42.3 (24.6)	61.4 (33.7)

Data are presented as mean (SD).

ADL: activities of daily living; MHOQ: Michigan Hand Outcomes Questionnaire; TJA: total joint arthroplasty.

**Table 3.** Comparison of the TJA and trapeziectomy groups on the MHOQ scores based on GEE analysis.

	Overall Between groups		3-months Interaction group-time		12-months Interaction group-time	
	$\beta$ (95% CI)	<i>p</i> -value	$\beta$ (95% CI)	<i>p</i> -value	$\beta$ (95% CI)	<i>p</i> -value
MHOQ-total	8.5 (1.6 to 15.3)	<b>0.02</b>	5.5 (−2.4 to 13.4)	0.17	3.4 (−5.8 to 12.7)	0.46
Function	6.4 (1.0 to 11.8)	<b>0.02</b>	0.7 (−8.6 to 10.0)	0.89	3.6 (−5.7 to 13.0)	0.44
ADL	9.4 (0.7 to 18.2)	<b>0.04</b>	5.8 (−6.4 to 18.0)	0.35	−0.8 (−12.0 to 10.3)	0.88
Work	11.0 (0.5 to 21.5)	<b>0.04</b>	7.2 (−5.5 to 19.9)	0.27	5.0 (−11.4 to 21.4)	0.55
Pain	8.6 (0.7 to 16.5)	<b>0.03</b>	8.7 (−1.9 to 19.4)	0.11	5.1 (−6.7 to 17.0)	0.40
Aesthetics	4.2 (−5.5 to 10.9)	0.53	2.3 (−7.4 to 12.0)	0.65	4.2 (−6.8 to 15.2)	0.45
Satisfaction	12.6 (2.4 to 22.9)	<b>0.02</b>	7.7 (−7.0 to 22.4)	0.30	3.0 (−12.4 to 18.4)	0.71

Statistically significant values shown in bold font. Analyses were performed by GEE models, with a group  $\times$  time interaction term characterizing the intervention effect of interest. Beta coefficients represent the mean difference between groups with trapeziectomy as a reference group.

ADL: activities of daily living; CI: confidence interval; GEE: Generalized Estimation Equation; MHOQ: Michigan Hand Outcomes Questionnaire; TJA: total joint arthroplasty.

Three-point pinch strength showed a clinically relevant positive difference for the TJA group at 3 months and 12 months.

### Return to work

Fewer than 50% of the patients were employed at the baseline. Fifteen patients in the TJA group worked a median of 20.5 hours (IQR: 19 to 26.5) per week versus 15 patients in the trapeziectomy group working 23 (IQR: 17 to 26.5) hours per week. The TJA group started working after a median of 6 (IQR: 1 to 10) weeks postoperatively, and the trapeziectomy group after 7 (IQR: 4.5 to 9) weeks ( $p=0.91$ ). After 3 months, five patients in the TJA group returned to their original work and six were doing modified work compared to three in the trapeziectomy group for original work ( $p=0.77$ ) and seven for modified work. After 1 year, eight patients in the TJA group had returned to their original work and three were doing modified work. In the trapeziectomy group, this was five and four patients, respectively.

### Patient satisfaction

Patients were asked if they would consider having the surgery again under the same circumstances. At 3 months, 21 of 26 patients in the TJA group responded with 'yes' compared to 17 of 27 in the trapeziectomy group. At 1 year, this was 23 of 26 patients versus 17 of 27 patients, respectively. There was no significant difference in satisfaction between the groups at 3 months (OR 2.0; 95% CI: 0.54 to 8.31;  $p=0.37$ ) or at 12 months (OR 4.38; 95% CI: 0.94 to 28.60;  $p=0.05$ ). The median satisfaction score (NRS 0 to 10) at 3 months was 7 (IQR: 6 to 8) for the TJA group, compared to 6 (IQR: 3 to 7.5) for the trapeziectomy group ( $p=0.03$ ). After 1 year, the TJA group scored 7.5 (IQR: 6.3 to 8) compared to 6 (IQR: 6 to 8;  $p=0.06$ ) for the trapeziectomy group.

### Complications

Two TJAs had to be converted to trapeziectomy owing to a trapezium fracture that occurred during reaming. Three other patients had perioperative

**Table 4.** Secondary outcomes.

Outcome measure	TJA group		Trapeziectomy group		Difference between groups at 3 months, $\Delta$ , [95% CI]; <i>p</i> -value	Difference between groups at 12 months, $\Delta$ , [95% CI]; <i>p</i> -value		
	Baseline (n=31)	3 months (n=29)	12 months (n=29)	Baseline (n=31)			3 months (n=28)	12 months (n=22)
DASH score (0–100)	37.5 (30.4 to 46.3)	18.3 (14.6 to 27.1)	15.0 (5.0 to 22.5)	44.2 (35.2 to 57.5)	36.7 (29.6 to 45.4)	23.3 (12.9 to 36.7)	< <b>0.0001</b>	<b>0.03</b>
Range of motion (degrees)								
MCP joint flexion	50 (10)	41 (11)	46 (13)	51 (11)	35 (9)	39 (12)	6.1 (0.7 to 11.5); <i>p</i> = <b>0.03</b>	6.7 (0.2 to 13.8); <i>p</i> = <b>0.04</b>
MCP joint extension	–15 (–26 to –6.0)	–12 (–20 to 0)	–12 (–25 to 0)	–9 (–20 to 0)	–17 (–20 to 0)	–22 (–27 to –12)	5; <i>p</i> =0.28	10; <i>p</i> =0.03
IP joint flexion	64 (15)	60 (13)	63 (12)	64 (12)	55 (13)	63 (11)	3.9 (–11.8 to 2.0); <i>p</i> =0.16	0.17 (–6.7 to 6.3); <i>p</i> =0.96
IP joint extension	–20 (–29 to –10)	–18 (–22 to –10)	–15 (–25 to –10)	–20 (–30 to –15)	–15 (–20 to –10)	–22 (–26 to –5)	0.67	0.56
Palmar abduction	40 (7)	35 (8)	37 (8)	35 (8)	36 (8)	38 (8)	0.76 (–3.6 to 5.1); <i>p</i> =0.73	1.31 (–3.5 to 5.8); <i>p</i> =0.63
Kapandji (0–10)	9 (9 to 10)	9 (8 to 10)	9 (9 to 10)	9 (8.8 to 10)	9 (8 to 9)	9 (9 to 10)	0.61	0.77
Strength (kg)								
Grip	17.4 (8.4)	15.4 (7.4)	22.1 (7.7)	16.1 (6.7)	12.2 (5.7)	20.1 (7.4)	3.1 (0.4 to 6.6); <i>p</i> =0.08	2.0 (2.3 to 6.4); <i>p</i> =0.35
Pinch	3.4 (1.3)	3.5 (1.4)	4.4 (0.9)	3.3 (1.2)	2.8 (1.1)	3.8 (1.3)	0.6 (0.0 to 1.2); <i>p</i> = <b>0.04</b>	0.6 (–0.1 to 1.2); <i>p</i> =0.08
Key pinch	4.9 (1.6)	4.7 (1.3)	6.0 (1.0)	4.7 (1.6)	3.5 (1.2)	4.8 (1.5)	1.2 (0.5 to 1.9); <i>p</i> < <b>0.001</b>	1.2 (0.4 to 1.9); <i>p</i> = <b>0.003</b>
Three-point pinch	4.3 (1.6)	3.9 (1.2)	5.1 (0.9)	4.4 (1.6)	3.2 (1.3)	4.5 (1.6)	0.7 (0.0 to 1.3); <i>p</i> = <b>0.05</b>	0.6 (0.2 to 1.3); <i>p</i> =0.15

Data are presented as mean (SD) or median (IQR) unless otherwise specified. Statistically significant values shown in bold font. Normally distributed  $\Delta$  values between groups tested using unpaired *t*-tests. Mann-Whitney U tests were used for DASH, Kapandji and MCP extension.

DASH: Disorders of Arm, Shoulder and Hand; IP: interphalangeal; MCP: metacarpophalangeal; TJA: total joint arthroplasty.



complications. In the trapeziectomy group, a flexor carpi radialis injury occurred and was repaired. The patient noticed no adverse effects in her recovery. Another patient needed revision surgery after incomplete trapezium resection, requiring a ligament reconstruction and tendon interposition (LRTI). In the TJA group, one patient had an injury of the extensor pollicis longus tendon. She eventually needed a tendon transfer after rupture of the initial repair. Twelve patients in the TJA group experienced complications within 1 year, compared to 16 patients in the trapeziectomy group (OR 0.60; 95% CI: 0.19 to 1.82;  $p=0.44$ ). In six TJA patients, these complications were mild and the symptoms resolved within 1 year; they included sensibility disturbance ( $n=2$ ), persisting pain ( $n=2$ ), superficial wound infection ( $n=1$ ) and mild complex regional pain syndrome ( $n=1$ ).

Revision surgery was required for six patients in the trapeziectomy group compared to one in the TJA group (OR 0.14; 95% CI: 0.003 to 1.30;  $p=0.10$ ). The trapeziectomy revisions were because of symptomatic metacarpal collapse. The decision for revision surgery was made in one case after 3 months and in the other five after 6 to 12 months. One of the two TJA patients whose implant procedure had to be converted to a trapeziectomy also received an LRTI. After the primary operation for TMJ OA, some patients needed additional surgery for possibly associated conditions. Carpal tunnel release, trigger finger release, release of the first extensor compartment and MCP joint arthrodesis were carried out in four patients in the trapeziectomy group. In the TJA group, one patient needed a carpal tunnel release, the second patient had a trigger finger release together with a release of the first extensor compartment. Another patient had an MCP arthrodesis combined with a trigger finger release. Six trapeziectomy patients were treated with steroid injections for trigger thumb ( $n=2$ ), carpal tunnel syndrome ( $n=1$ ) and complaints related to scarring or adhesions ( $n=3$ ), compared to two TJA patients with injections for trigger thumb ( $n=1$ ) and extensor pollicis brevis tendinitis ( $n=1$ ).

Radiological follow-up showed metacarpal collapse ( $n=8$ ), abutment on adjacent structures ( $n=9$ ), with or without ST OA ( $n=5$ ). The two TJA patients who were converted to trapeziectomy also showed radiological metacarpal collapse and ST OA, which was not obvious at the time of inclusion. No radiological abnormalities related to the prosthesis (e.g. cup loosening, dislocation) were found at 1 year.

## Discussion

The primary objective of this RCT was to determine whether TJA has better results from the patient's

perspective than trapeziectomy 1 year after treatment for TMJ OA. We were unable to show superiority of TJA over trapeziectomy in daily hand function using the MHOQ. Despite the higher MHOQ scores in the TJA group, the differences were not statistically significant or clinically relevant, when corrected for time. Secondary outcomes, such as pinch strength, key pinch strength and MCP flexion, did show significantly better values for the TJA group. The TJA group also scored significantly higher on patient satisfaction at 3 months. The trapeziectomy group reached the same satisfaction level at 1 year. Increased MCP extension was seen only in the trapeziectomy group and MCP flexion was better in the TJA group, suggesting that the TJA prevented a Z-collapse. This is consistent with the findings of DeGeorge et al. (2018). Complications attributable to the type of surgery, requiring revision surgery, were only seen in the trapeziectomy group.

There are several limitations to our study. Assumptions that were made to calculate sample size may have affected the internal validity of the study. The MCID for MHOQ total score examined at 1-year follow-up is 17 points and the Smallest Detectable Change (SDC) is 11 points (Marks et al., 2014; 2019). Since the registration of our study protocol in 2013, the use of the MHOQ as an outcome measure has increased and it has been found that high SDs of 17 points are common in TMJ OA, even in large cohorts. As the variation between our groups is high, this may have led to an overestimation of the effect size. The high SDs that we found equalled the MCID, which makes it less easy to detect a clinically relevant difference between the groups. Therefore, it is questionable whether the MHOQ has sufficient discriminative ability to detect differences between groups treated for TMJ OA.

The immobilization protocol may also have affected the outcomes in our study. To avoid bias, we decided to immobilize patients in both groups for the same period of 4 weeks, which is commonly used after trapeziectomy. However, there is a wide variety in the duration of immobilization with a tendency towards shorter immobilization periods (Hermann-Eriksen et al., 2022; Howard et al., 2011; Tchurukdichian et al., 2020; Thien et al., 2007; Wouters et al., 2018). Long immobilization may have negatively influenced the various grip strengths, activities of daily living and return to work. It remains unclear whether there is any benefit or increased risk associated with the duration of immobilization after the two surgical treatments.

The design of the prosthesis and the surgical technique that was used for TJA might also have influenced the outcomes. We used a single mobility,

semi-constrained prosthesis. The concept of dual mobility has subsequently been adopted after its successful use in hip joint replacements. Although dual mobility prostheses seem to have biomechanical advantages, the outcomes of single versus dual mobility prostheses in TMJ TJA have not been reported. We determined the cup position without fluoroscopic support and reamed the trapezium without cannulated guidance. There were two trapezium fractures that may have been caused by this relatively uncontrolled positioning. Fluoroscopically guided cup positioning and cannulated reaming of the trapezium may lead to better biomechanical loading of the implant (Brauns et al., 2019; Caekebeke and Duerinckx, 2018).

Earlier return to work would reduce overall costs for society and therefore mitigate the extra costs involved in using a prosthesis. We decided to assess only women, and only 50% were employed and the results are therefore difficult to interpret. Including working men would give a more complete picture.

The best available evidence for choosing between surgical options for the treatment of TMJ OA are the systematic reviews performed by Wajon et al. (2015) and Vermeulen et al. (2011). Recently Challoumas et al. (2022) reported a meta-analysis of randomized studies that compared trapeziectomy with or without LRTI, arthrodesis and joint replacement. In this study, joint replacement had a 99% probability of being the best treatment modality for function and a 62% probability of being most effective for key pinch strength. However, only the RCT by Thorkildsen and Røkkum, (2019) was available for that review; it compared trapeziectomy and LRTI with the Elektra joint replacement using the DASH score as the primary outcome measurement. In comparison with our study, their study population was smaller, patients were aware of the surgical intervention and unfortunately the prosthesis used in this specific study has been abandoned owing to its poor durability (Froschauer et al., 2020).

There is only one retrospective cohort study comparing trapeziectomy and the Maïa prosthesis, with a 9-year follow-up (Seaourt et al., 2021). The MHOQ outcomes of this study are comparable to our own and the secondary outcomes indicate the same positive difference for pinch strength and MCP hyperextension. Better pinch and grip strength after TJA compared to trapeziectomy have been reported in several earlier studies (Cebrian-Gomez et al., 2019; Degeorge et al., 2018; Robles-Molina et al., 2017).

Complications are a serious concern when using TJAs. However, implant failure appears to be less of an issue for modern implants (Holme et al., 2021)

Relatively large cohort studies of modern implants (Arpe, Ivory, Maïa) show that the 10-year survival is in the range of 85% to 95% (Bæk Hansen, 2021). The main concern after trapeziectomy is shortening of the thumb, which may result in symptomatic abutment, pain and loss of strength, possibly causing the need for a secondary procedure. In this study, we have noted a large number of patients receiving secondary surgery after trapeziectomy. The patients were dissatisfied with the primary treatment, mainly because of persisting pain at the base of the thumb metacarpal, which increased with loading. Radiographic examinations supported the diagnosis of metacarpal collapse as a cause of the persisting pain with increasing hyperextension deformity, suggesting collapse and signs of a Z-deformity. There was no indication in the records of these patients that conservative options had not been used, or that the operations were premature.

It is important to realize that the study aimed to compare the 'simple' trapeziectomy with a prosthesis, since there was no evidence supporting additional procedures in trapeziectomy (Davis, 2021; Vermeulen et al., 2011; Wajon et al., 2015). We did no capsular interpositions, but we are unable to state whether the number of subsequent procedures would have been smaller if capsular interposition had been used.

A last factor that might have influenced the outcomes of the trapeziectomy group is the surgical approach. We assumed no effect on outcome, so we chose the dorsal approach, for the purpose of avoiding awareness of study group allocation. However, recently Hamasaki et al. (2021) have shown that the dorsal approach is largely inferior to trapeziectomy by an anterior approach in terms of treatment satisfaction and reducing the number of adverse events. This information was published after our study was designed.

The question remains whether the limited differences in outcome after a trapeziectomy justify the extra costs involved in using a prosthesis. The 5-year outcomes, which we hope to publish within 2 years, will focus on long-term complications and prosthesis survival. An analysis of relevant costs would be of interest in future research.


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**Informed consent** Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

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