Cost-utility analysis of thumb carpometacarpal resection arthroplasty: A

2 health economic study using real-world data

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arthroplasty; quality of life

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4 **ABSTRACT**

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Purpose: Knowledge about the costs and benefit of hand surgical interventions is important for surgeons as well as payers and policy makers. Little is known about the cost-effectiveness of surgery for thumb carpometacarpal osteoarthritis (CMC I OA). The objective of this study was to examine patient quality of life and economic costs with a focus on the cost-utility ratio one year after surgery for CMC I OA compared with continued nonoperative management. Methods: Patients with CMC I OA indicated for resection arthroplasty were included in a prospective study. Quality of life (EQ-5D-5L), direct medical costs and productivity losses were assessed up to 1 year after surgery (postop). Baseline data at recruitment and costs sustained over 1 year before surgery (preop) served as a proxy for nonoperative management. Total costs to gain one extra quality-adjusted life year (QALY), the incremental cost-effectiveness ratio (ICER), were calculated from a health care system and a societal perspective. Results: The mean EQ-5D-5L value for the 151 included patients improved significantly from 0.69 to 0.88 (postop). Productivity loss during the preop period was 47% for 49 working patients, which decreased to 26% 1 year after surgery. Total costs increased from USD 20,451 in the preop year to USD 24,374 in the postop year. This resulted in an ICER of USD 25,370/QALY for surgery compared to simulated nonoperative management. Conclusions: The calculated ICER is clearly below the suggested threshold of USD 92,000 indicating

24 Level of evidence: Economic II

that thumb carpometacarpal surgery is a cost-effective intervention.

25 INTRODUCTION

26	Rising healthcare costs are triggering the need for economic evaluations. The evaluation of benefits
27	of a medical intervention in comparison to its costs allows a more comprehensive consideration of its
28	value.¹ Economic studies analyzing the direct medical costs of hand surgical interventions have been
29	published in recent years, for example, for the treatment of patients with Dupuytren's disease, ²⁻⁴
30	finger joint arthroplasty patients ^{5,6} and those receiving hand transplantations. ⁷ For osteoarthritis
31	affecting the first carpometacarpal joint (CMC I OA), one study examined the direct medical costs and
32	loss of productivity after surgical and nonoperative treatment.8 However, a cost-utility analysis has
33	yet to consider the potential gain in quality of life (QoL) in relation to costs.
34	Osteoarthritis of the CMC I with persisting symptoms is often treated surgically. Despite its good
35	outcomes and gain in QoL, 9,10 such an intervention can be associated with a long postoperative sick
36	leave period of up to 137 days. 11 This loss of productivity may lead to considerable costs and
37	therefore, to substantial economic consequences for the patient, employer, and society. ^{1,12} In hand
38	surgery, de Putter et al. 12 showed that productivity losses contributed up to 56% of the total costs
39	incurred after hand and wrist injuries. Marks et al. ⁸ found that direct medical costs and costs due to
40	loss of productivity were almost equally high up to 1 year after surgery. In contrast, 91% of the costs
41	for nonoperatively treated patients were attributed to productivity losses, because treatment costs
42	are quite low.
43	In health economic studies, benefits can be measured in healthy year equivalents, usually expressed
44	by gains in quality-adjusted life years (QALYs) and by the incremental cost-effectiveness ratio
45	(ICER). 1,13 There is no explicit threshold defining a cost-effective intervention in Switzerland. Other
46	countries suggest thresholds of £20,000 to £30,000 (UK¹⁴ = USD 27,000 to USD 41,000), €45,000
47	(Ireland ¹⁵ = USD 54,000) or up to USD 150,000 per QALY gained in the US. ¹⁶ The World Health
48	Organization recommends a threshold of one to three times a country's annual gross domestic
49	product (GDP) per capita, ¹⁷ which would range from USD 92,000 to USD 276,000 for Switzerland
50	(2019 GDP ¹⁸ .

The objective of our study was to assess the change in QoL and costs for patients after surgery for CMC I OA compared to continued nonoperative management using real-world evidence from patient questionnaires, clinical measurements, individual electronic health records of patients and claims data. The hypothesis was that QoL would substantially improve at a reasonable cost within 1 year after surgery and result in a favorable cost-utility ratio.

MATERIALS and METHODS

Design

This prospective health economic study was performed in a private tertiary Swiss orthopedic hospital. Benefits and costs associated with CMC I OA surgery compared to nonoperative management were determined using a before and after surgery comparison. Cost-utility was evaluated from a health care system and a societal perspective with a follow-up period of 1 year. The study protocol was approved by the local ethics committee. We adhered to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist. 19

Patients

Patients scheduled for surgery for treatment of symptomatic CMC I OA were eligible for this study when they fulfilled the inclusion criteria as outlined in Table 1. Eligible patients were consecutively enrolled until a total of 150 patients were operated on and did not drop out from the study within 3 months after surgery. The sample size was calculated to detect a minimally important difference in the 1-year EQ-5D value, which is reported to be mean 0.074²⁰ with a standard deviation of 0.30. The significance level was set at 0.05 and the power at 80% while considering a maximum loss to follow-up of 10%.

Intervention

Since our aim was to analyze the costs of routine surgical treatment, we included all types of resection arthroplasties performed at our clinic. Surgeons chose the operative method based on their

individual preferences and experience. The interventions for CMC I OA treatment included: simple trapeziectomy; trapeziectomy with suspension-interposition according to Epping and Noack,²¹ Weilby²² or Sigfusson and Lundborg;²³ or trapeziectomy with suspension-interposition using an allograft,²⁴ pyrocarbon implant (Pyrocardan, Curmed, Ostermundigen, Switzerland) or absorbable gelatine sponge (Surgifoam®; Ethicon, Somerville, NJ, USA).

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Outcome measures

Patients completed a questionnaire and were clinically assessed at six time-points throughout the study period: at enrollment (mean 33 days before surgery), immediately prior to surgery, and at 2 weeks (questionnaire only), 3 and 6 months as well as 1 year after surgery. The primary outcome measure was the European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L) questionnaire. 25 The EQ-5D-5L responses were converted into utilities ranging from -0.66 (lowest QoL) to 1 (highest QoL) according to the German value set. 26 The EQ-5D is valid and reliable, and the most frequently used instrument to evaluate health states using utilities and to calculate QALYs in patients with upper extremity orthopedic disorders.²⁷ Secondary outcomes included the following: Patient-reported hand function was measured with the brief Michigan Hand Questionnaire (MHQ) that generates a final score ranging from 0 to 100 points, with higher values indicating best hand function. Furthermore, patients rated their pain at rest and during activities on a 0-10 numeric rating scale, where 0 indicates no pain and 10 maximum pain. The clinical examination included maximum grip and key pinch strength measurements undertaken in a standardized sitting position using a Jamar dynamometer (Saehan Corp., Masan, South Korea) and pinch gauge (B&L Engineering, Santa Ana, CA), respectively. Preoperative radiographs of the CMC I joint were used to grade the severity of OA ranging from stage I to stage IV according to the Eaton classification.²⁸

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Cost and productivity data

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Total costs were assessed by collecting direct medical costs and productivity loss data for the year before surgery (preop) and the first postoperative (postop) year. Switzerland has universal coverage by mandatory health insurance covering a comprehensive basket of health services. This mandatory health insurance is bought from private insurers. Eleven major private Swiss health insurance companies provided direct medical inpatient and outpatient claims data. Claims data included alldiagnosis direct medical costs of all treatments, complications, drugs and consultations across all providers. A discount rate was not used due to the short period of 2 years including the preoperative and postoperative years. Costs were recorded in Swiss francs (CHF) and converted to US dollars (2017 conversion rate: 1 CHF = USD 1.026). Productivity losses (i.e. indirect costs) due to CMC I OA were calculated using the human capital approach. Productivity data for working patients were collected at enrollment, immediately prior to surgery and at each follow-up using the Work Productivity and Activity Impairment Questionnaire -Specific Health Problem (WPAI-SHP) Version 2.0²⁹; this tool comprises six questions on absenteeism (absence from work) and presenteeism (reduced productivity when at work) including one question on limitations with regular daily activities other than work. Unemployed patients were only asked to answer the latter question regarding their non-professional activities at the aforementioned time points. Patients who retired during the study period were considered retired from the beginning of the study. Additional work-related data included: (1) the number of hours usually worked per week, (2) whether the level of employment had been reduced due to the CMC I OA, (3) the duration of absence from work after surgery and (4) the current monthly personal income in brackets of 2,000 CHF up to 16,000 CHF and higher.

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Statistical methods

All data were entered into a web-based electronic database using REDCap software³⁰ and missing data were not replaced. The change in QoL was analyzed using a paired t-test. Quality-adjusted life years were calculated by multiplying utilities with the length of time of this specific health state. The

QALY between two assessment points was calculated by the mean of the utilities recorded at these points. For the primary analysis of this study, we assumed that if patients had not undergone surgery, they would have maintained their preoperative QoL, measured by the EQ-5D-5L questionnaire at study enrollment, throughout the follow-up period and the costs incurred in the year before the operation would subsequently remain constant. The comparison of this maintained health state with surgical treatment was referred to as the "base case".

Annual direct medical costs were calculated for the preop and postop year. The ICER was calculated

Annual direct medical costs were calculated for the preop and postop year. The ICER was calculated by dividing the difference in annual costs by the QALYs gained (postop minus preop period). The 95% confidence intervals (95% CI) of costs and ICER were calculated using non-parametric

Productivity losses were calculated by multiplying the overall work impairment in percent due to CMC I OA³² with annual earnings and expressed as a percent of the work activity level.

Sensitivity analysis

bootstrapping.31

According to our base case definition, the QoL index of symptomatic patients continuing a hypothetical nonoperative management would remain constant over time, and this has been shown in previous studies also reporting constant costs as that documented in the preoperative year. 33,34

This is an optimistic scenario for OA, which is characterized by irreversible articular surface destruction; nonoperative treatment may prolong but not prevent the disease's progression. In contrast, some patients may experience some symptomatic improvement from nonoperative management, at least in the short term. 35,36 Thus, we believe that our base case assumption including a stable trajectory of QoL during follow-up for nonoperative treatment of symptomatic patients is a fair one. Nevertheless, we verified the extent to which this assumption could influence our results with a sensitivity analysis including two scenarios. Firstly, alternative trajectories of QoL were simulated during the year of nonoperative management: i) a linear deterioration of 10% in QoL and ii) a linear increase of 10% in QoL during the first three months post-treatment (e.g. due to intraarticular injection) after which QoL remained constant. The second scenario involved hypothetically

increased costs of 10% for the year after enrollment compared to the documented costs of the preop year due to intensified nonoperative treatment to maintain the initially achieved QoL status.

Because CMC I resection arthroplasty is often done on an outpatient basis in other countries, we performed an additional sensitivity analysis that involved extrapolating the costs of our outpatient surgeries (n=23) to all patients and calculating the respective ICER.

165 RESULTS

Patient enrollment and baseline characteristics

Between March 2014 and January 2017, 187 patients were eligible and 164 patients were included in the study. Ten patients declined surgery and three withdrew consent within 3 months after surgery leading to a total of 151 patients. Of the 151 patients who complied with the study procedure, one had missing 1-year follow-up data. The mean age of our patient cohort was 65 years (SD 8.3), 77% were females, 48% reported symptoms longer than 3 years and the mean length of hospital stay was 3 days (Table 2).

Patient-reported and clinical outcomes

The mean EQ-5D value increased significantly during the study period from 0.69 (SD 0.19) at enrollment to 0.88 (SD 0.11) 1 year after surgery (P < 0.05, Figure 1). The preop and postop QALYs were 0.69 (SD 0.19) and 0.85 (SD 0.10), respectively. The incremental QALY for CMC I OA patients compared to nonoperative management was 0.16 (SD 0.18) after 1 year. Patient-reported outcomes of hand function and pain during activities and at rest significantly improved throughout the 1-year postop period (P < 0.05, Figure 2). Mean grip and key pinch strength immediately prior to surgery was 20 (SD 11) and 3.7 (SD 2.0); these values increased significantly to 24 (SD 9) and 3.9 (SD 1.7) at 1 year, respectively (P < 0.05). Although statistically significant, the increase in key pinch strength does not seem to be clinically relevant.

Cost-utility analysis

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Direct medical costs were provided by eleven major Swiss insurance companies for 133 patients (88%). Costs increased from USD 11,280 incurred in the nonoperative preop year to USD 17,489 in the postop year (Table 3). The calculated productivity loss during the preop period was 47% for the 49 working patients, which decreased to 26% one year after surgery; presenteeism was the main contributor to loss of productivity before surgery, whereas absenteeism predominated after surgery (P < 0.05, Figure 3). Forty-three patients returned to work after a mean of 67 days. Six patients could not return to work, five due to persisting thumb problems and one due to mental health issues unrelated to the thumb.. The ICER was USD 25,370/QALY gained (95% CI: 133 – 50,608) for CMC I OA surgery compared to nonoperative management 1 year after surgery from a societal perspective including productivity losses (Table 3). Based on the sensitivity analysis assuming a QoL increase and decrease and/or increased costs due to intensified nonoperative treatment, the ICERs (including productivity losses) ranged between USD 15,097 to USD 40,057/QALY (Table 4). When the data of outpatients were extrapolated to all inpatients assuming that all patients would have had an outpatient surgery, the ICER including direct medical costs was USD 14,490/QALY (95% CI: 742-28,238). When productivity losses were included, the ICER was USD 2,845/QALY (95% CI: 21,368-27,059).

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204 **DISCUSSION**

This cost-utility analysis done in a tertiary orthopedic hospital revealed a significantly improved QoL of patients with CMC I OA after surgery compared to nonoperative treatment. The reasonable additional costs of CMC I OA surgery of around USD 4,000 compared to nonoperative treatment and the increased QoL yielded an ICER of USD 25,370/QALY. These results indicate that surgery for CMC I OA is a cost-effective intervention compared to nonoperative treatment, because it falls well below the suggested threshold of USD 92,000/QALY for high-income countries. 13,37

These thresholds for cost-effective interventions vary depending on the type of treated disease, and are lower for mild diseases and higher for life extensions rather than QoL improvements. 13 Our ICER is comparable with the cost-effectiveness of strengthening and stretching for rheumatoid arthritis of the hand compared to usual care estimated at £18,000 (= USD 24,000) /QALY³⁸ or 25,000 CHF (= USD 26,000) /QALY for arthroscopic rotator cuff repair compared to nonoperative treatment, 39 and clearly below 36,000 CHF (= USD 37,000) /QALY for patients after total shoulder arthroplasty compared to nonoperative treatment.40 When comparing the ICERs between studies, the calculation method needs to be considered. We are aware of three previous studies that evaluated the ICER for various hand conditions. 4,6,41 An ICER of £11,000 (= USD 15,000) /QALY was established for patients with Dupuytren's disease based on the comparison of two surgical methods and modelled data.⁴ A second study also using modelling techniques compared a therapy regimen including up to three steroid injections before surgery versus surgery or immediate open surgical release for the treatment of trigger finger and calculated an ICER of USD 118,827/QALY.⁴¹ The third study focused on the costs per unit gain of functional improvement in patients with rheumatoid arthritis undergoing metacarpophalangeal arthroplasty compared to nonsurgical treatment.⁶ The reported ICERs were less than USD 1,150 per gained unit in the MHQ and USD 50,000 to USD 150,000 per gained unit using the generic Arthritis Impact Measurement Scale 2; these cost-effectiveness values are not directly comparable to ICERs of costutility studies, where costs per QALY gained are determined. The increasing need for cost containment forces doctors not only to choose the treatment with the best potential outcome, but also to consider the associated costs. Therefore, knowledge about which treatment is cost-effective is essential. Furthermore, it is important to know that costs do not consist of direct medical costs only, but that the costs due to loss of productivity can be considerably higher. 42 When we consider the societal perspective, this highlights the need for treatments that aim at re-integrating the patients as quickly as possible back into the workforce. In our study, patients returned to work on average 67 days after surgery, which is in line with the patients of Weiss et al. 43 who were on sick leave for 9 weeks after suture suspension arthroplasty. Yet these results are in

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contrast to other studies that showed considerably longer absences from work after CMC I surgery ranging between 94 and 271 days. 11,44 This discrepancy might be explained by various psychosocial and work-related factors that influence return to work such as the job type⁴⁵, which we did not assess in our study. This study has several limitations The first limitation considers the assumption that the QoL index would remain constant over time without surgery. Some patients may benefit from further nonoperative management, whereas QoL would continue to decrease for other patients because of advancing osteoarthritis and its related limitations. Therefore, we assumed that a constant QoL index would best represent the average situation (i.e. base case comparison) and with the sensitivity analyses, alternative scenarios were applied. Second, only all-diagnosis direct medical costs including additional costs of other health-related conditions such as comorbidities, were available. Due to our pre-post design, the impact of non-CMC I OA costs on incremental costs should be minimized because patients were compared with themselves such that they act as their own controls. In addition, any costs due to possible surgical adverse events are captured in our calculation. Marks et al.8 calculated the direct medical costs for CMC I OA surgery from the hospital cost accounting system and revealed costs of €5,770 (= USD 6,930) for the 1-year postoperative follow-up period. This value is similar to our incremental direct medical costs of USD 6,209 (equivalent to €5,355). Therefore, our study design seems to be a reasonable approach with the advantage of including all costs occurring outside the clinic. Third, we did not include costs from the patients' perspective such as travel costs between the hospital and home as well as personal medical expenses. Fourth, as the study was conducted in a tertiary Swiss orthopedic hospital, the results should be extrapolated with caution to different settings and countries, in which CMC I surgery is usually done on an outpatient basis. Lastly, the interventions in our study included different surgeries associated with varying costs. However, this is consistent with our real-world approach that reflects the well-known variability of surgical techniques. Future studies should investigate the cost-effectiveness of different surgical interventions for CMC I OA.

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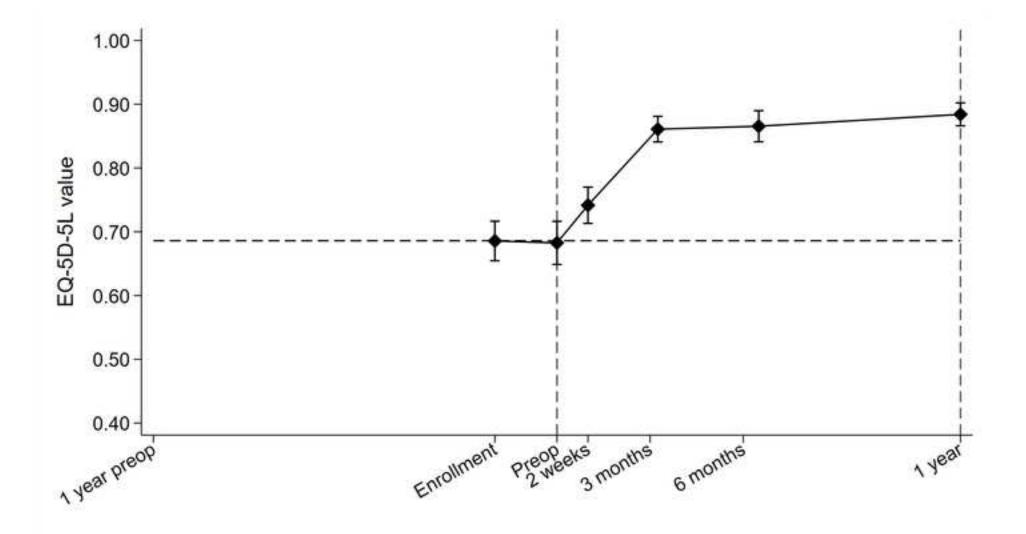
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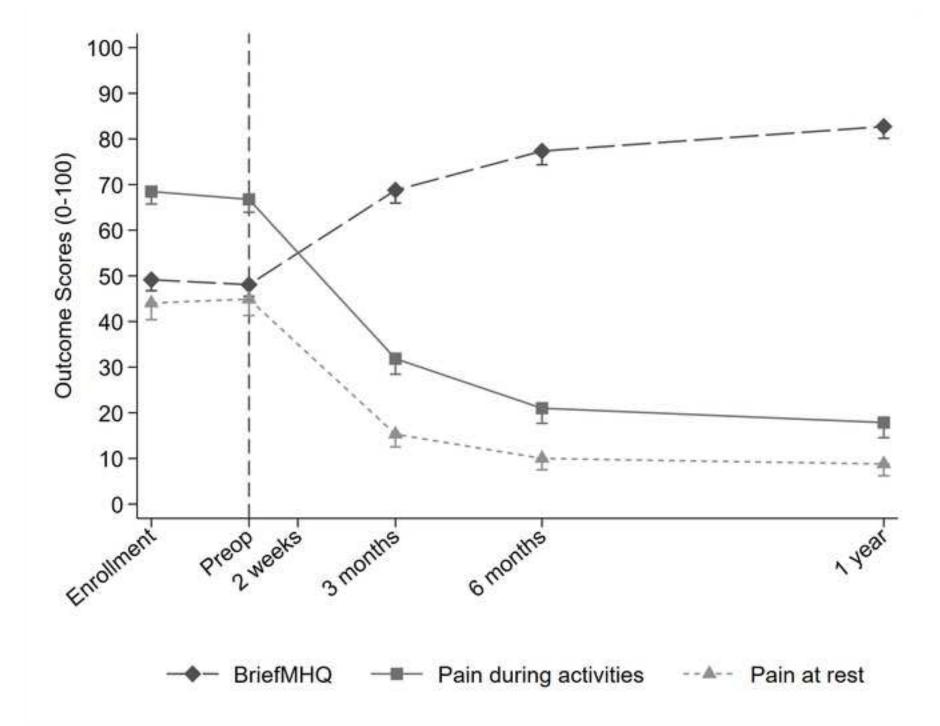
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382	FIGURE LEGENDS
383	
384	
385	Figure 1. Quality of life measured by the European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L)
386	questionnaire at each follow-up time point. The horizontal dashed line indicates the base case EQ-
387	5D-5L value for nonoperative management.
388	
389	Figure 2. Hand function (brief Michigan Hand Questionnaire [briefMHQ]; 100 = best function) and
390	pain at each follow-up time point. The original pain scale from 0 to 10 was adapted for presentation
391	purposes, where 100 = worst possible pain.
392	
393	Figure 3. Productivity losses for all working patients (n = 48) before and after thumb carpometacarpal
394	arthroplasty. The horizontal line at 0 weeks indicates the end of the preoperative period.





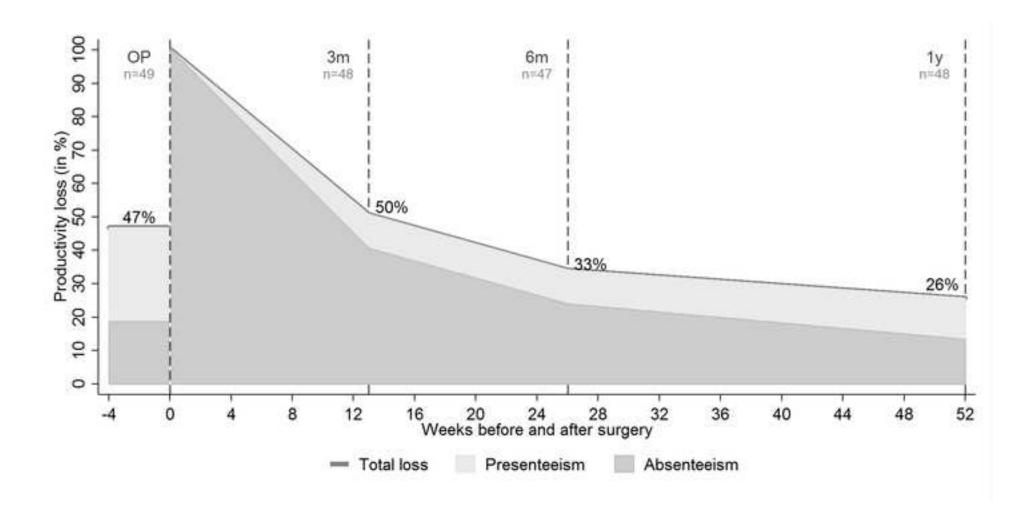


Table 1. Inclusion and exclusion criteria

Inclusion criteria

- Scheduled for surgery because of symptomatic CMC I OA
- Older than 18 years and older
- Written informed consent

Exclusion criteria

- Other joints operated during the same intervention, except arthrodesis of the metacarpophalangeal I joint
- Revision surgery
- Rheumatoid arthritis
- Participation in other hand surgery studies
- Concomitant disease that would preclude accurate evaluation (i.e. neuromuscular or metabolic disorder)

Table 2. Baseline patient characteristics (N = 151)

	n (%)*
Working patients	49 (32)
Eaton classification of osteoarthritis	
Stage II	15 (10)
Stage III	80 (53)
Stage IV	56 (37)
Duration of symptoms	
< 1 year	9 (6)
1 to 3 years	69 (46)
> 3 years	73 (48)
Nonoperative treatment in the preoperative year	
Steroid infiltration	92 (61)
Splint/bandage	80 (53)
Oral medication	78 (52)
Occupational therapy	32 (21)
No treatment	18 (12)
Other	14 (9)
Surgical technique	
RSI according to Weilby	101 (67)
RSI according to Epping and Noack	15 (10)
RSI according to Sigfusson and Lundborg	11 (7)
Simple trapeziectomy	10 (7)

Trapeziectomy with interposition of an allograft	7 (5)
Pyrocarbon implant	6 (4)
Trapeziectomy with interposition of an absorbable gelatine sponge	1 (1)

RSI: trapezium resection with suspension-interposition

^{*} Percentages might differ from 100 due to rounding errors

 Table 3. Quality-adjusted life years (QALYs), direct medical costs and productivity losses in US dollar.

Parameter	n	Nonoperative	Surgery
		management	mean (SD)
		mean (SD)	
QALYs	151	0.69 (0.19)	0.85 (0.10)
Direct medical costs*	133	11,280 (12,970)	17,489 (12,938)
Inpatient cost data	133	3,770 (9,529)	8,983 (9,159)
Outpatient cost data	133	7,511 (6,393)	8,506 (6,285)
ICER for CMC I OA surgery compared to nonoperative	130**	37,015/QALY	
management from a health care system perspective			
Productivity losses***	49	26,033 (24,739)	22,707 (24,666)
Total costs (direct costs + productivity losses)****	133	20,451 (22,917)	24,374 (20,685)
ICER for CMC I OA surgery compared to			
onoperative management (societal perspective 130** 25,370/QALY		0/QALY	
including productivity losses)			

SD: standard deviation

- * Provided by the health insurance companies for 133 patients including all medical costs for CMC I OA as well as other conditions.
- ** Patients with complete QALY and cost data for all time points
- *** For 49 working patients
- **** Total costs = ((direct costs + productivity losses) of 49 patients + direct costs of 84 patients)/133

Table 4. Sensitivity analysis of incremental cost-effectiveness ratios (ICERs) for thumb carpometacarpal arthroplasty compared to nonoperative management

ICERs of thumb carpometacarpal arthroplasty compared to hypothetical nonoperative treatment [mean (95% CI)]

Hypothetically lower or higher utility index of nonoperated patients	Hypothetically increased costs of nonoperated patients [USD]* (in the first year after enrolment compared to the year before enrolment due to more intensive nonoperative treatment)		
(compared to preoperative utilities)	Unchanged costs (base case)	10% increased costs	
Unchanged utility index (base case)	25,370 (133 - 50,608)	18,285 (-6,867 - 43,438)	
10% lower**	20,946 (449 - 41,444)	15,097 (-5,423 - 35,617)	
10% higher***	40,057 (-3,556 - 83,669)	28,870 (-13,597 - 71,338)	

ICERs presented with 95% CI = 95% confidence interval, where the bold value indicates the ICER for the study-defined base case, which assumed that if patients had not undergone surgery, they would have maintained their preoperative health state throughout the follow-up period

^{*} Costs include direct medical costs plus productivity losses

^{**} Linear decrease of the utility index during the nonoperative year

^{***} Linear increase of the utility index during the first three months after nonoperative treatment and thereafter remaining constant up to 1 year