TREATMENT OF PATIENTS WITH HAND OSTEOARTHRITIS: OUTCOME MEASURES, PATIENT SATISFACTION, AND ECONOMIC EVALUATION

Miriam Marks

The research presented in this thesis was performed in the Department of Research and Development, Upper Extremities and Hand Surgery, at the Schulthess Clinic, Zurich, Switzerland, in cooperation with the Department of Orthopaedics at the Leiden University Medical Center, Leiden, The Netherlands.

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TREATMENT OF PATIENTS WITH HAND OSTEOARTHRITIS: OUTCOME MEASURES, PATIENT SATISFACTION, AND ECONOMIC EVALUATION

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	Dr. W.B. van den Hout

It is what we make out of what we have, not what we are given, that separates one person from another.

(Nelson Mandela, 1918 – 2013)

CONTENTS








CHAPTER **ONE**

GENERAL INTRODUCTION



OSTEOARTHRITIS OF THE HAND

Osteoarthritis (OA) is the most prevalent joint disorder leading to serious functional limitation and reduced quality of life, as well as to considerable social and economic costs[1-3]. The hand is one of the most common sites of OA. Hand OA frequently occurs together with OA at other joints such as the hip or knee[1].

Prevalence

Prevalence rates of hand OA vary depending on definition, measurement methods, and study populations. Some authors report prevalence data on radiographic OA, which is not necessarily associated with pain and disability, while others concentrate on symptomatic OA, whose prevalence is considerably lower[4].

In the hand, the distal and proximal interphalangeal (DIP and PIP) joints, as well as the trapeziometacarpal (TMC) joints, are most often affected by OA. Symmetrical localisation in the same joints of the two hands is often seen, as well as clustering by row (DIP or PIP joints) and by ray (finger)[5, 6]. Radiographically proven hand OA is most prevalent in the DIP joints (35 - 54%), followed by the TMC joints (7 - 21%), and the PIP joints (8 - 18%)[4, 7, 8]. Both hand and TMC OA occur more frequently in women and their prevalence increases significantly with age[4, 7, 8].

In the 60-70 age group, prevalence rates of radiographically proven TMC OA are between 24%[7] and 57%[9] and increase up to 91% in people over the age of 80[7, 9]. In contrast to radiographic TMC OA, only 2.9% of women in a population older than 60 years report symptoms at the thumb base[10].

Aetiology

Hand OA has a multifactorial aetiology, and can be considered the product of an interplay between systemic and local risk factors[11]. Age seems to be the most important determinant[1, 3, 12, 13]. Furthermore, family disposition plays a major role, with genetic factors contributing up to 59% of the variance of risk for developing hand OA[1, 12, 14]. Recent studies further suggest an association of hand OA with obesity, repetitive joint use, bone mineral density, a history of hand injury, joint laxity, and generalised OA[1-3, 8, 12, 13, 15]. As men have a significantly lower risk of 0.81 for hand OA than women[16], the role of hormones in postmenopausal women has been discussed with conflicting conclusions[12].

Diagnostic and classification criteria

There are no uniform criteria for the diagnosis and classification of hand OA[13]. The American College of Rheumatology (ACR) Committee on Diagnostic and Therapeutic Criteria defined and validated the system most frequently used for the classification of hand OA (Box 1)[17].

These classification criteria are intended to select the clinical features which identify those with hand OA and which separate them from patients without hand OA. This set of criteria has a sensitivity of 94% and a specificity of 87%[17]. It is useful for the classification of hand OA as a single entity for study purposes but it is not intended for use in the diagnosis of an individual patient[3, 17].

For the diagnosis of hand OA, the European League Against Rheumatism (EULAR) published ten key recommendations based on research evidence and expert consensus (Box 2)[15]. They are intended to assist clinicians in diagnosing hand OA but, unlike the ACR classification criteria, not to classify hand OA for research[15].

Box 1 The American College of Rheumatology (ACR) classification criteria for osteoarthritis of the hand[17]

Hand pain, aching, or stiffness AND 3 or 4 of the following features:
- Hard tissue enlargement of 2 or more of 10 selected joints*
- Hard tissue enlargement of 2 or more distal interphalangeal (DIP) joints
- Fewer than 3 swollen metacarpophalangeal (MCP) joints
- Deformity of at least 1 of 10 selected joints

* The 10 selected joints are the 2nd and 3rd DIP, the 2nd and 3rd PIP, and the TMC joints of both hands

Box 2 Summary of recommendations for the diagnosis of hand OA, as defined by the EULAR[15]

- Consider risk factors.
- With typical symptoms (pain, stiffness, intermittent symptoms, and characteristic sites) a diagnosis can be made in adults aged over 40.
- Clinical hallmarks of hand OA are Heberden and Bouchard nodes and / or bony enlargement.
- Functional impairment in hand OA may be as severe as in rheumatoid arthritis.
- Patients with polyarticular hand OA are at increased risk of knee OA, hip OA and generalised OA.
- Recognised subsets with different risk factors, associations, and outcomes include interphalangeal joint OA, thumb base OA, and erosive OA.
- Erosive hand OA has specific characteristics.
- The differential diagnosis for hand OA is wide. Consider psoriatic arthritis, rheumatoid arthritis, gout, and haemochromatosis.
- Plain radiographs provide the gold standard for morphological assessment of hand OA.
- Blood tests are not required for diagnosis of hand OA but may be required to exclude coexistent disease.

Clinically, hand OA presents with pain, stiffness, reduced hand function, and restriction of movement[18, 19]. Other symptoms include crepitus, joint deformity, or joint swelling leading to patients being dissatisfied with the appearance of their hands (Figure 1)[18, 20, 21]. In addition to the history and clinical examination, the diagnosis of hand OA is often confirmed on radiography[15].

Thumb base OA

Osteoarthritis at the base of the thumb occurs as a result of degenerative changes in the TMC joint. It may be associated with generalised osteoarthritis or it may rarely arise as a consequence of trauma or injury[22]. In the osteoarthritic TMC joint, the joint space width is decreased because of a reduction in cartilage thickness as well as a loss of bone stock[23]. Furthermore, the scaphoid-metacarpal distance is reduced by a combination of subluxation, ligament laxity, and loss of cartilage or even trapezium bone[23].

Patients affected by TMC OA usually complain of pain at the base of the thumb with some distal and proximal radiation, thumb weakness, and crepitus at the thumb base[18, 19, 22]. They

Figure 1 Hand OA with swollen PIP and DIP joints and a thumb adduction contracture

typically report difficulties or pain during pinch related activities such as writing or grasping small objects[22]. Clinically, there is often a dorso-radial subluxation and / or an adduction contracture (Figure 1), preventing the patient flattening the hand[18]. Subluxation and laxity of the joint are present in the early stages of the disease, while the joint becomes stiff in the later stages[24]. In order to compensate for the limited flexibility of a stiff and adducted thumb, hyperextension of the metacarpophalangeal (MCP) joint, known as Z-deformity, is often seen (Figure 2)[24, 25]. This compensatory mechanism allows the patient to abduct the thumb far enough to grasp large objects[24].

Two specific clinical tests for OA at the TMC joint are the axial grind test and the traction-shift test[26]. For the grind test, the examiner rotates the metacarpal bone under axial compression in the direction of the trapezium[20, 24]. The traction-shift test provokes subluxation and subsequent relocation of the TMC joint through alternated dorsal and palmar pressure at the base of the metacarpal bone under traction. Both tests are positive when the procedure elicits pain[22, 26]. However, the traction-shift test shows greater sensitivity and specificity than the grind test[26].

If TMC OA is suspected, physicians usually confirm the diagnosis by plain radiographs (Figure 2)[22]. In the literature, staging of radiographically proven TMC OA according to Eaton[27] is very common, although its inter-rater reliability remains questionable[28]. Looking at the radiograph, the examiner should also consider the scaphotrapeziotrapezoid joint, because symptoms may also originate from this site[22].

Figure 2 Radiograph of the right hand showing a TMC OA grade IV according to Eaton and a Z-deformity of the MCP joint.

PATIENTS' LIMITATIONS IN DAILY LIFE

A comprehensive framework to describe functioning and disability is the International Classification of Functioning, Disability and Health (ICF)[29]. The ICF defines functioning as a complex interplay between the health domains of body functions and structures, activities and participation, personal factors, and environmental factors[29]. Hand OA leads to considerable functional consequences, which can be allocated to the first two domains and are influenced by personal and environmental factors[19, 30].

Patients affected by hand OA usually report significant restrictions in their daily life. Pain combined with reduced finger joint mobility and decreased grip strength forces the patient to reduce his daily hand-related activities or even to avoid special tasks. The most commonly described difficult tasks are wringing out washcloths, and opening jars and bottles[19]. In a population of more than 2,000 US people older than 60 years, 38% of the persons with symptomatic hand OA report difficulties with carrying an object of approximately 4.5kg. Dressing and eating was difficult for 23% and 14% of these people, respectively[10]. Furthermore, patients complain about aesthetic aspects of their hands[3, 20, 21]. Overall, hand OA leads to a considerable reduction of health-related quality of life[3, 21, 31].

Osteoarthritis at the thumb base causes substantially more pain and disability than OA of the PIP or DIP joints, which has been shown in a population of 308 patients with OA at different joints of the hand[32]. If a patient suffers from TMC OA, both pinch related activities and grasping large objects exacerbate pain[22, 24]. Typically, writing, moving small objects, turning keys in locks, and unscrewing jar tops, are most uncomfortable for the patient[22, 24].

A particular issue in daily life is the opening of different kind of packaging. Rahman et al.[33] evaluated the forces applied to different household containers by healthy elderly persons. Their results show that people found it most difficult to apply force to a small medicine bottle requiring push-down and rotational movements[33]. An analysis of a Dutch web-based medicine reporting system, where individuals can report their experience with medicine anonymously, revealed that 10% of the reports concerned the package of the drug[34]. Primarily, patients complained about difficulties in opening the package, such as blister packs or bottles[34].

Another relevant issue is the opening of food containers. Up to 90% of people older than 60 years experience difficulties opening peelable packaging, such as cheese / meat packaging or are even unable to do so[35]. In particular, patients with hand disorders have problems in opening food containers due to pain, loss of grip strength, and reduced dexterity[36-38]. Due to the ageing society, the number of people with hand conditions and thus difficulties opening packaging will rise correspondingly. Packaging of the future should therefore be developed according to the needs of the consumers[39].

MANAGEMENT OF HAND OA AND TMC OA

Management of hand OA

Treatment options for patients with hand OA include pharmacological, non-pharmacological, and surgical procedures[1, 40, 41]. As hand OA is heterogeneous regarding its clinical and radiological presentation, the treatment strategy has to be considered for each patient individually[1]. There are various therapeutic approaches, depending on the site of OA, the degree of pain and disability, and the patient's expectations[1]. The EULAR developed eleven recommendations for the management of hand OA (Box 3)[42].

Because of the considerable and diverse functional consequences of hand OA, multidisciplinary and multidimensional rehabilitation programmes have been proposed[19, 43]. However, there is no

Box 3 Summary of recommendations for the management of hand OA defined by the EULAR[42]

- Individual combination of non-pharmacological and pharmacological treatment.
- Treatment according to the individual clinical presentation and patient characteristics.
- Joint protection education and exercises.
- Heat and ultrasound are beneficial.
- Orthoses for TMC OA are recommended.
- Local treatment is to be preferred over systemic treatment.
- Paracetamol is the oral analgesic of first choice.
- Oral non-steroidal anti-inflammatory drugs (NSAIDs) should be used at the lowest effective dose and for the shortest duration.
- Symptomatic slow acting drugs for osteoarthritis (SYSADOAs) may give symptomatic benefit.
- Intra-articular injection of long-acting corticosteroid is effective.
- Surgery is effective for severe TMC OA and should be considered when conservative treatment has failed.

evidence about the effectiveness of a non-pharmacological treatment programme in the short term[44], as can be seen, for example, in patients with rheumatoid arthritis[45, 46].

Conservative management of TMC OA

For TMC OA, treatment strategies consist of either conservative or surgical management, with corticosteroid injections, splinting, and resection arthroplasty being the most popular interventions[47].

Conservative management includes injections, splinting, hand exercises, activity modification, acupuncture, heat, electrotherapy, and analgesics[22, 48].

In a survey among more than 1100 American hand surgeons, 89% of the responders reported preferring corticosteroid injections in the conservative treatment of TMC OA, while the rest use hyaluronic acid or do not usually give injections[47]. Other healthcare providers involved in the conservative management of TMC OA are physiotherapists and occupational therapists. In contrast to surgeons, they use a range of treatment strategies with no predominant methods[48]. Splinting, exercise therapy, and advice on activities of daily living are the most commonly used treatment modalities[48].

Corticosteroid injections can significantly reduce pain in the short term, with a single injection being effective for about 4 weeks to 6 months[49-52]. It has also been shown that patients with early stages of TMC OA (Eaton stage I or II) reported longer symptom improvement (median 17 weeks) compared with patients in stage III or IV (median 4 weeks)[52].

If therapists decide to splint the thumb, there are two possible types of orthosis for patients with TMC OA: a soft neoprene splint or a custom-made rigid thermoplastic orthosis (Figure 3). There is evidence that both types decrease pain and improve hand function, with the soft neoprene splint being more comfortable for the patients[53-55].

Exercise therapy includes exercises to strengthen the intrinsic thenar and extrinsic thumb muscles in order to improve joint stability[22]. Stretching of the first web space may help to prevent an adduction contracture[22]. Exercise therapy seems to have only a minor effect on pain and hand function, although it might increase grip strength in patients with TMC OA for a short time[53, 54, 56]. In the long-term, however, pain relief from various conservative treatment strategies (drug therapy, physiotherapy, orthoses, and corticosteroid injections) has not been observed[57]. Since evidence for the long-term effectiveness of conservative management is limited, Damen et al. suggested operating on the patient, especially in cases where pain is limiting the patient's daily activities[57].

Surgical management of TMC OA

Surgical treatment options include trapeziectomy alone or in combination with ligament reconstruction (LR), tendon interposition (TI), or both (LRTI). Other surgical treatments are arthrodesis of the TMC joint, implant arthroplasty, arthroscopic or open debridement of the TMC joint, metacarpal osteotomy, and partial trapeziectomy with or without interposition[47, 58].

Trapezium resection with LRTI was the primary choice for 62 - 68% of American hand surgeons who had performed surgery[47, 58]. Evidence about the superiority of one procedure over another in terms of pain reduction and restoration of hand function is, however, limited[59-61]. Some studies suggest that trapeziectomy alone results in fewer adverse events than trapeziectomy with LRTI[59-61]. Whether LRTI produces better long-term outcomes because of the preserved scaphoid-metacarpal distance has still to be confirmed[61].

Figure 3 Soft neoprene splint (left) and rigid custom made TMC splint (right)

The hand surgeons in the Schulthess Clinic (Zurich, Switzerland) primarily perform the LRTI according to the description of Epping[62] or Weilby[63] using the flexor carpi radialis (FCR) tendon as interpositional material (Figure 4):

Both surgical techniques start with a curved incision over the radial aspect of the wrist using a modified Moberg technique. The branches of the superficial radial nerve are located and preserved. Using blunt dissection, the radial artery is identified in the fatty tissue between the tendons of the extensor pollicis brevis and extensor pollicis longus and protected as well. The wrist capsule is opened and the trapezium is removed, taking care to preserve the FCR tendon which runs deep to the bone. A second incision is made in the mid-forearm in the proximal course of the FCR tendon. The ulnar half of the tendon is released proximally and mobilised distally to its insertion on the base of the second metacarpal bone. Ligament reconstruction according to Epping is realised by pulling the FCR tendon strip through a channel drilled at the base of the first metacarpal bone. After pulling it tight, the tendon slip is blocked with a trapezium fragment and sutured at the metacarpal base. Using the Weilby technique, the FCR tendon strip is wound around the abductor pollicis longus (APL) tendon and fixed in the remaining portion of the FCR tendon. Finally, in both techniques, the tendon is rolled up and placed in the gap remaining between the distal part of the scaphoid and the first metacarpal

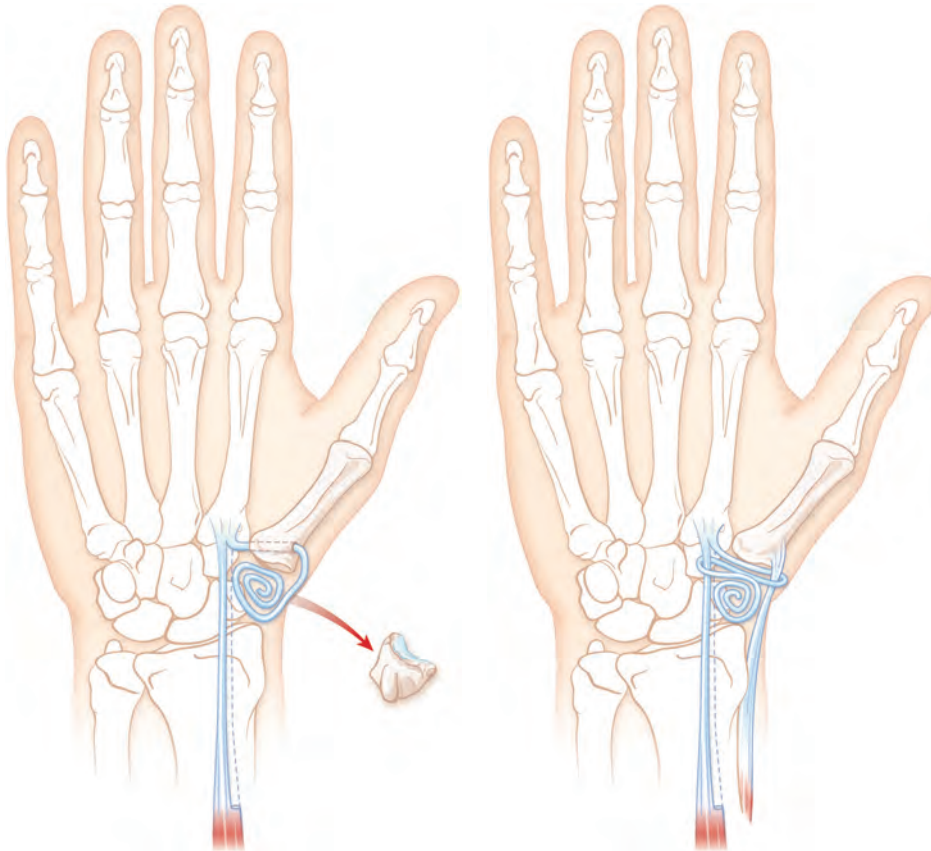

Figure 4 Trapeziectomy with ligament reconstruction and tendon interposition, according to Epping (left) and Weilby (right)

bone. The wrist capsule is closed with interrupted absorbable sutures and wound closure is accomplished using an intracutaneous running suture.

After surgery, all patients follow a standardised rehabilitation protocol consisting of specific instructions, splinting, and hand therapy.

OUTCOME MEASURES FOR PATIENTS WITH HAND OA

Standardised and validated outcome measures are essential to monitor the disease process and to evaluate its outcome[13]. Nowadays, it is not only patients and healthcare professionals who are interested in outcomes, but also hospital managers, lawyers, policy-makers, and the media[64].

Several specific sets of outcome measures, known as core sets, are relevant for evaluating patients with hand OA. Based on the ICF, a comprehensive and a brief core set have been developed and validated in order to assess patients with any hand condition[65-68]. These two detailed and complex core sets are known mainly to therapists and are not widely implemented

in clinical practice. A simpler, more general core set of outcome measures for hip, knee, and hand OA was introduced at the Outcome Measures in Rheumatology (OMERACT) III conference. It comprises the assessment of pain, physical function, patient's global assessment, quality of life, and joint imaging[69]. These three core sets do not recommend specific outcome measures but rather areas that are relevant for patients with conditions affecting the hand[65-69]. The outcome measures that should be used for a comprehensive assessment of the disease status and treatment outcome in patients with hand OA have not yet been defined[64].

There are several ways to categorise outcome measures. Categories can be based on the ICF domains or OMERACT dimensions, on the body region, or on the type of outcome measure. Different types of outcome measure include clinical tests, imaging, performance tests, and patient-reported outcome measures (PROMs).

Clinical tests are the traditional way of evaluating hand function and include the assessment of grip strength and joint range of motion, which provides an objective analysis of the disease status[70].

Radiographs are reviewed to determine the stage of osteoarthritis in the affected joint and comorbidities of other joints which might influence the patient's complaints[22]. The Kellgren-Lawrence score, a grading system for OA of any joint, is widely used for staging hand OA[71]. Eaton and Littler developed a specific staging system for TMC OA[27]. While the Kellgren-Lawrence score shows good reliability[72, 73], the inter-rater reliability of the Eaton classification remains questionable[28].

Performance tests ask the patient to carry out standardised tasks similar to those of everyday daily life. Most tests use the time taken to complete the task as an outcome measure. Examples include the Arthritis Hand Function Test[74], the Jebsen Hand Function Test[75], and the Purdue Pegboard Test[76]. However, there is a lack of evidence with respect to the extent to which these tests provide methodologically sound measurement properties[64].

The methods mentioned above do not take into account any subjective evaluation based on the patient's self-assessment of pain, activities of daily living (ADLs), and the ability to return to a previous occupation. In recent years, therefore, subjective evaluations have emerged as increasingly important outcome measures in hand surgery[70].

PROMs comprise single questions or questionnaires, in which patients rate their pain, hand function, limitations in ADLs and participation, as well as their quality of life. Different PROMs for patients with hand disorders have been reviewed in the literature[13, 64, 70, 77-82]. However, there is no consensus on tools most appropriate for assessing activity limitations and participation restrictions from the patient`s perspective[64].

For TMC OA, Angst et al. proposed a core set to assess outcomes after resection interposition arthroplasty[83]. It consists of the Short Form 36 (SF-36), the Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH) or the Patient-Rated Wrist Evaluation (PRWE), and a customised form including assessment of range of motion, strength, and other clinical tests. Although showing good construct validity in this particular study, the reliability of the customised form and the responsiveness of the whole set have not been investigated. An overview of the PROMs validated for patients with either hand OA or TMC OA is given in table 1.

Table 1 Overview of patient-reported outcome measures (PROMs) used for assessing patients with hand OA and TMC OA

Questionnaire	Specific for	Content	Validation studies available for hand OA	Validation studies available for TMC OA
AUSCAN[84] Australian / Canadian Osteoarthritis Hand Index	Hand OA	15 items divided into 3 subscales: pain, stiffness, and hand function	✓ 85-88	✓ 89
FIHOA[90] Functional Index for Hand Osteoarthritis	Hand OA	10 items about ADLs	✓ 88, 90, 91	✓ 90*
MHQ[92] Michigan Hand Outcomes Questionnaire	Hand disorders	37 items divided into 6 subscales: hand function, ADLs, pain, work performance, aesthetics, and satisfaction with hand function; gives scores for each hand separately	✓ 93-95*	
Brief MHQ[96] Brief Michigan Hand Outcomes Questionnaire	Hand disorders	12 items including pain, function, ADLs, work, aesthetics, and satisfaction		✓ 96*
PEM[80] Patient Evaluation Measure	Hand disorders	18 items divided into 3 parts: Process of treatment, hand function and pain, and overall assessment	✓ 94*	
SACRAH[97] Score for the Assessment and Quantification of Chronic Rheumatic Affections of the Hand	Rheumatic hand disorders	23 items divided into 3 subscales: hand function, stiffness, and pain	✓ 97-99	
Cochin scale[100]	Rheumatic hand disorders	18 items about ADLs	✓ 101	
PRWE[102] Patient-Rated Wrist Evaluation	Hand / wrist disorders	15 items divided into 2 parts: pain and hand function	✓ 89, 103, 104	✓ 83, 89, 105
DASH[106] Disabilities of the Arm, Shoulder and Hand Questionnaire	Upper extremity disorders	30 items including pain and hand function	✓ 94, 103, 104*	✓ 83, 89, 107
quickDASH[108] quick Disabilities of the Arm, Shoulder and Hand Questionnaire	Upper extremity disorders	11 items including pain and hand function	✓ 104, 109*	✓ 110

* Only part of the study population consists of patients with hand OA or TMC OA

THE CONCEPT OF PATIENT SATISFACTION

The evaluation of patient satisfaction is becoming more and more important in the assessment of treatment outcome. Satisfied patients show increased treatment compliance and are more likely to return to the same healthcare provider[80, 111].

Patient satisfaction is a complex construct. It is a very individual experience and linked to specific personal characteristics and specific situations that makes the rating of each patient unique[80]. Weaver et al. defined treatment satisfaction as *"a recipient's rating of or report on salient aspects of the process and the results of his or her treatment experience according to predetermined criteria"*[112]. It can be regarded as a cognitive evaluation or an emotional response to a given situation[80].

Quantifying satisfaction is demanding because of the influence of a variety of, so far, poorly defined factors on the patient`s perception of a satisfactory outcome[80, 113]. There are several dimensions which contribute to the individual perception of satisfaction (Figure 5). On the one hand they include aspects such as facilities, service features, continuity of care, humaneness, and competence, and on the other hand, the process and outcome of the treatment[80, 114]. Furthermore, patient satisfaction is influenced by specific personal characteristics comprising expectations, demographics, and personal preferences[115].

In the context of quality management, many healthcare institutions have already taken action to monitor patient satisfaction with respect to processes and services[113, 116]. Assessing treatment satisfaction has also become increasingly popular[113]. However, clinicians and

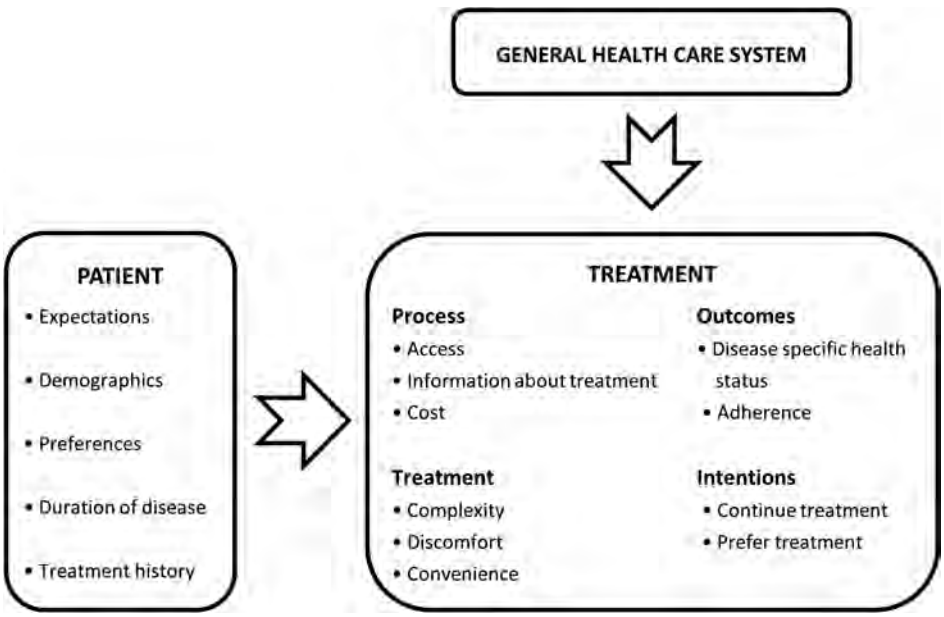

Figure 5 Concept of patient satisfaction (adapted from Revicky[115]). Satisfaction is determined by various factors pertaining to the patients themselves, the process, outcomes, treatment characteristics and intentions, as well as by the general health care system.

researchers are using several tools to evaluate treatment satisfaction, including various Likert scales and questionnaires of equivocal methodological quality, which precludes statistical comparisons of the different studies[113].

In hand surgery, studies have shown that objective parameters do not necessarily correlate with the patient's perception of treatment success. Several researchers have described the discrepancy between objective and subjective outcome assessments following orthopaedic interventions on the hand[117-119]. For example, Mandl et al. revealed that objectively quantified outcomes following metacarpophalangeal (MCP) arthroplasty are not necessarily associated with the subjective satisfaction of the patient[117]. In particular, strength as well as range of motion showed only low to moderate, non-significant correlation with patient satisfaction. MacDermid et al. support these results in that they found no significant correlation between strength, range of motion, radiographic findings, and patient satisfaction following joint arthroplasty in patients with TMC OA[118]. These findings emphasise the importance of assessing patient satisfaction instead of only objective outcomes and should encourage doctors to reconsider their primary outcome measure[113].

ECONOMIC ASPECTS OF HAND OA

The severe limitations in daily life faced by people with hand OA may also affect their working ability[38]. On average, employees with OA in any joint are absent from work for 20 days per year[120]. Patients with hand OA sometimes even have to take early retirement due to their hand problems[38]. With increasing retirement age, the issue of future employment restrictions for people with hand OA is likely to become more pronounced[38]. The relevance of costs associated with absence from work is substantiated by data from the Netherlands[121]. In patients with hand and wrist injuries, the costs of working days lost are considerably higher than the healthcare costs[121].

Patients with TMC OA may be off work due to the condition itself, but surgical intervention may also lead to relatively long sick leave. Following trapezium resection with tendon interposition, patients may be totally unable to work for some eight weeks (median, range 2 - 36), followed by a further eight weeks period with a working ability of only 50%[122].

Costs associated with loss of productivity and absenteeism, in combination with the direct healthcare expenses, have substantial economic consequences for the patient, the employer, and society[38, 121]. Direct medical costs for patients with generalised OA account for almost USD 13,000 annually[123]. It is therefore important to know the actual costs associated with hand OA and its related treatment. However, economic evaluations in orthopaedics and especially in hand surgery are scarce. The few economic studies published cover the treatment of Dupuytren's disease[124-126], hand and wrist injuries[121, 127], ganglia and trigger digits[126, 128]. Knowledge about the cost-utility of different treatment options for hand and TMC OA would assist the surgeon in choosing the best treatment for the patient, bearing in mind the economic consequences[129, 130].

Different methods are available to evaluate the economic effect of interventions. Cost-effectiveness analyses relate the costs of two (or more) interventions to the outcomes, such as death, complication rates, or a questionnaire score. They give a ratio of the difference in costs of the interventions divided by the difference in outcomes[131]. The cost-effectiveness analysis can be extended to a cost-utility analysis, where the costs are related to utility outcomes. The

result is usually expressed as quality-adjusted life-years (QALYs). The utilities are derived from quality of life questionnaires, such as the SF-36[132] or the EuroQol-5D (EQ-5D)[133]. The area under the curve with time leads to the number of QALYs[130, 131, 134].

Additionally, the incremental cost-utility ratio (ICER) is usually given as an outcome parameter in the comparison of two treatment strategies. It estimates the additional costs that must be invested to achieve one additional clinical benefit of the new treatment over the standard treatment[129, 131].

THE AIM OF THE THESIS

The aim of this thesis is to investigate patients´ limitations in daily life, outcome measures, clinical outcomes emphasising patient satisfaction, and economic aspects of the treatment of patients with hand OA, focussing on patients suffering from TMC OA.

This thesis is divided into two parts, each of three chapters.

Part ONE, comprising chapters two, three, and four, aims to describe patients' limitations in daily life in individuals with various hand disorders and relevant outcome measures for patients with TMC OA. **Chapter two** focuses on the particular problem of opening food containers and aims to develop guidelines for the industry on how to produce easy-to-open packaging. The objective of **chapter three** is to identify and compare the outcome measures that are currently used for patients with TMC OA. In **chapter four**, the measurement properties of a particular questionnaire, the MHQ, for the assessment of patients with TMC OA are evaluated.

Part TWO contains chapters five, six, and seven and describes the outcomes of surgical and non-surgical management in patients with TMC OA with respect to patient satisfaction and economic aspects. In order to gain knowledge about factors determining patient satisfaction, **chapter five** reviews such factors for patients after orthopaedic surgery on the hand. **Chapter six** analyses the outcome of surgical and conservative treatment of TMC OA with a focus on patient satisfaction. **Chapter seven** completes this thesis with an economic analysis of the conservative and surgical treatment of TMC OA with respect to healthcare costs and loss of productivity.

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CHAPTER **TWO**

PACKAGING - A PROBLEM FOR PATIENTS WITH HAND DISORDERS? A CROSS-SECTIONAL STUDY ON THE FORCES APPLIED TO PACKAGING TEAR TABS

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Miriam Marks
Carina Muoth
Jörg Goldhahn
Andrea Liebmann
Ina Schreib
Stephan F Schindele
Beat R Simmen
Thea PM Vliet Vlieland

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45. Jahreskongress der Schweizerischen Gesellschaft für Handchirurgie (SGH). Biel, Switzerland 2011



ABSTRACT

Introduction Patients with hand disorders frequently experience difficulties opening peelable packaging.

Purpose To investigate the forces patients can apply to tear tabs and to compare the results with normative data to make recommendations for the industry and clinical practice.

Study design Descriptive, cross-sectional.

Methods One hundred patients with hand disorders were studied. The pinch pull force (PPF) applied to tear tabs of different lengths and materials (aluminum, plastic) was measured with a specially designed device. Key pinch was measured with a pinch gauge. Normative data were taken from another study on 402 healthy adults.

Results Patients were able to apply most force to the longest aluminum tab, using the key grip, but this was only 53% of the force exerted by healthy people. Key pinch determines PPF ($R^2 = 0.548$, $p \leq 0.001$).

Conclusions Manufacturers should provide long aluminum tear tabs. Health professionals are encouraged to measure key pinch to detect difficulties in opening packages.

Level of Evidence Level IV.

INTRODUCTION

Many consumers experience difficulties in opening packaging but these are most apparent in elderly and disabled people[1]. People older than 65 often suffer from hand disorders such as osteoarthritis, which is prevalent in up to 76% of this population[2]. Taking symptoms such as pain, loss of grip strength, and reduced dexterity into account[2-5], it can be assumed that many consumers have difficulties in opening packaging[6].

Rahman et al.[7] evaluated the forces healthy elderly people needed to open different household containers such as medicine bottles, an aerosol can of air freshener, a trigger pump spray bottle, and a dual-pinch safety squeeze bottle. Their results show that the last of these required the highest force to open it, although many participants commented on its ease of use[7]. The Department of Trade and Industry (DTI) in the United Kingdom also investigated the forces people are able to generate onto peelable packaging such as cheese or ham containers[8]. Using three different tab lengths, the researchers measured pull strength using either the key or the tip-to-tip pinch grip and determined that the force applied by people with dexterity problems was only about half that of healthy people[8].

Although there is awareness of the issue of package opening, there is a lack of information on how much force patients with hand disorders are actually able to apply to packaging. Data about grip strength for both healthy people[9] and patients[10, 11] have been published in the medical literature, but these data are not much use to the industry because they do not consider different opening techniques, tab size, or tab material, which determine the friction force between the skin and the tear tab[1, 12].

PURPOSE

The objectives of this study were to investigate the forces that patients with hand disorders are able to generate onto different tear tabs, to compare the results obtained with normative data, and to identify the difficulties in opening different types of packaging, to make recommendations on packaging design to the industry. A further aim was to study the correlation between forces applied to a 14mm long plastic tear tab and clinical measurements to suggest relevant outcome measures in clinical practice.

METHODS

Patients

Between September 2010 and November 2010, patients with hand problems who consulted a hand surgeon or an occupational therapist at the Schulthess Klinik in Zurich, Switzerland, were consecutively enrolled in this cross-sectional study. Inclusion criteria were a disorder of the dominant hand leading to meaningful restrictions in daily life, age ≥ 16 years, and written informed consent. Patients were excluded if they had undergone surgery within the last three months, had a cardiac pacemaker fitted, or were unable to understand German. The full study protocol was approved by the local ethics committee.

Assessments

Pinch Pull Force

To measure the forces people are able to generate onto different kind of tear tabs, the Fraunhofer Application Center for Processing Machinery and Packaging Technology (AVV, Dresden, Germany) developed the Pinch Pull Force Tester (PPF tester), a technical device containing a force gauge, which simulates packaging (Figure 1)[12]. Tear tabs of different sizes and materials were inserted into this device to measure the force with which the patient was able to pull these tabs, that is the pinch pull force (PPF). Tear tabs made of aluminum and plastic were available in three different lengths: 7, 14 , and 21mm (Figure 2). The patients washed their hands to prevent the tear tabs slipping because of sweat or body lotion, and performed the following test procedure in a standardized sitting position. First, they pulled the 7mm plastic tab once with the tip-to-tip pinch, then once using the key (lateral) pinch grip on the same tab. Next, the 7mm aluminum tab was inserted and the patients were asked to pull again, first with the tip-to-tip and then with the key grip. The next tab in size was then inserted and the patients repeated the process. Because of the software calibration, all patients followed exactly the same sequence, resulting in a total of 12 measurements for each patient. There was a recovery time of about 30 seconds during the tab changes. Each tab was discarded after use and a new one provided for the next participant. Patients were instructed to pull the tear tab straight up with their dominant hand, as hard as they could. They were not allowed to support the tearing hand on the device, for example, by rolling it over the top of the tester while using the key grip. The other hand was used to hold the device in place. Patients who were not sure about their handedness used the hand normally used for opening packaging.

Difficulties in package opening

A questionnaire containing pictures of eight widely used packagings with different opening mechanisms was given to the patients. They were asked to indicate whether they experienced difficulties in daily life in opening the following: meat/cheese packaging (peelable packaging), a bottle (screw cap), a coffee packet (peelable), a jam jar (screw lid), cereals (peelable), a yoghurt cup (peelable), a beverage can with a ring pull, and a plastic-wrapped package to be opened with a pull strip (Figure 3). Difficulties were defined as discomfort during opening and/or needing an assistive device and/or being unable to open it at all.

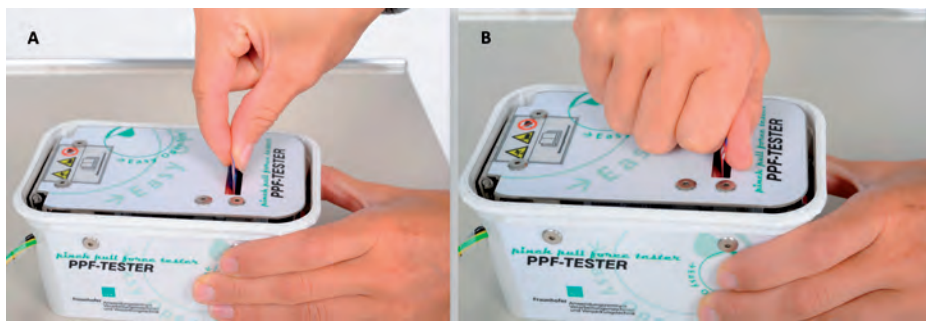

Figure 1 Pinch Pull Force tester with a 7mm tear tab inserted. (A) Tip-to-tip grip. **(B)** Key grip.

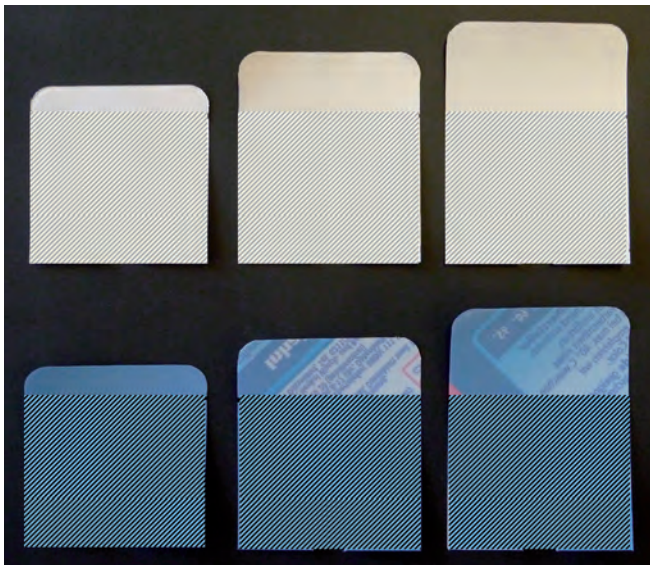

Figure 2 Tear tabs made of aluminum (above) and plastic (below). The shaded part of the tab is inserted into the Pinch Pull Force tester. Patients pull on the protruding end, which is 7, 14, or 21mm long.

Figure 3 Pictures of the different packagings that were given to the patients. **(A)** Meat/cheese (peelable), **(B)** bottle (screw cap), **(C)** coffee (peelable), **(D)** jam jar (screw lid), **(E)** cereals (peelable), **(F)** yoghurt cup (peelable), **(G)** beverage can with a ring pull, and **(H)** plastic-wrapped package with a pull strip.

Clinical measurements

Key and tip-to-tip pinch maximal strengths were measured with the help of a digital pinch gauge (E-LINK, Biometrics Ltd, Gwent, UK) in a standardized sitting position[13]. Three trials were conducted for each grip, and the average value was calculated.

The range of motion of thumb opposition was quantified according to the Kapandji index. This score ranges from 1 to 10, with a higher score indicating better opposition[14].

To assess subjective function, patients filled out the Patient Evaluation Measure (PEM), a simple, reliable, and validated questionnaire for assessing outcomes in patients with hand disorders[15-17]. It has been translated into German according to the guidelines of Beaton et al.[18]. Only the second part, consisting of ten items about hand function, was used in this study. The total score ranges from 10 to 70, with lower scores indicating better hand function. Besides looking at the total PEM score, questions no. 3 (hand pain) and no. 6 (grip strength) were analyzed in more detail.

Patients filled out a German version of the EuroQoL 5D (EQ5D) to assess their quality of life[19, 20].

Normative data

The AVV recorded normative data from 402 healthy adults aged between 20 and 80 years, with a mean age of 53.8 years (standard deviation [SD] 19.2), using the same PPF tester and test procedure[21]. All raw data were made available for statistical analyses.

Statistics

Continuous data were analyzed using descriptive statistics with mean and SD. Normal distribution was confirmed by means of the Kolmogorov-Smirnov test and Q-Q plots. To achieve greater statistical power, nonparametric tests were used instead of parametric ones. The Friedmann test was used to test for significant differences between the different tear tab sizes and the Wilcoxon signed-rank test for differences between the two materials.

Guidelines for packaging manufacturers recommend that 95% of the consumer population should be able to handle the products effectively[21-24]. Though the consumer population includes stronger males and weaker females, and younger and older people, use of the 95th percentile of the weakest target group is recommended. The threshold for healthy people was therefore calculated using the 95th percentile of elderly females (≥ 60 years). The threshold for the patient population was calculated using the 80th percentile of all females. This excluded patients with the most severe hand problems, as they cannot be expected to be able to open difficult kinds of packaging.

As there was good correlation between the forces exerted on the different kinds of tear tab ($r = 0.57 - 0.92$), the following analyses were performed only with the 14mm long plastic tear tab, using the key grip, as this tab is very commonly used for meat or cheese packaging in European countries. Differences between normative values and the patients' data were analyzed with the help of the Mann-Whitney U test. Spearman's correlation coefficient was used to test for correlation between the PPF and clinical outcomes. All variables showing a significant coefficient of correlation with PPF ($r \geq 0.5$) were entered into a linear regression model with PPF using the key grip on the 14mm plastic tab as the dependent variable.

The analyses were done with SPSS 18.0 (www.spss.com) and R 2.12.0 (www.r-project.org). The level of significance was set at $p \leq 0.05$.

RESULTS

One hundred one consecutive patients with different hand disorders were recruited and gave their informed consent. One patient withdrew because of pain during the measurements, leaving complete data from 100 patients. The mean age of the 71 female and 29 male patients was 61 years (SD ± 12.7). Patients with different diagnoses were included; osteoarthritis of the hand and carpal tunnel syndrome were the most common (Table 1, Figure 4).

Table 1 Characteristics of 100 patients with hand disorders

	Total number	Mean (Standard Deviation)
Patients	100	
Sex (females/males)	71/29	
Age (yr)		61.0 (12.7)
<20	1	
20-30	2	
31-40	3	
41-50	6	
51-60	33	
61-70	33	
71-80	20	
>80	2	
Key/lateral pinch strength (kg)		4.6 (2.2)
Tip-to-tip pinch strength (kg)		2.6 (1.4)
Kapandji Score (0-10)		8.7 (1.4)
EuroQoL 5D (0-1)		0.7 (0.2)
Patient Evaluation Measure (10-70)		29.9 (13.8)

Pinch Pull Force

Comparisons between the different tear tab sizes and materials showed a number of significant differences: patients could apply more force to aluminum tear tabs than to plastic ones ($p \leq 0.001$). The longer the tab, the larger the force applied ($p \leq 0.001$). Furthermore, using the key grip rather than the tip-to-tip grip resulted in significantly higher force values for all tabs ($p \leq 0.05$), except for the 7mm aluminum tab ($p = 0.064$). Data from healthy people followed the same pattern.

The threshold forces that 80% of female patients could apply to the different tear tabs are given in table 2. For the 14mm long plastic tab using the key grip, for example, this threshold is 8N, whereas the 95% threshold for healthy people, calculated from the data of 91 females with an average age of 71.5 years, is 10.5N.

When compared with normative data for all tear tabs, patients are able to apply only 53.1% of the force that healthy persons can manage. Further comparisons stratified by material, tear tab size, and grip technique, show significant differences for the 14mm long plastic tab in all age groups (Figure 5).

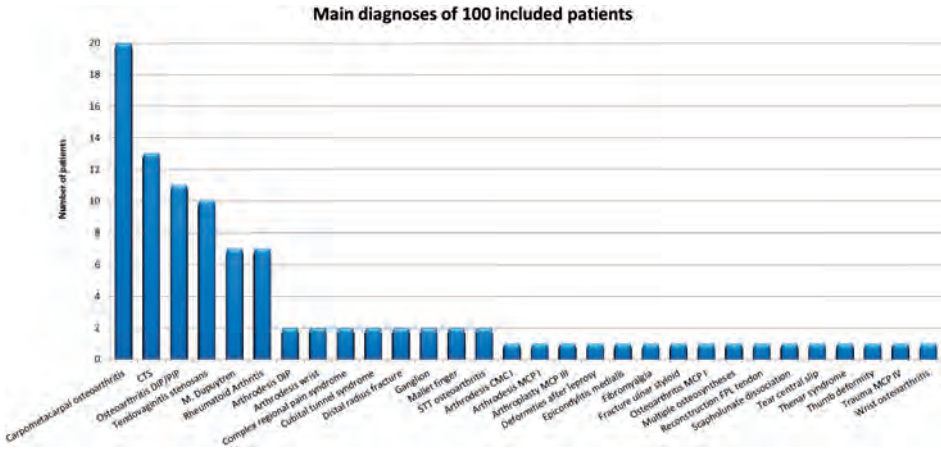

Figure 4 Frequency of diagnoses of the patient population. CTS = carpal tunnel syndrome; DIP = distal interphalangeal joint; PIP = proximal interphalangeal joint; STT = scaphotrapezial-trapezoid joint; CMC = carpometacarpal joint; MCP = metacarpophalangeal joint; FPL = flexor pollicis longus

Difficulties in package opening

Patients indicated five (median) out of the eight packaging types as causing difficulties (range 0-8). When asked about difficulties with different types of packaging, 82% of the patients mentioned jam jars, 78% peelable meat/cheese packaging, 69% bottles, 68% peelable coffee containers, and 62% peelable cereal packs (Figure 6).

Clinical measurements

The results of both pinch gauge measurements correlate well with those for the 14mm plastic tear tab (Table 3). Furthermore, good correlation was seen between the PEM total score and question 3, and with question 6. Moderate but significant correlation was seen between the EQ5D and key pinch strength, and between the two questionnaires. Only poor correlation was found between opposition of the thumb or the subjective grip of the patient (PEM question 6)

Table 2 80th percentile of the force that female patients could apply to different tear tab sizes and materials using either the tip-to-tip or the key grip

		7mm	14mm	21mm	p-Value
Material	**Grip**	**80th Percentile**	**80th Percentile**	**80th Percentile**	**Tab Size**
Aluminum	Tip-to-Tip	7.0N	8.1N	9.3N	≤ 0.001
Plastic	Tip-to-Tip	3.6N	5.4N	6.4N	≤ 0.001
p-Value Material	-	≤ 0.001	≤ 0.001	≤ 0.001	
Aluminum	Key	7.9N	10.4N	14.9N	≤ 0.001
Plastic	Key	4.6N	8.0N	9.2N	≤ 0.001
p-Value Material	-	≤ 0.001	≤ 0.001	≤ 0.001	

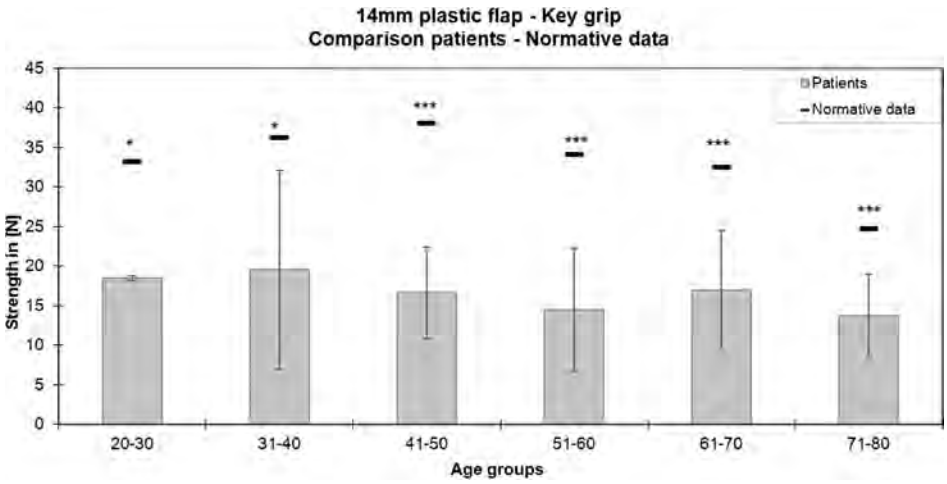

Figure 5 Mean values and standard deviation of the key pinch pull strength at the 14mm plastic tear tab for 100 patients compared with normative data stratified by age group. *p ≤ 0.05; ***p ≤ 0.001

and the 14mm plastic tear tab, and the key pinch strength. Entering key and tip-to-tip pinch strength values into a linear regression model showed that this model significantly determined the force on the 14mm plastic tear tab pulled with the key grip, and explained more than half of the variance (R^2 = 0.557, p ≤ 0.001). Entering only one variable into the model still resulted in R^2 = 0.548 (p ≤ 0.001) for key pinch and R^2 = 0.496 (p ≤ 0.001) for tip-to-tip pinch.

DISCUSSION

The results of this study investigating the forces that patients with hand disorders can generate onto different tear tabs showed that patients are able to apply the greatest force on the longest

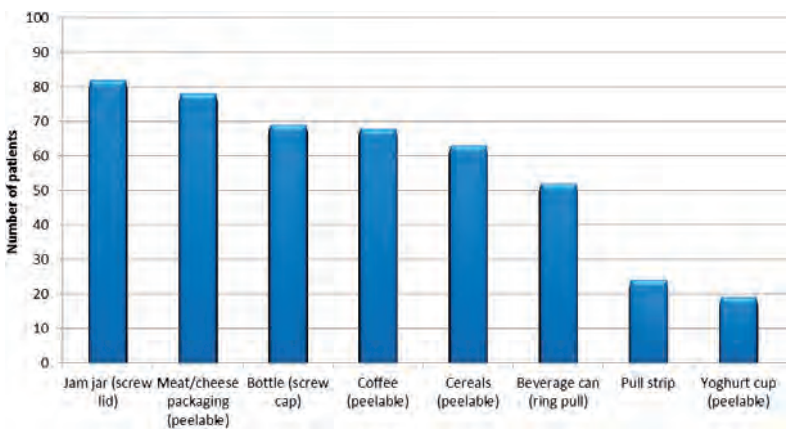

Figure 6 Number of patients having difficulties in opening different kinds of packaging in daily life

Table 3 Spearman's correlation coefficients for clinical measures and PPF of 100 patients with hand disorders

	PPF 14mm Plastic Tear Tab Key Grip	**PG Key Grip**	**PG Tip- to-Tip**	**Thumb Opposition**	**Age**	**EQ5D**	**PEM**	**PEM 3 (Pain)**	**PEM 6 (Strength)**
PPF 14mm Plastic Tear Tab Key Grip	1	0.77***	0.80**	0.27**	-0.03	0.43***	-0.43***	-0.24*	-0.39***
PG Key Grip		1	0.91**	0.14	0.02	0.54***	-0.44***	-0.33***	-0.37***
PG Tip- to-Tip			1	0.14	0.43	0.49**	-0.42**	-0.27**	-0.41**
Opposition				1	0.1	0.13	-0.27**	-0.20*	-0.22*
Age					1	0.12	-0.14	-0.22*	-0.12
EQ5D						1	-0.58***	-0.47***	-0.43***
PEM							1	0.74***	0.76***
PEM 3 (Pain)								1	0.48***
PEM 6 (Strength)									1

PPF = Pinch Pull Force; PG = Pinch gauge; EQ5D = EuroQoL 5D; PEM = Patient Evaluation Measure; PEM 3 = Patient Evaluation Measure item 3; PEM 6 = Patient Evaluation Measure item 6
Correlationr ≥ 0.5 is marked in bold
*p ≤ 0.05; **p ≤ 0.001; ***p ≤ 0.001

aluminum tab using the key grip, but that this is no more than 53% of the force exerted by healthy people. Peelable packaging, such as the meat/cheese packaging illustrated, is considered to be among the most difficult to open.

Pinch Pull Force

The longer the tear tab, the more force patients can apply, which reflects the normative data from the AVV[21]. It is easier to use the key grip on a longer tab, and significantly more force can be exerted. (In the present study, two patients with rheumatoid arthritis were unable to use the key pinch on the 7mm long tear tabs because of their finger deformities.) Trials show that the use of the key grip is feasible with a tear tab length of 10mm or more[21]. Regarding the material, patients could apply more force to aluminum tear tabs than plastic ones. This is explained by greater friction between the skin and the material, which allows higher pull strength values than the plastic tear tab with its very smooth surface[21].

These results are in line with those obtained by the DTI, which conducted a trial with a similar experimental setup for both healthy and disabled people[8, 25]. The longer the tab, the larger was the force applied. Using the key grip also led to significantly higher PPF values than using the tip-to-tip grip in both disabled and healthy people. Eighty-eight percent of elderly healthy people were able to apply 10N to a 12mm long plastic tear tab, whereas only 69% of disabled people could exert 10N. These figures are lower than the results of the present study, which can be explained by the DTI using a tear tab that was 2mm shorter.

Difficulties in package opening

More than three-quarters of the patients considered meat/cheese packaging to be difficult to open. This proportion is significantly higher than that found in elderly people, of whom only 40-50% have

difficulties in opening peelable seals[6, 26]. This type of package causes considerable difficulties, with 9% of disabled people not being able to open it at all[1]. However, opening packaging requires more than just hand strength. Besides manual function, sensitivity as well as visual and cognitive aspects are important when opening consumer products[26]. Hand conditions not only result in reduced strength but in many cases are also accompanied by other restrictions that explain the great difficulties patients have in opening packaging. Furthermore, factors such as the visibility and simplicity of the opening mechanism play important roles in the ease of opening a package[1, 21].

Clinical measurements

Results show that pinch strength determines the level of force applied in PPF testing. Although not very high, the correlation of the PEM and EQ5D with strength indicates that PPF and the pinch grip are associated with subjective function and quality of life. This is supported by other studies, for example following distal radius fractures, where objectively measured strength correlated moderately well with patients' subjective satisfaction with their own strength[27].

Recommendations for the industry

Even small changes in the size of the tear tab, the material used, or its geometry have a large impact on the force needed to open the packaging[12, 21, 22, 25]. With respect to peelable packaging, the results of this study suggest that tabs should be at least 14mm long and made of a rough material, for example, aluminum. If a package with a 14mm long plastic flap can be opened with a force of 8N, 80% of patients with hand disorders will be able to open it successfully. Further aspects that need to be considered are good accessibility of the tear tab, its visibility (which can be improved by special coloring), and the simplicity of the opening mechanism with a clear description of how to use it, as well as uniform packaging for different products[21].

Although packaging is supposed to protect the contents and be sealed, manufacturers are encouraged to produce consumer-friendly packaging that will promote greater overall consumer satisfaction, not only among disabled people.

Recommendations for clinical practice

A specific PPF tester is not available in clinical practice. However, given that pinch grip correlated well with PPF, health professionals are encouraged to use the pinch gauge as an alternative assessment tool. As key pinch measurement shows favorable values in the regression model, this grip technique should be the evaluation tool of choice in clinical practice. If patients have low key pinch values, it can be assumed that they will have considerable difficulties in opening consumer products. Furthermore, health professionals should advise patients to use the key grip for peelable packaging to achieve more power.

Limitations

One limitation of the study is that the sequence of PPF measurements was the same for every patient because of the software used. Fatigue might therefore have caused lower values for the later measurements with the largest tab. The differences in values for the short and the long tabs might have been more pronounced had the measurement sequence been randomized.

The main limitation, however, is the imprecise inclusion criterion "hand disorder". Patients presenting with a variety of diagnoses were included, leading to a broad range of data and

therefore large SDs. Nevertheless, this study population closely resembles the population routinely consulting orthopedic secondary care hand surgeons. Further studies focusing on the difficulties of particular groups of patients, for example, those with rheumatoid arthritis, would yield more information about providing special containers and aids for these populations. In addition, it would be interesting to know more about the forces that patients can apply to real food containers. This is a question for further research.

CONCLUSIONS

Patients with hand disorders are able to apply most force to the longest aluminum tab using the key grip. When compared with normative data, patients are able to apply no more than 53% of the force exerted by healthy people. Among the most difficult packs to open are those with peelable packaging, such as are used for meat and cheese. Recommending the industry to produce peelable packaging with tabs that are at least 14mm long will allow customers to use the key grip. The tear tab should be made of a rough material, for example, aluminum. As the key pinch grip shows good correlation with PPF, health professionals are encouraged to use the pinch gauge as an outcome measure to detect relevant difficulties in package opening and hence quality of life.

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CHAPTER **THREE**

OUTCOME MEASURES AND THEIR MEASUREMENT PROPERTIES FOR TRAPEZIOMETACARPAL OSTEOARTHRITIS: A SYSTEMATIC LITERATURE REVIEW

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Miriam Marks
Jan W Schoones
Christoph Kolling
Daniel B Herren
Jörg Goldhahn
Thea PM Vliet Vlieland

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ABSTRACT

The objective was to identify all outcome measures used in studies on trapeziometacarpal osteoarthritis (TMC OA) and evaluate their measurement properties. In a two-step systematic literature review, we first identified studies including TMC OA patients and extracted all outcome measures. They were categorized according to the Outcome Measures in Rheumatology (OMERACT) core set for OA including five dimensions: pain, physical function, global assessment, imaging, and quality of life (QoL). Secondly, we retrieved articles on the measurement properties of the identified outcome measures for TMC OA patients. First, 316 articles including 101 different outcome measures were identified, addressing the OMERACT pain and function domains most frequently but under-representing QoL. Second, 12 articles investigating measurement properties of 12 outcome measures were identified. The methodological quality of these studies was poor to fair, implying that based on the literature no recommendations to use any of the outcome measures can yet be made.

INTRODUCTION

Numerous studies have evaluated conservative and surgical treatments for patients with trapeziometacarpal osteoarthritis (TMC OA), with both approaches generally found to be effective in reducing pain and increasing function[1-5]. Several specific sets of outcome measures, known as core sets, are considered relevant to the best way of measuring treatment outcomes for TMC OA. Angst et al.[6] proposed a core set to assess outcomes after resection interposition arthroplasty of the TMC joint; this consisted of the Short Form 36 (SF-36), Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) or the Patient-Rated Wrist Evaluation (PRWE), and a customized form including assessment of range of motion (ROM), strength, and other clinical tests. Although showing good construct validity in this particular study, the reliability of the customized form and responsiveness of the whole set have not been investigated.

Three other core sets are available; they do not recommend specific outcome measures but rather areas that are relevant for patients with conditions affecting the hand. Based on the International Classification of Functioning, Disability and Health (ICF), a comprehensive and brief core set have been developed and validated to assess patients with any hand condition[7-10]. These two detailed and complex core sets are known mainly to hand therapists and are not widely implemented in clinical practice. A simpler, more general core set of OA outcome measures (hip, knee, hand) was developed at the Outcome Measures in Rheumatology (OMERACT) III conference[11, 12]. It is intended to serve as an international standard for clinical trials. This set contains the domains 'pain', 'physical function', 'patient's global assessment', 'joint imaging', and 'quality of life (QoL)', but, like the ICF core set, it does not comprise specific outcome measures.

In research and daily practice, decisions for treatments are made, amongst others, based on the results of health status questionnaires. Before such an instrument may be implemented, its measurement properties, such as reliability, validity, and responsiveness, should be assessed and considered adequate for the target population. It is important to use reliable and valid outcome measures in order to avoid biased results and conclusions[13]. Quality criteria for evaluating measurement properties of health status questionnaires have been introduced and are widely accepted[14-18]. However, these criteria do consider the outcome measure itself but not the methodological quality of the study. To evaluate whether a study on a specific outcome measure is of good methodological quality, the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist has been recently developed[19].

Given the high prevalence of TMC OA[20, 21] and the many available treatment methods, a standardized assessment is essential for comparing the interventions and providing evidence of best practice. So far, it remains unclear to what extent researchers are using valid and reliable assessment tools in TMC OA studies and whether these meet the recommendations of the core sets mentioned previously. Furthermore, the methodological quality of studies investigating measurement properties of outcome measures for hand patients has not been investigated yet.

In order to identify suitable outcome measures and to make recommendations for outcome measures to be used for patients with TMC OA, our objectives were to (1) identify all subjective and objective outcome measures used in clinical trials of conservative and surgical treatments of TMC OA; (2) to relate them to the OMERACT core set; and (3) to evaluate the measurement

properties of standardized outcome measures employed in patients with TMC OA as well as the methodological quality of these studies.

METHODS

We performed this systematic literature review in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement for developing study protocols and reporting systematic reviews[22, 23]. The review protocol was registered in the Netherlands National Trial Register (no. 2602).

Step 1: Literature search for TMC OA studies

An experienced librarian performed the search for articles published up to November 2010 in the following databases: PubMed, EMBASE, Web of Science, Cochrane Library, CINAHL, Academic Search Premier, ScienceDirect, and PEDro. The following search strategy was applied to PubMed and optimized for the other databases: ("trapeziometacarpal osteoarthritis" OR "trapezio metacarpal osteoarthritis" OR "carpometacarpal osteoarthritis" OR "carpo metacarpal osteoarthritis" OR "thumb osteoarthritis" OR ((Osteoarthritis OR Osteoarthroses OR Osteoarthritides OR Osteoarthritis OR Osteoartrosis OR Osteoartritis OR "Degenerative Arthritis" OR "Degenerative Arthritides" OR Arthrosis[tw] OR Arthroses) AND (Carpometacarpal Joints OR Carpometacarpal Joint OR carpometacarpal OR trapeziometacarpal OR thumb OR thumbs OR "thumb base" OR carpometacarpal* OR ((Metacarpus OR Metacarpal) AND (Carpal OR Carpus OR Carpo OR Carpi)) OR ((Trapezium OR Trapezoid OR Trapezium OR Trapezial) AND (Metacarpus OR Metacarpal OR Carpal OR Carpus OR Carpo OR Carpi))))). As language restriction is unreliable or not possible in all databases, we conducted the search without any such restrictions.

Inclusion criteria for the review were (a) clinical study involving a minimum of 10 people with TMC OA who had received any conservative or surgical treatment for TMC OA; (b) study designs including all randomized controlled trials and observational (prospective or retrospective) studies; (c) studies in which the effectiveness of the treatment was evaluated with at least one outcome measure; (d) the paper was written in English or German.

Exclusion criteria were (a) studies investigating patients with generalized OA; (b) studies in which the results of patients with TMC OA could not be separated from those of patients with other conditions; (c) reviews, case reports, post-mortem and veterinary studies, and conference abstracts not published as full journal articles, because they lacked full information about the study design; and (d) studies not in English or German, as we had no reliable translators.

Two independent reviewers reviewed the titles and abstracts that had been identified. The full texts of the selected abstracts were retrieved and again analyzed independently by two of the authors. Consensus on inclusion of the studies was reached by discussion.

We checked the references of the included articles to find other suitable papers and subjected them to a similar selection process.

Data for the following variables were extracted using a predefined form: authors, publication year, number of patients, patient demographics, intervention, and follow-up period, as well as all objective and subjective outcome measures used in the studies. The level of evidence was determined using the slightly modified rating scheme described by Wright et al. [24].

Some authors analyzed the same study population more than once and presented their findings in several publications. These articles were analyzed as individual studies, in case inadequate descriptions of the study populations made it impossible to identify the overlap.

We classified all concepts included in the outcome measures, such as pain or strength, according to the five domains of the OMERACT core set ('pain', 'physical function', 'patient's global assessment', 'joint imaging', 'QoL')[11]. We chose this core set as the reference tool because it is simpler and better known to hand surgeons than the complex ICF concept. For the purpose of this study, the domain 'function' included isolated functions of the hand (such as extending the thumb) and activities of daily living (ADLs) making use of the hand; 'global assessment' was defined as an overall assessment of the hand condition, including treatment satisfaction, symptom improvement, and disease activity. 'QoL' was defined as a multidimensional appraisal of various aspects of health, including pain and function. 'Imaging' included all techniques such as radiography or magnetic resonance imaging. Given that some outcome measures cover more than one concept, each item, element, or dimension of a combined outcome measure was analyzed separately to assign it to several corresponding OMERACT domains.

Step 2: Measurement properties

In the period up to April 2012, we performed a second literature search on the measurement properties of the identified outcome measures for TMC OA in the databases mentioned previously. We applied the same strategy as in step 1 adding the following terms on measurement properties:

... AND (Psychometrics OR Psychometric OR Psychometr* OR "psychological variable" OR "psychological variables" OR Validity OR valid OR validated OR validation OR Validities OR "Validation Studies"[Publication Type] OR valid* OR Reliability OR Reliable OR Unreliability OR Unreliable OR Responsiveness OR Unresponsiv* OR Irresponsiv* OR Responsive* OR "Reproducibility of Results"[Mesh] OR Reproducibility OR Reproducible OR Irreproducib* OR Reliabilities). A cited reference search for the target articles was also carried out.

We included studies with a population of at least 50% of the patients suffering TMC OA or analyzing patients with TMC OA as a subgroup, and evaluating any measurement property of an outcome measure revealed in step 1, regardless of whether the investigation of measurement properties was the primary objective of the study or only mentioned tangentially. Studies investigating patients with hand OA, for example, where the proportion of TMC OA patients was less than 50%, were excluded.

The following eight measurement properties of the outcome measures were rated according to the criteria developed by Terwee et al.[17], which we slightly modified for our purpose (see definitions in Appendix 1): internal consistency, content validity, criterion validity, construct validity, reproducibility (agreement and reliability), responsiveness, floor or ceiling effects, and interpretability. Two reviewers independently extracted all these data and results were graded as positive (+), doubtful (?), or poor (-). As several studies investigated the same tool, the different studies were synthesized using the rating achieved by most of the articles.

The methodological quality of the articles reporting on the measurement properties of outcome measures was rated on a 4-point scale according to the COSMIN checklist[19]. This checklist is used to assess whether a study on a specific outcome measure tool meets the standards for good methodological quality. A score is calculated for each of nine standards (COSMIN boxes A-I) which somewhat differ from those criteria of Terwee[17]: A. internal consistency, B. reliability,

C. measurement error, D. content validity, E. structural validity, F. hypotheses testing, G. cross-cultural validity, H. criterion validity, and I. responsiveness. There are two additional boxes given; the generalizability and interpretability box. The corresponding 15 items are intended to be used as data extraction forms to extract all data on study characteristics and interpretability issues (e.g., norm scores, floor/ceiling effects, and relevancy for subgroups[19]. An assessments of the statistical methods used in articles based on the Item Response Theory (IRT) (box general requirements for studies that applied IRT Models) was not performed, as this procedure was not used in any of the included studies. Each standard (box) included various items (number ranging from 5 to 18 per box). An overall quality score for that standard was obtained by taking the worst rating of any item (worst score counts principle). The resulting rating could be excellent, good, fair, or poor[18]. There is no formal interpretation of how to combine the measurement property scores (Terwee et al.'s checklist) and the methodological quality scores of studies according to the COSMIN checklist. The COSMIN group stated that the quality of an instrument under investigation remains unclear if the methodological quality of a study is inadequate[19]. For that reason, in the present study, we considered the measurement properties of a tool to be equivocal if the methodological quality of the related studies was rated as poor, irrespective of its rating on the Terwee scale.

RESULTS

Step 1: Literature search for TMC OA studies

Our initial search identified 2979 articles. After removing duplicates, checking references and the two-phase review process, we finally included 316 articles (Figure 1, references in Appendix 2) investigating 13 231 patients (Table 1). Forty-five articles from 17 different research groups reported on patients who had also been subjects in other studies included in our review. Four articles reported on 273 patients affected by hand OA, but the precise number of patients with TMC OA could not be determined[25-28]. Different surgical procedures were investigated in 268 articles, while conservative treatments were studied in 66 papers. The methodological quality of most of the articles was low: 244 were level IV studies.

In total, we identified 101 different outcome measures, not counting 22 ways to examine radiographs and the self-developed instruments which were excluded.

These 101 outcome measures addressed the OMERACT domain 'pain' in 298 articles, 'physical function' in 303, 'global assessment' in 187, 'imaging' in 213 and 'QoL' in 13 (Table 2). A visual analogue scale (VAS) was most often applied (n = 93) in the domain 'pain'. 'Physical function' most frequently included measurement of muscle strength and ROM. Grip strength (n = 218) was the most commonly assessed measure of strength, often using a dynamometer (n = 122). Thumb ROM was most often based on abduction (n = 179), in most cases not stating the method used to measure it (n = 114) but sometimes mentioning use of a goniometer (n = 26).

'Global assessment' was done primarily by evaluating treatment satisfaction (n = 160), using nine different tools. 'Imaging' consisted mainly of rating the stage of OA on the radiographs (n = 160), most frequently using the Eaton classification (n = 132). The Colville questionnaire was used to evaluate 'QoL' in five of the 13 articles investigating this dimension.

Twenty-one different standardized questionnaires were used; the DASH was the most common, having been applied in 46 articles.

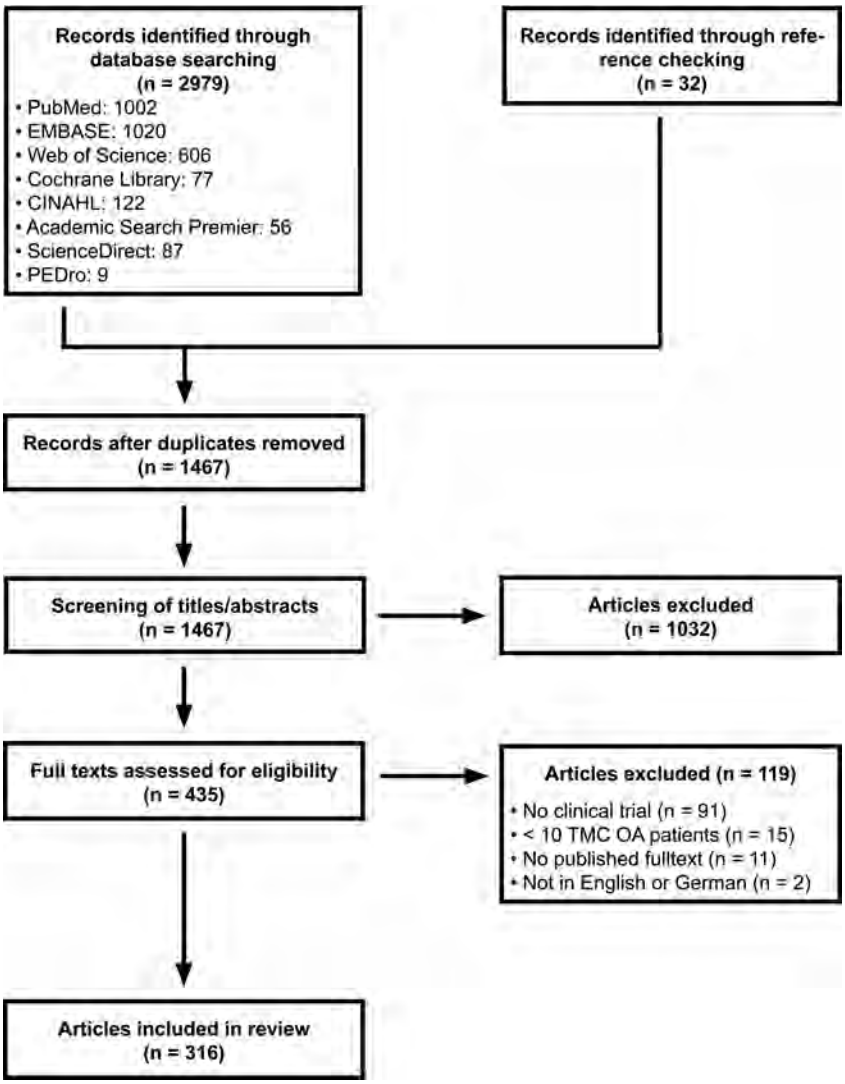

Figure 1 Study selection process for step 1

Step 2: Measurement properties

The second literature search yielded 538 articles, of which we included 12[6, 29-39] in the final analysis (Figure 2, Table 3).

These articles examined the measurement properties of 12 outcome measures specifically in patients with TMC OA (Table 4). The DASH and the PRWE were the ones most extensively studied. None of the studies examined all eight measurement properties. Positive ratings (+) were seen for the DASH[6, 29-33, 39], quickDASH[30, 39], Australian / Canadian Osteoarthritis Hand Index (AUSCAN)[31], and Nelson Score[33]. In contrast, the Eaton classification[34-37], CMC grind test[38], and

Table 1 Characteristics of the 316 clinical studies on TMC OA. Due to inadequate descriptions, not all variables could be extracted from all studies.

	Sum of all studies (% of all articles)	Median (range) per study
Year		2000 (1968-2010)
Patients[a]	13 231	32 (10-315)
Females[b] (% of population)	8855 (83.2)	26 (0-162)
Males[b] (% of population)	1784 (16.8)	5 (0-38)
Hands[c]	12 521	34 (0-315)
Age[d] (years)		59.1 (33.7-74.6)
Follow up[e] (years)		2.9 (0.04-16.4)
Level of evidence[f] (%)		4 (1-4)
Level I	33 (10)	
Level II	13 (4)	
Level III	26 (8)	
Level IV	244 (77)	
Intervention[g]		
Implant arthroplasty	92	
Trapeziectomy + ligament reconstruction + tendon interposition	67	
Trapeziectomy + tendon interposition	49	
Trapeziectomy	36	
Arthrodesis	33	
Injection	28	
Splint	16	
Trapeziectomy + interposition with various material	15	
Various surgical interventions[h]	14	
Trapeziectomy + ligament reconstruction	11	
Various conservative treatments[i]	8	
Osteotomy	8	
Physical/occupational therapy	5	
Drugs	5	
Unspecified conservative treatments	4	

[a] taken from 315 articles
[b] taken from 259 articles
[c] taken from 270 articles
[d] taken from 273 articles
[e] taken from 287 articles
[f] due to rounding errors, the sum of the percentages may be less than 100%
[g] more than one intervention per study possible
[h] including unspecified surgical interventions, different surgical interventions in one study group, tendon interposition without trapeziectomy, debridement, synovectomy or denervation
[i] including laser therapy, iontophoresis, radiation therapy, leech therapy, nettle sting, acupuncture, phonophoresis

Table 2 Concepts and outcome measures used in 316 articles about TMC OA categorized according to the OMERACT core set. The OMERACT domain is given in capital letters. Furthermore, the outcome measures are arranged according to whether they are specific for the hand / upper extremity or if they are generic outcome measures.

OMERACT domain and outcome measure	**Articles (n)**
PAIN	**298[a]**
Hand specific	
Visual Analogue Scale (VAS)	93
Likert scale(s)	48
Joint tenderness	23
Carpometacarpal grind test	14
Alnot classification	5
Self-developed questionnaire for hand pain	111
Generic	
Intake of analgesics	27
McGill Pain Questionnaire	1
PHYSICAL FUNCTION	**303[a]**
Hand specific	
Strength	267
Range of motion	223
Stability	42
Dexterity	30
Sensibility	25
Subjective hand function	24
Stiffness	19
Wound healing	9
Self-developed function tests	9
Pegboard tests	8
Functional Index of Hand OA (FIHOA) / Dreiser index	5
Jebsen-Taylor Test	4
Muscle outline	2
Cochin Scale	2
Sollerman Hand Function Test	2
Green Test	1
Upper extremity specific	
Activities of daily living (ADLs) - Self-developed questionnaire	75
Activities of daily living (ADLs) - Method not specified	25
Hand Functional Index (HFI) of the Keitel Functional Test (KFT)	2
Abilhand	1
Generic	
Sleep disturbance	2
Fatigue	1

Table 2 (Continued)

OMERACT domain and outcome measure	Articles (n)
GLOBAL ASSESSMENT	**187[a]**
Treatment satisfaction	160
Subjective result	22
Self-developed questionnaire	4
Disease activity	1
IMAGING	**213[a]**
Stage of thumb OA (radiographs)	160
Scapho-metacarpal distance	104
QUALITY OF LIFE	**13[a]**
Colville Questionnaire	5
Arthritis Impact Measurement 2 (AIMS2)	3
Medical Outcomes Study Short Form 36 (SF-36)	4
Medical Outcomes Study Short Form 12 (SF12)	1
PAIN + FUNCTION	**291[a]**
Hand specific	
Australian/Canadian Osteoarthritis Hand Index (AUSCAN)	5
Patient-Rated Wrist Evaluation (PRWE)	4
Sequential Occupational Dexterity Assessment (SODA)	3
Nelson Score	1
Upper extremity specific	
Disabilities of the arm, shoulder and hand questionnaire (DASH)	46
QuickDASH	3
Generic	
Health Assessment Questionnaire - Disability Index (HAQ-DI)	3
Western Ontario McMaster Universities Osteoarthritis Index (WOMAC)	1
PAIN + FUNCTION + GLOBAL	**173[a]**
Hand specific	
Buck Gramko Scale	10
Michigan Hand Questionnaire (MHQ)	4
Patient Evaluation Measure (PEM)	1
OMERACT-OARSI Response Index	1
OMERACT NOT ASSIGNABLE	
Hand specific	
Hand appearance	43
Crepitus	24
Thumb shortening	10
Confidence with hand use	1

Table 2 (Continued)

OMERACT domain and outcome measure	Articles (n)
Generic	
Complications	234
Return to work	69
Comfort with device	6
Laboratory results	2
Met expectations	2
Intake of hormones	2
Pain Anxiety Symptoms Scale (PASS)	1
Center for the Epidemiological Study of Depression instrument (CES-D)	1
Pain Catastrophizing Scale (PCS)	1

[a] Number of articles covering this domain. Although pain, for example, might be evaluated by more than one outcome measure, this value does not necessarily reflect the sum of the instruments given below.

Hand Functional Index of the Keitel Functional Test (HFI / KFT)[6] rated poorly. Ratings for the PRWE[6, 29, 31] and SF-36[6, 29-31] were equivocal.

The methodological quality of these articles, rated according to the COSMIN checklist was generally fair to poor and most of the measurement properties have not been investigated (Figure 3, Table 5). The positive results of the DASH were weakened by the poor methodological quality of the studies investigating its responsiveness[32], while the overall quality of the study considering the Nelson score was also rated as poor[33].

DISCUSSION

In our review of the outcome measures used in TMC OA studies, we identified 316 papers. We found a wide variety of outcome measures, with pain and function being the most frequent and QoL underrepresented. Studies rarely examined the measurement properties of outcome measures specifically for patients with TMC OA, and the methodological quality of those that did so was fair, so that no recommendations for the use of any outcome measure can be made.

The heterogeneity of the outcome measures employed raises serious issues about the statistical comparison of different interventions, as shown in a recent systematic review of the surgical management of TMC OA[2]. This concerns not only studies on patients with TMC OA but also studies on hand OA, where many different outcome measures have also been used[40]. The finding that numerous tools (some self-developed) were used to assess the effectiveness of treatment highlights the need to develop homogeneous, standardized, and validated outcome measures for patients with TMC OA, in order to facilitate comparisons of patient populations and the outcomes of different surgical and non-surgical procedures.

Apart from the variety, we also found that specific aspects of outcome were not covered equally. The OMERACT core set includes the assessment of QoL as a strongly recommended module[11], but only few studies on TMC OA include it. Given that hand OA greatly affects the

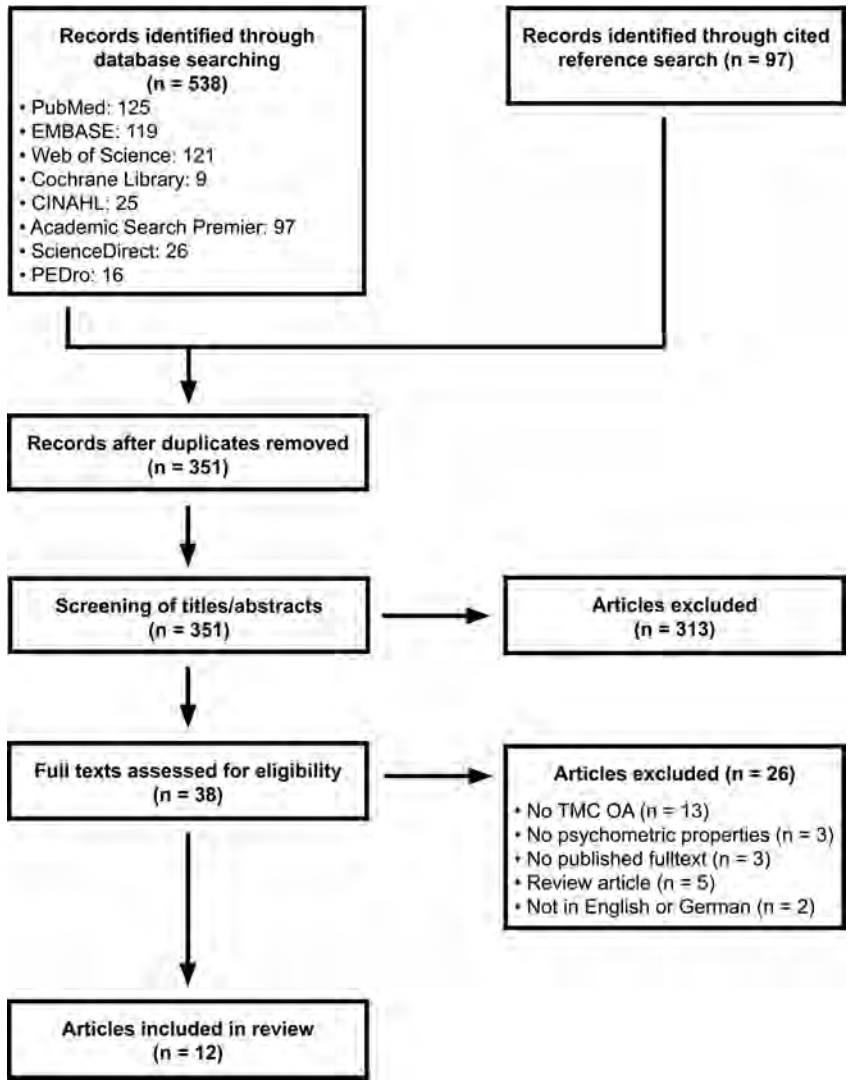

Figure 2 Study selection process for step 2

quality of life[40], several authors recommend using a generic outcome measure such as the SF-36 to evaluate QoL in patients with hand disorders[6, 40-42]. The observed predominance of objective measures (such as muscle strength and ROM) performed by healthcare providers shows that many researchers still do not make the subjective patient perspective their primary focus. This implies underrepresentation of concepts such as psychological consequences, aesthetic changes, and effects on leisure activities, which are important to patients with hand OA[43].

The measurement properties of the DASH and PRWE were the most extensively examined ones in patients with TMC OA. Overall, the DASH was rated more favourably than the PRWE, especially

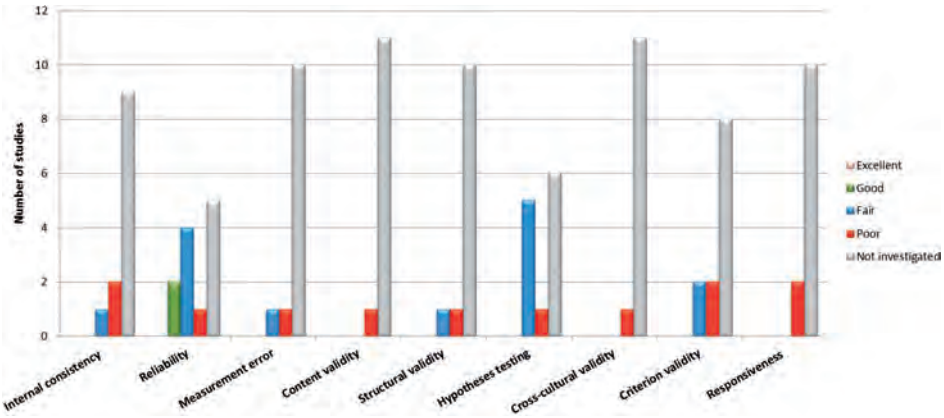

Figure 3 Distribution of the methodological quality of 12 studies about measurement properties rated with the COSMIN checklist.

regarding responsiveness, and floor and ceiling effects. It should be noted, however, that the methodological quality of the studies on the responsiveness of DASH was low[32, 33]. If the study methodology is of poor quality, the quality of the instrument remains equivocal[19]. Furthermore, the specificity and sensitivity of this tool in these particular patients remains questionable because the score is influenced by function/dysfunction of the elbow and shoulder[33, 41, 44]. For this reason, it might be better to use a hand-specific questionnaire such as the AUSCAN or Nelson score. The AUSCAN has only been examined for construct validity in patients with TMC OA, which does not permit any firm conclusions on its overall value in this patient group. The reliability and responsiveness of the AUSCAN were, however, found to be satisfactory for patients with general hand OA[25, 45]. Apart from its measurement properties, other characteristics of a questionnaire such as feasibility and associated costs have to be considered. While the DASH is freely available, the AUSCAN has to be purchased. The Nelson Score, a questionnaire specifically designed to assess the outcome following TMC OA surgery, has so far only been applied by the developers themselves[33]. Interpretation of their findings is further hampered by the poor methodological quality of the study including assessing only 36 patients. The Eaton classification to assess the stage of OA is the only imaging method that has been studied for reliability in patients with TMC OA. Although its reliability remains questionable, it seems to be the best method of staging currently available[37]. The patient's global assessment was done primarily by evaluating patient satisfaction. Researchers used several instruments, such as a VAS, Likert scale is, and different questionnaires, all of which still have to be tested for their measurement properties in patients with TMC OA. To date, there is no validated instrument available in hand surgery to measure patient satisfaction, which might be due to the numerous health-related, personal, and environmental factors influencing patient satisfaction[46]. The present review yielded equivocal ratings regarding construct validity and floor effect for the SF-36 with respect to QoL, and its responsiveness has not been investigated for TMC OA patients. Although other researchers have found a relatively low sensitivity to change in patients with carpal tunnel syndrome[47-49] and distal radius fractures[50, 51], a generic instrument to

Table 3 Study characteristics of the 12 included articles about measurement properties of outcome measures for

Study	Outcome measure	No. of patients with TMC OA	Age, years (mean, SD)	Sex (% females)
John et al., 2008*	PRWE, DASH, SF-36	103 (112 cases)	68 ± 9.8	83
Angst et al., 2009*	quickDASH, DASH, SF-36	103 (112 cases)	68 ± 9.8	83
Angst et al., 2005*	PRWE, DASH, SF-36, HFI/KFT	103 (112 cases)	68 ± 9.8	83
MacDermid et al., 2007	PRWE, DASH, AUSCAN, SF-36	120	65 ± 8.1	82
De Smet, 2004	DASH	15	56 (median)	93
Niekel et al., 2009	DASH, quickDASH, CES-D, PCS, PASS	107		
Citron et al., 2007	Nelson Score	36		
Dela Rosa et al., 2004	Eaton classification	30 (40 cases)	59	87
Kubik III and Lubahn, 2002	Eaton classification	40	60	83
Hansen et al., 2012	Eaton classification	43 (50 cases)	60	72
Spaans et al., 2011	Eaton classification	40 cases	60	73
Merritt et al., 2010	CMC grind test	54 (70 cases)	60 ± 13.4	85

Study	Outcome measures	Missing items	Handling of missing items	Distribution of the scores
John et al., 2008*	PRWE, DASH, SF-36	PRWE: ≤ 12%		PRWE: left skewed
Angst et al., 2009*	quickDASH, DASH, SF-36			
Angst et al., 2005*	PRWE, DASH, SF-36, HFI/KFT	PRWE ≤ 14%; DASH ≤ 17%; SF-36 ≤ 6%; HFI/KFT = 7%		Non-parametric
MacDermid et al., 2007	PRWE, DASH, AUSCAN, SF-36			SF-36: normal distribution; other instruments: non-parametric
De Smet, 2004	DASH			
Niekel et al., 2009	DASH, quickDASH, CES-D, PCS, PASS			Non-parametric
Citron et al., 2007	Nelson Score			
Dela Rosa et al., 2004	Eaton classification	N/A	N/A	N/A
Kubik III and Lubahn, 2002	Eaton classification	N/A	N/A	N/A
Hansen et al., 2012	Eaton classification	N/A	N/A	N/A
Spaans et al., 2011	Eaton classification	N/A	N/A	N/A
Merritt et al., 2010	CMC grind test	N/A	N/A	N/A

* These articles report on the same cohort

AUSCAN = Australian/Canadian Osteoarthritis Hand Index; CES-D: Center for the Epidemiological Study of Depression instrument; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire;

patients with TMC OA according to the COSMIN generalizability and interpretability boxes.

Treatment	Setting	Countries	Language	Patient selection	Response rate (%)
Resection Interposition Arthroplasty	Hospital	Switzerland	German	Consecutive	72
Resection Interposition Arthroplasty	Hospital	Switzerland	German	Consecutive	72
Resection Interposition Arthroplasty	Hospital	Switzerland	German	Consecutive	72
Resection Interposition Arthroplasty	Hospital	Canada			
Surgery	Hospital	Belgium		Consecutive	
None described	Hospital	The Netherlands		Convenience	27
Surgery	Outpatient clinic	UK	English	Consecutive	
None described	Hospital	USA	N/A	Random	N/A
None described	Hospital	USA	N/A	Random	N/A
Pre-operative analysis	Hospital	Denmark	N/A		N/A
Various	Hospital	The Netherlands	N/A	Convenience	N/A
None	Private orthopaedic clinic, occupational medicine clinic, general community	USA	N/A	Convenience	N/A

Floor effect	Ceiling effect	Scores for relevant (sub) groups	MIC or MID
PRWE: 16-24%			quickDASH/ DASH: 4.5-11.3
PRWE ≤ 24%; DASH = 0%; SF-36 ≤ 16%; HFI/KFT = 0%	PRWE = 0%; DASH ≤ 20%; SF-36 ≤ 83%; HFI/KFT = 16%	Norm data given for SF-36 and DASH	
Existent for PRWE, DASH, and AUSCAN	Existent for AUSCAN	Scores for patients with solely hand OA compared to patients with hand OA and OA at other joints	
Existent	Not existent	Scores for other hand disorders included	
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

HFI/KFT: Hand Functional Index of the Keitel Functional Test; N/A: not applicable; PASS: Pain Anxiety Symptoms Scale; PCS: Pain Catastrophizing Scale; PRWE: Patient-Rated Wrist Evaluation; SF-36: Medical Outcomes Study Short Form 36

Table 4 Rating of the measurement properties of outcome measures tested for patients with TMC OA according to Terwee et al.[16]. They were graded as positive (+), doubtful (?), or poor (-). Blank boxes show that these properties have not been investigated.

Outcome measure instrument	Internal Consistency	Content validity	Criterion validity	Construct validity	Reproducibility	Responsiveness	Floor or ceiling effect	Interpretability
DASH	+ [29]		+ [38]	+ [6, 28-31]		+ [31, 32]	+ [6]	? [30]
AUSCAN[30]				+				?
PRWE	+ [28]			+ [6, 28]	+ [28]	- [28]	- [6, 28]	? [30]
Nelson Score[32]	+	?		?	?	+		
SF-36	+ [29]			? [6, 28-30]			- [6]	
Eaton classification (stage of OA)[33-36]					-			
Carpometacarpal grind test[37]			?		-			
quickDASH	+ [29]		+ [29,38]	? [29,38]				
CES-D[38]				?				
PCS [38]				?				
PASS[38]				?				
HFI/KFT[6]				-			-	

AUSCAN = Australian/Canadian Osteoarthritis Hand Index; CES-D: Center for the Epidemiological Study of Depression instrument; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; HFI/KFT: Hand Functional Index of the Keitel Functional Test; PASS: Pain Anxiety Symptoms Scale; PCS: Pain Catastrophizing Scale; PRWE: Patient-Rated Wrist Evaluation; SF-36: Medical Outcomes Study Short Form 36

Table 5 Methodological quality of studies investigating outcome measure instruments in patients with TMC OA. In accordance with the COSMIN checklist, the method of investigating each measurement property was rated excellent, good, fair, or poor

Author	Outcome measure	Internal consistency	Reliability	Measurement error	Content validity	Structural validity	Hypotheses testing	Cross-cultural validity	Criterion validity	Responsiveness
John et al., 2008[28]*	PRWE, DASH, SF-36	Poor	Fair	Fair			Fair	Poor	Poor	
Angst et al., 2009[29]*	quickDASH, DASH, SF-36	Fair					Fair		Fair	
Angst et al., 2005[6]*	PRWE, DASH, SF-36, HFI/KFT					Poor	Fair			
MacDermid et al., 2007[30]	PRWE, DASH, AUSCAN, SF-36					Fair	Fair			
De Smet , 2004[31]	DASH									Poor
Niekel et al., 2009[38]	DASH, quickDASH, CES-D, PCS, PASS						Fair		Poor	
Citron et al., 2007[32]	Nelson Score, DASH	Poor	Poor	Poor	Poor		Poor			Poor
Dela Rosa et al., 2004[33]	Eaton classification		Fair							
Kubik III and Lubahn, 2002[34]	Eaton classification		Fair							
Hansen et al., 2012[35]	Eaton classification		Good							
Spanns et al., 2011[36]	Eaton classification		Fair							
Merritt et al., 2010[37]	CMC grind test		Fair						Fair	

*These articles report on the same cohort.
AUSCAN = Australian/Canadian Osteoarthritis Hand Index; CES-D: Center for the Epidemiological Study of Depression instrument; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; HFI/KFT: Hand Functional Index of the Keitel Functional Test; PASS: Pain Anxiety Symptoms Scale; PCS: Pain Catastrophizing Scale; PRWE: Patient-Rated Wrist Evaluation; SF-36: Medical Outcomes Study Short Form 36

measure QoL is recommended because it allows the comparison between different conditions and patient populations[52].

Assessing the methodological quality of studies is an important point in systematic reviews. However, there are no uniform guidelines, for how to assess the methodological quality for different types of studies. For randomized controlled trials (RCTs), the Cochrane collaboration recommends its risk of bias tool[53]. For observational studies, there are various checklists and scores available, but none of these can be recommended to be used as a gold-standard[54]. Other common checklists, such as the CONSORT[55], the PRISMA[22, 23], and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[56] statements, are not intended to serve as quality appraisal tools but to guide authors when reporting RCTs, systematic reviews and observational studies, respectively. For grading the methodological quality of studies investigating measurement properties, the COSMIN checklist[19] is the only available tool, so far.

Our review has certain limitations. As only English and German articles have been included, some studies published in other languages might have been missed. Additionally, many articles lacked information on the study population and methods, making it impossible to determine actual overlap among studies and calculate the exact numbers of patients investigated. Furthermore, the low methodological quality of all the studies, assessed by the COSMIN checklist, prohibits recommendations. The scoring of this tool is rather rigid, giving the overall rating of a specific measurement property as poor even if only one item is scored as such. For each measurement property, the number of missing items and their handling has to be scored. Though this information is lacking in most of the studies, this leads to an overall fair rating, although the study achieved better ratings regarding the other items of that property. For this reason, the methodological quality of the articles might have been underestimated. Another limitation of the study is that we used the Wright classification for rating the levels of evidence. Following our rating, a revised classification for evidence-based medicine was published[57]. As the primary purpose of our publication was not to report the evidence levels of studies on TMC OA but rather to focus on measurement instruments, it was decided not to repeat the classification.

Based on the results of the present study, no recommendation for a particular outcome measure can be made. A combination of hand-specific questionnaires, which are most suitable for detecting changes in patients with TMC OA, general health status questionnaires, and clinical data are suggested. However, more research on the psychometric properties of outcome measures in methodological sound studies is needed before we can make any firm recommendations about the use of specific tools.

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CONFLICT OF INTERESTS

None declared.

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APPENDIX 1: DEFINITIONS OF THE PSYCHOMETRIC PROPERTIES ACCORDING TO TERWEE ET AL.[1] AND THEIR RATINGS (SLIGHTLY MODIFIED)

Internal consistency

Definition: Internal consistency is a measure of the extent to which items in a questionnaire (sub)scale are correlated (homogeneous), thus measuring the same concept. Internal consistency is an important measurement property for questionnaires that intend to measure a single underlying concept (construct) by using multiple items.

Positive (+) rating: A positive rating was assigned if a factor analysis was performed on adequate sample size (7 × number of items and ≥ 100) or if Cronbach's alpha was calculated per subscale and was between 0.70 and 0.95.

Doubtful (?) rating: No factor analysis performed, or doubtful design or method.

Poor (-) rating: Cronbach's alpha was < 0.70 or > 0.95, despite adequate design and method.

Content validity

Definition: Content validity examines the extent to which the concepts of interest are comprehensively represented by the items in the questionnaire.

Positive (+) rating: A positive rating was assigned if a clear description was provided of the measurement aim, the target population, the concepts that were being measured, the item selection and target population, and if the investigators or experts were involved in item selection.

Doubtful (?) rating: A clear description of above-mentioned aspects was lacking or only the target population was involved, or a doubtful design or method was used.

Poor (-) rating: The target population was not involved.

Criterion validity

Definition: Criterion validity is the extent to which scores on a particular questionnaire relate to a gold standard. According to Mokking et al.[2], there is no gold standard for a health related patient reported outcome. Only if a shortened version is compared to its original long version, can it be considered as the gold standard (e.g. the quickDASH versus the full DASH).

Positive (+) rating: A positive rating was assigned if the correlation with a true gold standard was ≥ 0.70.

Doubtful (?) rating: No convincing arguments that the gold standard is really the gold standard, or a doubtful design was used.

Poor (-) rating: The correlation to the gold standard was < 0.7 despite adequate design and methods.

Construct validity

Definition: Construct validity is the extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured.

Positive (+) rating: A positive rating was assigned if specific hypotheses were formulated and at least 75% of the results were in accordance with these hypotheses. Though the testing of hypotheses is quite a new approach for testing construct validity, a "+" was also assigned if the target outcome measure correlated ≥ 0.7 with another outcome measure evaluating the same construct.

Doubtful (?) rating: Doubtful design or methods.

Poor (-) rating: Less than 75% of the hypotheses were confirmed, despite adequate design and methods or correlation with another outcome measure evaluating the same construct was < 0.7.

Reproducibility

Reproducibility concerns the degree to which repeated measurements in stable persons (test - retest) provide similar answers, and can be divided into agreement and reliability:

Agreement

Definition: Agreement concerns the absolute measurement error, which means how close the scores on repeated measures are, expressed in the unit of the measurement scale at issue. Small measurement error is required for evaluative purposes in which one wants to distinguish clinically important changes from measurement error.

Positive (+) rating: A positive rating was assigned if the minimal important change (MIC) was smaller than the smallest detectable change (SDC), if the MIC was outside the limits of agreement (LOA) or if convincing arguments that agreement is acceptable were given. In addition to this definition by Terwee et al.[1], a "+" was also assigned if the Intraclass correlation coefficient (ICC) or kappa was ≥ 0.7.

Doubtful (?) rating: Doubtful design or methods, or MIC not defined.

Poor (-) rating: The MIC was greater than the SDC or the MIC was inside the LOA, despite adequate design and methods.

Reliability

Definition: Reliability is the extent to which patients can be distinguished from each other, despite measurement errors (relative measurement error).

Positive (+) rating: A positive rating was assigned if the ICC or weighted Kappa was ≥ 0.70.

Doubtful (?) rating: Doubtful design or methods (e.g. time interval not mentioned).

Poor (-) rating: ICC or weighted Kappa was < 0.70 despite adequate design and methods.

Responsiveness

Definition: Responsiveness is the ability of a questionnaire to detect clinically important changes over time.

Positive (+) rating: A positive rating was assigned if the SDC had been calculated, if the SDC was smaller than the MIC or the MIC laid outside the LOA, or if the response ratio (RR) was greater than 1.96 or the area under curve (AUC) was greater than 0.7. Though many researchers calculate effect sizes (ES) or standardized response means (SRM), a "+" was assigned if these figures were ≥ 0.8.

Doubtful (?) rating: Doubtful design or methods.

Poor (-) rating: A poor rating was assigned if the SDC was greater than the MIC, if the MIC was equal or laid inside the LOA, if the RR was smaller than 1.96 or the area under curve (AUC) was smaller than 0.7, or if ES or SRMs were smaller than 0.7.

Floor or ceiling effects

Definition: Floor or ceiling effects are considered to be present if more than 15% of respondents achieved the lowest or highest possible score, respectively

Positive (+) rating: A positive rating was assigned if less than 15% of the respondents achieved the highest or lowest possible scores.

Doubtful (?) rating: Doubtful design or methods.

Poor (-) rating: More than 15% of the respondents achieved the lowest or highest possible score.

Interpretability

Definition: Interpretability is the degree to which one can assign qualitative meaning to quantitative scores. Investigators should provide information about what (change in) score would be clinically meaningful.

Positive (+) rating: A positive rating was assigned if mean and standard deviation (SD) scores were presented for at least four relevant subgroups of patients, and if MIC was defined.

Doubtful (?) rating: Doubtful design or methods, less than four subgroups, or if MIC was not defined.

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APPENDIX 2: INCLUDED ARTICLES

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CHAPTER **FOUR**

MEASUREMENT PROPERTIES OF THE GERMAN MICHIGAN HAND OUTCOMES QUESTIONNAIRE IN PATIENTS WITH TRAPEZIOMETACARPAL OSTEOARTHRITIS

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Miriam Marks
Laurent Audigé
Daniel B Herren
Stephan Schindele
Rob GHH Nelissen
Thea PM Vliet Vlieland

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ABSTRACT

Objective To investigate the reliability, validity, and responsiveness of the Michigan Hand Outcomes Questionnaire (MHQ) in patients with trapeziometacarpal (TMC) joint osteoarthritis (OA).

Methods In this prospective observational study, patients diagnosed with TMC joint OA who received either conservative or surgical treatment were included. At baseline and at 1 year following the beginning of treatment, we measured key pinch strength and the patients filled out the MHQ, the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, and the Short Form 12 health survey. Patients also completed these questionnaires 2 – 11 days after the last study visit. In order to analyze the measurement properties of the MHQ, we calculated test–retest reliability (intraclass correlation coefficient [ICC]), internal consistency (Cronbach's alpha for the 6 subscales), construct validity (Pearson's correlation coefficient [r]), responsiveness (effect sizes), and the minimum important change (MIC).

Results We included 177 patients, of whom 109 were scheduled for surgery. The mean ± SD MHQ total score for surgical patients increased from 48 ± 14 at baseline to 75 ± 18 at 1 year ($p \leq 0.001$). In contrast, no treatment effect was observed in the conservative group ($p = 0.74$). The MHQ total score showed excellent test–retest reliability (ICC = 0.95) and correlated strongly with the DASH ($r = -0.77$). Internal consistency of the MHQ subscales ranged between 0.77 and 0.89. A large effect size of 1.7 was found for the surgical patients, with an MIC of 17 points.

Conclusion The MHQ demonstrated good reliability, validity, and responsiveness in patients with TMC joint OA and can be recommended as a suitable assessment instrument in this population.

Significance & Innovations

- The Michigan Hand Outcomes Questionnaire (MHQ) is widely used in clinical trials to assess the outcome of interventions in patients with various hand disorders.
- Although the MHQ has already been used in studies that included patients with trapeziometacarpal (TMC) joint osteoarthritis (OA), its measurement properties have not yet been investigated in this population.
- Based on good results regarding reliability, validity, and responsiveness, we can recommend the MHQ as a suitable assessment instrument for patients with TMC joint OA.

INTRODUCTION

Among the joints of the hand, the trapeziometacarpal (TMC) joint is, after the distal interphalangeal joints, the joint most frequently affected by osteoarthritis (OA). The prevalence is 14.2% in the 50-59 years age group and increases with higher age[1–3]. TMC joint OA causes symptoms such as pain and loss of grip strength, as well as limiting daily activities and social participation[1, 4]. Given this high prevalence, it is essential to have a standardized assessment tool that allows comparison of interventions and provides evidence of best practice. In recent years, subjective evaluations based on the patient's self-assessment of function, activities of daily living (ADL), and quality of life, as well as on patient satisfaction, have emerged as increasingly important outcome measures for musculoskeletal conditions in general. Various questionnaires are available to assess subjective aspects in patients experiencing TMC joint OA, with the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire[5] being the one used most frequently[6]. However, the validity and responsiveness of this tool in these particular patients remain questionable as the score is also influenced by function/dysfunction of the elbow and shoulder. For this reason, it might be more appropriate to administer a hand-specific questionnaire[6]. The Michigan Hand Questionnaire (MHQ), developed by Chung et al.[7], is one such hand-specific questionnaire. In contrast to other commonly used function questionnaires, the MHQ has some unique features. First, it yields results for each hand separately. Second, it consists of a multidimensional construct, including a section on aesthetics, which is especially important in patients with rheumatoid arthritis[8, 9]. The MHQ consists of 37 items categorized into 6 subscales as follows: hand function, ADL, pain, work performance, aesthetics, and satisfaction with hand function. The MHQ has been translated and culturally adapted into several languages[10–15]. Furthermore, a short version of the MHQ (the BriefMHQ), including only 12 items, has recently been developed[16,17]. However, from the brief version it is not possible to derive subscale scores or to distinguish between the right and left hand.

The measurement properties of the original MHQ have been assessed in patients with rheumatoid arthritis[9, 18–20], carpal tunnel syndrome[19, 21, 22], and distal radius fractures[19, 23], as well as in patients with various other hand problems[10, 12, 21, 24, 25], with overall good reliability, validity, and responsiveness. Furthermore, the MHQ compares favorably with other hand outcomes instruments[8]. Although it has already been used in several studies that included patients with TMC joint OA, the measurement properties of the MHQ have not yet been demonstrated in this population[26, 27]. The aim of the present study was to investigate the reliability, validity, and responsiveness of the MHQ in patients with TMC joint OA.

PATIENTS AND METHODS

Study design

The MHQ study was part of a prospective observational study on the effects of conservative and surgical treatment for TMC joint OA. The study was carried out in accordance with the ethical principles of the Declaration of Helsinki and approved by the local ethics committee (Kantonale Ethikkommission Zurich, Switzerland).

Patients and interventions

Patients were eligible for the study if they had radiologic-proven TMC joint OA diagnosed by an experienced hand surgeon and had undergone either conservative or surgical treatment for that condition between September 2011 and November 2012. All eligible patients were asked to participate by their treating hand surgeon, and were consecutively enrolled in the study once they had given written informed consent. Exclusion criteria were as follows: TMC joint OA was not the main problem at the time of consultation, rheumatoid arthritis or other diseases interfering with hand function, concomitant surgery on other finger joints, legal incompetence, poor general condition precluding study participation, previous inclusion in the study for the other hand, and insufficient knowledge of the German language to complete the questionnaires.

Treatment consisted of conservative management (injection, analgesics, or occupational therapy) or surgery (resection/suspension/interposition arthroplasty or arthrodesis) as chosen by the surgeon in discussion with the patient in each case.

Outcome measures

Patients in the main study were assessed before treatment and at 3, 6, and 12 months after the start of treatment. For this substudy on the measurement properties of the MHQ, we used data from baseline and the 1-year followup. At baseline, sociodemographic and disease-related data were gathered. At each study visit, patients were assessed clinically and completed a questionnaire set consisting of the MHQ, the DASH, and the Short Form 12 (SF-12) health survey, version 2.0. Two to 11 days after the 1-year followup, patients filled out the questionnaire set again.

Key pinch strength was assessed using a digital pinch gauge (ELINK, Biometrics) in a standardized sitting position. The average of 3 measurements on the affected hand was retained for further analysis.

The MHQ has been translated into German[11]. The 6 subscales were calculated using the algorithm published by Chung et al[7]. The raw figures were converted to a score ranging from 0 to 100. Higher scores indicate better performance, except for the pain subscale, where a higher score denotes more pain. The MHQ total score was obtained by summing the scores for all 6 subscales (after reversing the pain scale) and then dividing the sum score by 6[28]. For the present analysis, only the data for the affected hand were retained.

The DASH is a questionnaire commonly used to evaluate pain and function of the upper extremity and does not distinguish between affected and nonaffected upper extremities[5, 29]. It shows sound measurement properties for patients with TMC joint OA, although the items are not purely hand-specific and are partly influenced by function/dysfunction of the elbow and shoulder joints[6]. Like the MHQ, the DASH total score ranges from 0 to 100, where higher scores indicate greater disability.

The SF-12 is a short version of the SF-36, which assesses quality of life[30]. Its 12 questions cover the 8 subscales of physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health, leading to the 2 component summary measures of physical health and mental health. The SF-12 itself has not been investigated in patients with TMC joint OA, although its original version, the SF-36, has[31–34]. At the 1-year followup, we asked about the perceived change in the thumb condition related to baseline and patients answered on a 5-point Likert scale. This scale was transformed into a dichotomous scale, with patients who had answered "much better" or "slightly better" being allocated into

the improved group. Patients who answered "unchanged," "slightly worse," or "worse" were allocated into the comparison group of unimproved subjects.

Statistical analysis

Sociodemographic and disease-related characteristics were analyzed descriptively. We determined the items initially missing from the questionnaires returned at baseline and contacted the patients by telephone to ask them to complete their answers in order to have as few missing items as possible. The Wilcoxon signed rank test was carried out in each subgroup for the MHQ total score, the DASH, the SF-12, and the key pinch to see whether there were significant treatment effects in patients treated surgically or conservatively.

Evaluation of the measurement properties of the MHQ was based on the definitions and recommendations of the Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN) Group[35–37], which are outlined below.

Reliability is defined as the degree to which the measurement is free from measurement error and is usually established by test–retest reliability, internal consistency, and estimated measurement error. Test–retest reliability was estimated by the intraclass correlation coefficient (ICC) using the data from the 1-year followup and those collected 2 - 11 days later. No change in the thumb condition was expected within this short period. An ICC ≥ 0.7 is considered acceptable, but values ≥ 0.8 are much better[36]. Using baseline data, we calculated Cronbach's alpha for each subscale to evaluate internal consistency. Values between 0.7 and 0.9 are regarded as good internal consistency, higher values indicate redundancy[36]. To obtain the measurement error, the standard error of measurement (SEM) was calculated by dividing the SD of the difference between test and retest by √2. Not every change in a measurement instrument can be considered as a true change; a change might occur due to measurement errors. The smallest detectable change (SDC) represents the change beyond measurement error, and any change smaller than the SDC can be regarded as measurement error. The SDC was calculated as 1.96 x √2 x SEM[36].

Construct validity is the degree to which an instrument measures the construct(s) it is intended to measure and can be further divided into convergent and discriminant construct validity. Convergent construct validity means that the instrument under investigation highly correlates with another instrument that reflects a similar construct[36]. In the case of the MHQ, we chose the DASH as a comparator, as it intends to measure function and pain of the upper extremities, including the hand. Discriminant construct validity means that instruments that measure different constructs show only slight or no correlations[36]. For this purpose, we chose key pinch as a comparator for the MHQ function subscale, because hand function includes more aspects than only key pinch strength. Moreover, we selected the SF-12 mental health score, which intends to measure a completely different construct than the MHQ.

According to the recommendations of the COSMIN Group[35–37], we tested predefined specific hypotheses to investigate the construct validity. The number of hypotheses to be tested has not been defined by this group[38], so we assumed that 5 would be sufficient to prove or reject the construct validity of the MHQ. Using the baseline data, the following 3 hypotheses for convergent construct validity were tested with Pearson's correlation coefficients: 1) the MHQ ADL subscale correlates strongly with the DASH, with r ≤ -0.7, 2) the MHQ pain subscale correlates strongly with the DASH, with r ≥ 0.7, and 3) the MHQ total score correlates strongly with the DASH, with

r ≤ -0.7. For discriminant construct validity, the following hypotheses were tested: 1) the MHQ hand function subscale correlates mildly with key pinch strength, with 0.5 ≥ r ≥ 0.3, and 2) the MHQ hand function subscale does not correlate with the SF-12 mental health score, with r ≤ 0.3.

Responsiveness is defined as the ability of an instrument to detect change over time in the construct to be measured[35]. Although not recommended by de Vet et al.[36], we calculated measures of responsiveness because this is common in many publications on measurement properties of hand function instruments[39]. For this purpose, we used the data of the subgroup(s) of patients (surgical and/or conservative) in whom, on the group level, a statistically significant change over time was seen for the majority of all outcome measures used. In this or these subgroup(s), effect sizes (Cohen's d) and standardized response means (SRMs) were calculated. An effect size of 0.2 is regarded as small, of 0.5 as medium, and of 0.8 as large[40]. In accordance with the recommendations of the COSMIN Group[35–37], we tested predefined hypotheses, similar to the approach we used for validity, i.e., 1) the effect size of the MHQ total score in a subgroup of improved patients is ≥ 0.8, and 2) the effect size of the MHQ total score is higher than the effect size of the DASH.

For interpretability, which is defined as the degree to which qualitative meaning can be ascribed to quantitative scores, we calculated the minimum important change (MIC). The MIC was defined as the smallest change that patients consider important and was calculated using an anchor-based method. For the anchor, we used the question about perceived change in the thumb condition at 1 year related to baseline. The MIC was calculated with receiver operating characteristic (ROC) curves and the optimal cut point, which reflects the MIC, was chosen for which was smallest ([1 - sensitivity] + [1 - specificity])[41]. The MIC should be higher than the SDC[36]. Furthermore, the area under the ROC curve (AUC) shows the ability of the MHQ to discriminate between improved and unimproved patients. A value of 0.5 indicates no discriminative ability, while an AUC ≥ 0.75 is regarded as appropriate[42].

Floor/ceiling effects were calculated from the percentage of patients showing the highest (100) or lowest (0) value in each subscale at baseline. If > 15% of the patients achieve the lowest/highest values, a floor/ceiling effect is present[43].

RESULTS

After screening 260 patients, we included 177 patients in our study (Figure 1). After inclusion, 3 patients scheduled for surgery cancelled their treatment. Nevertheless, their baseline data were analyzed. For the 1-year followup, we used data from 60 patients, 48 of whom completed the questionnaires twice (at the final visit and a few days later) for test–retest analysis. The mean age was 63.5 years and patients had been experiencing their symptoms for 2 years (median; range 0.2–40 years) (Table 1). Considering the returned baseline questionnaires, 2% of the MHQ items was initially missing (Table 2). The mean ± SD MHQ total score for surgical patients increased from 48 ± 14 at baseline to 75 ± 18 at 1 year ($p \leq 0.001$). These patients also showed significant improvements in the DASH ($p \leq 0.001$) and in the SF-12 physical health scores ($p \leq 0.001$), whereas no significant improvements were seen in the SF-12 mental health scores ($p = 0.71$) and in key pinch ($p = 0.64$). In the conservative group, no treatment effect was observed since neither the MHQ, the MHQ subscales, the DASH, the SF-12, nor the key pinch showed statistically significant changes ($p > 0.3$ for all measures).

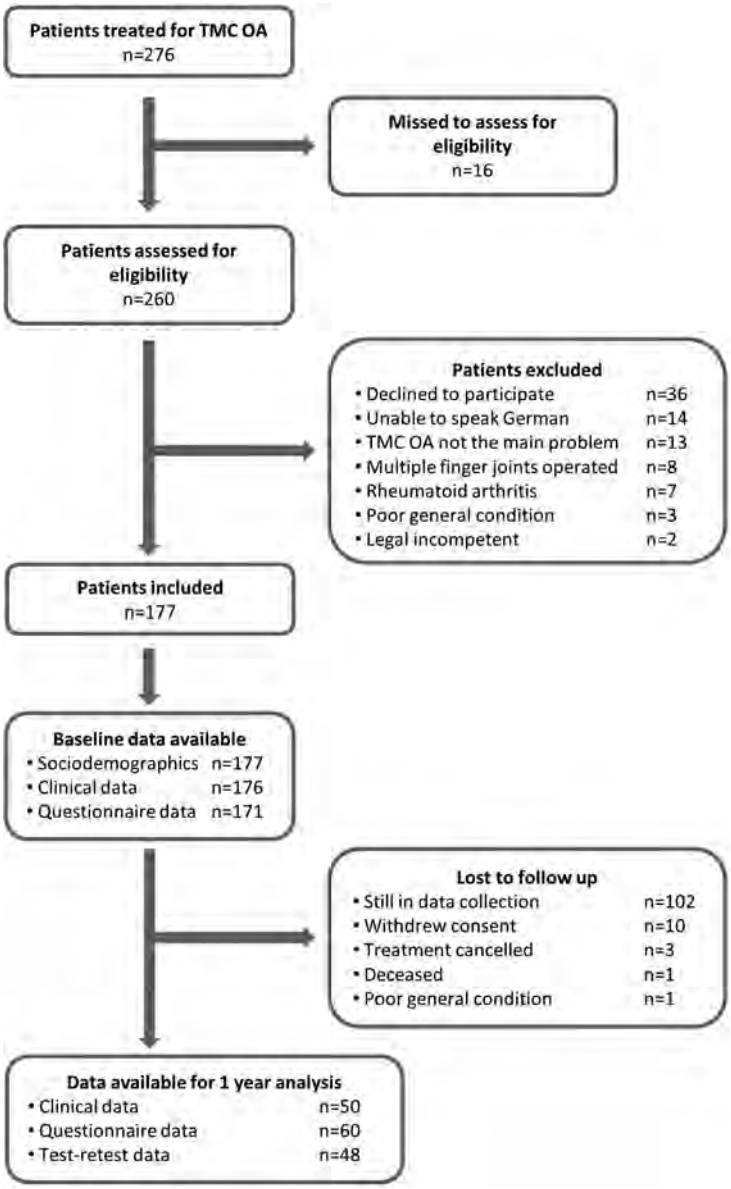

Figure 1 Patient selection diagram. TMC = trapeziometacarpal joint; OA = osteoarthritis

Reliability

Test–retest reliability was high for the MHQ and its subscales, with the ICC ranging between 0.85 (hand function and aesthetics) and 0.95 (total score) (Table 2). Internal consistency for the MHQ subscales showed a Cronbach's alpha range of 0.77 - 0.89. The measurement error of the MHQ total score (SEM) was 3.9 (Table 2), resulting in an SDC of 11 points (Table 3).

Table 1 Baseline characteristics of 177 patients with TMC OA*

Characteristic	Value
Female sex, no. (%)	145 (82)
Age, years	63.5 (9.2)
Symptom duration, median (range) years	2.0 (0.2-40)
Treatment, no. (%)	
Scheduled for surgery	109 (62)
Conservative	68 (38)
Drug intake; no. (%)	63 (37)
MHQ total score	53 (16)
MHQ hand function	55 (18)
MHQ ADL	56 (22)
MHQ work	56 (21)
MHQ pain	59 (18)
MHQ aesthetics	74 (26)
MHQ satisfaction	34 (21)
DASH score	43 (18)
SF-12 physical health score	39 (8)
SF-12 mental health score	50 (12)
Key pinch, kg	3.6 (2.1)

* Values are the mean ± SD unless indicated otherwise
TMC = trapeziometacarpal; OA = osteoarthritis; MHQ = Michigan Hand Outcomes Questionnaire; ADL = activities of daily living; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; SF-12 = Short Form 12 health survey

Table 2 Reliability, measurement error, and floor/ceiling effects of the MHQ and its subscales, the DASH and the SF-12*

	ICC	Cronbach's α	SEM	Floor effect, %	Ceiling effect, %	Missing items, %†
MHQ hand function	0.85	0.81	6.8	0.6	0.6	
MHQ ADL	0.89	0.89	7.0	0	1.8	
MHQ work	0.94	0.87	6.0	0	3.5	
MHQ pain	0.92	0.77	6.0	0.6	0	
MHQ aesthetics	0.85	0.86	8.5	0.6	19	
MHQ satisfaction	0.88	0.84	8.2	3.5	0.6	
MHQ total score	0.95		3.9	0	0	2
DASH	0.93	0.95	4.4	0	0	3.1
SF-12 physical	0.91		3.0	0	0	1.5‡
SF-12 mental	0.89		3.3	0	0	1.5‡

* MHQ = Michigan Hand Outcomes Questionnaire; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; SF-12 = Short Form 12 health survey; ICC = intraclass correlation coefficient; SEM = standard error of measurement; ADL = activities of daily living
† Missing items are given for each entire questionnaire
‡ Based on all 12 items of the SF-12

Table 3 Responsiveness, minimum important change (MIC), and smallest detectable change for the MHQ subscales, DASH, SF-12, and key pinch strength for 35 patients with TMC joint OA who underwent surgery and attended followup after one year*

	Baseline score, mean ± SD	1-year score, mean ± SD	p	ES	SRM	MIC	SDC†
MHQ hand function	50 ± 19	73 ± 17	≤ 0.001	1.2	1.0	16	19
MHQ ADL	47 ± 20	77 ± 22	≤ 0.001	1.4	1.2	25	19
MHQ work	54 ± 17	70 ± 28	≤ 0.01	0.7	0.6	24	17
MHQ pain	64 ± 16	26 ± 23	≤ 0.001	1.9	1.8	19	17
MHQ aesthetics	71 ± 28	84 ± 22	≤ 0.01	0.5	0.4	1	24
MHQ satisfaction	30 ± 19	70 ± 23	≤ 0.001	1.9	1.5	30	23
MHQ total score	48 ± 14	75 ± 18	≤ 0.001	1.7	1.7	17	11
DASH	46 ± 15	26 ± 20	≤ 0.001	1.1	1.1	22	12
SF-12 physical	37 ± 9.0	45 ± 12	≤ 0.001	0.7	0.7	1	8
SF-12 mental	49 ± 14	50 ± 10	0.71	0.1	0.1	4	9
Key pinch, kg‡	3.5 ± 2.2	3.7 ± 2.0	0.64	0.1	0.1	1.5	

* MHQ = Michigan Hand Outcomes Questionnaire; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; SF-12 = Short Form 12 health survey; TMC = trapeziometacarpal; OA = osteoarthritis; ES = effect size; SRM = standardized response mean; ADL = activities of daily living
† Based on test–retest data from 48 patients ‡ N = 31

Validity

Two convergent construct validity hypotheses, i.e., correlation of MHQ ADL with the DASH ≤-0.7 and correlation of MHQ total score with the DASH ≤ -0.7, were verified, as the correlations of the MHQ ADL subscale and MHQ total score with the DASH were r=-0.76 and r = -0.77, respectively (Table 4). The pain subscale correlated only moderately well with the DASH (r = 0.67), which leads to the rejection of the other convergent construct validity hypothesis (correlation of MHQ pain with the DASH ≥ 0.7). The 2 discriminant construct validity hypotheses, i.e., correlation of MHQ hand function with key pinch strength between 0.5 ≥ r ≥ 0.3 and correlation of MHQ hand function with SF-12 mental health ≤ 0.3 were confirmed by the mild correlation between the hand function subscale and key pinch (r = 0.36) and the poor correlation between hand function and the SF-12 mental health score (r = 0.21), respectively.

Responsiveness

As there was no significant effect of conservative treatment for the MHQ or for any of the other outcome measures, effect size and SRM were only calculated for the surgical group (n = 35). The effect size of the MHQ total score was 1.7 (Table 3). The two hypotheses regarding responsiveness (effect size MHQ total score ≥ 0.8 and effect size MHQ total score greater than the effect size of the DASH) were therefore verified.

Table 4 Construct validity: correlations of the MHQ and its subscales with the DASH, SF-12, and key pinch strength using baseline data*

	MHQ							DASH	SF-12 physical	SF-12 mental	Key pinch (kg)
	Hand function	**ADL**	**Work**	**Pain**	**Aesthetics**	**Satisfaction**	**Total score**				
MHQ hand function	1										
MHQ ADL	0.54†	1									
MHQ work	0.33†	0.57†	1								
MHQ pain	-0.41†	-0.67†	-0.63†	1							
MHQ aesthetics	0.32†	0.27†	0.28†	-0.23‡	1						
MHQ satisfaction	0.62†	0.64†	0.49†	-0.69†	0.40†	1					
MHQ total score	0.70†	0.81†	0.73†	-0.79†	0.59†	0.85†	1				
DASH	-0.44†	-0.76§	-0.65†	0.67§	-0.30†	-0.64†	-0.77§	1			
SF-12 physical	0.23‡	0.45†	0.56†	-0.46†	0.12	0.38†	0.48†	-0.63†	1		
SF-12 mental	0.21¶	0.30†	0.39†	-0.30†	0.32†	0.35†	0.43†	-0.36†	0.03	1	
Key pinch (kg)	0.36§	0.44†	0.25†	-0.32†	0.31†	0.41†	0.46†	-0.36†	0.17#	0.08	1

* MHQ = Michigan Hand Outcomes Questionnaire; DASH = Disabilities of the Arm, Shoulder and Hand questionnaire; SF-12 = Short Form 12 health survey; ADL = activities of daily living

† $p \leq 0.001$

‡ $p \leq 0.01$

§ $p \leq 0.001$; correlations relevant for hypotheses testing

¶ $p \leq 0.01$; correlations relevant for hypotheses testing

$p \leq 0.05$

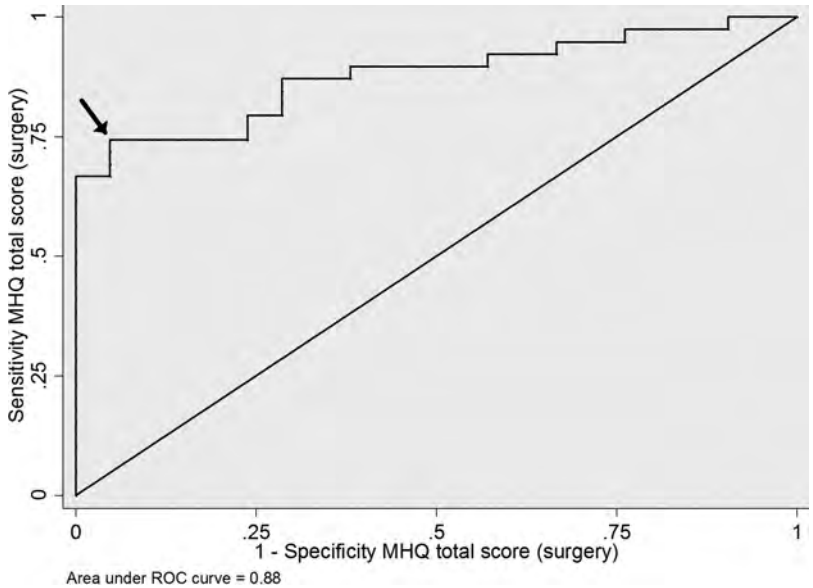

Figure 2 Receiver operating characteristic (ROC) curve for the Michigan Hand Outcomes Questionnaire (MHQ) total score at 1 year for 35 surgical patients

Interpretability

The AUC for the MHQ total score was 0.88 for surgical patients and the resulting MIC was 17 points (Figure 2 and Table 3), which is larger than the SDC of 11 points. We found a ceiling effect for the aesthetics subscale but no floor/ceiling effects were present for the other subscales and the MHQ total score (Table 2).

DISCUSSION

The results of this study provide evidence that the MHQ demonstrates good reliability, validity, and responsiveness in the assessment of patients with TMC joint OA. Regarding reliability and validity, our data support the excellent test–retest reliability of the MHQ that has already been shown in other studies[10, 20]. In our study, internal consistency was satisfactory, whereas item redundancy was apparent in other studies[18].

According to Terwee et al.[43], construct validity can be rated positively if predefined hypotheses are tested and if at least 75% of the results are in correspondence with the hypotheses. As we were able to support 4 out of the 5 hypotheses, we concluded that the MHQ demonstrates good validity for the assessment of patients with TMC joint OA. However, our hypothesis that the MHQ pain subscale correlates highly with the DASH had to be rejected, even though the correlation coefficient of 0.67 was quite strong. This slightly weaker correlation could be due to the fact that only 3 items out of 30 in the DASH are about pain, while the other 27 items concern ADL. Other studies[10, 12] investigating patients with various hand disorders found similar, but somewhat poorer, correlations between the MHQ and the DASH.

In terms of responsiveness, large effect sizes in the surgical group were shown for the MHQ total score, as well as for the pain and satisfaction subscales. The lowest effect sizes seen in our group were related to the MHQ aesthetics subscale. This fact, combined with the relatively high baseline scores and the ceiling effect, indicates that the appearance of the hand may not be as important to patients with TMC joint OA as it is to patients with rheumatoid arthritis[18]. On average, patients who underwent metacarpophalangeal joint arthroplasty for rheumatoid arthritis had baseline values in the MHQ aesthetics subscale 40 points lower than our patients, and in that group the SRM of 1.2 was very high[18].

Our data show a higher effect size and SRM of the MHQ total score than the DASH. Better responsiveness of the MHQ compared with the DASH has also been shown in other studies investigating patients with finger injuries[24], carpal tunnel syndrome, and wrist pain[21]. The poorer responsiveness of the DASH might be because the score is influenced by function/dysfunction of the elbow and shoulder joints.

The medium effect size of the SF-12 physical health score indicates that patients who had undergone surgery for their TMC joint OA also experienced a moderate improvement in their quality of life. The SF-12 should not be used as a single outcome measure in patients with thumb or hand OA, but rather it is recommended as an additional tool to investigate the impact of treatment on the patient's quality of life perception[31, 44].

Regarding interpretability, the present study showed that the MHQ allows an appropriate distinction between improved and unimproved patients. The large AUC attests to the discriminative ability of the MHQ. Similar AUCs were found for patients with rheumatoid arthritis following silicone metacarpophalangeal joint arthroplasty and carpal tunnel syndrome[19]. However, we found MIC values in our population different from those reported by Shauver and Chung in their patients mentioned previously[19]. Possible reasons for this are the different conditions in the patient groups and the disparate methods used to calculate the MIC. Shauver and Chung[19] used the satisfaction subscale of the MHQ as an anchor for the ROC curve, whereas we used an additional question regarding perceived change of the thumb condition as the external criterion, since this is recommended in the literature[36, 45].

Beside measurement properties, other aspects such as the administration mode and associated costs have to be considered when choosing a questionnaire. The time to complete the MHQ is between 8 and 20 minutes[20, 46] and the questionnaire with the scoring algorithm as well as an Excel scoring sheet is freely available[28]. Patients perceived the MHQ to be more complex to understand and complete than, for example, the DASH[46]. In order to avoid these issues, the BriefMHQ has recently been developed[16, 17]. The BriefMHQ shows similar measurement properties to the original version in a population including patients with rheumatoid arthritis, TMC joint OA, carpal tunnel syndrome, and distal radius fracture[16]. However, the BriefMHQ is not able to produce subscale scores or distinguish between the 2 hands. It is intended as a more efficient tool for clinical settings but not for research[47]. Despite indicating item redundancy, use of the original MHQ is still advocated, as it provides a more comprehensive analysis of the patient's condition[16]. In addition, the full MHQ can assess the 2 hands separately, so that stratification for hand dominance or the affected hand is possible[18]. Overall, the advantages regarding measurement properties, multidimensionality, and hand differentiation of the original MHQ may predominate over its brief version in scientific settings.

This study has some limitations. For the test–retest analysis, data from only 48 patients were available. For responsiveness and MIC, only the data from the 35 surgical patients were used because there was no statistical treatment effect in the conservative group. This approach reduced the sample size and the transferability of the results to patients treated conservatively. As we only intended to study reliability of the MHQ and not of key pinch, we were not able to show data for the ICC, SEM, and SDC for the latter. However, previous studies have indicated high test– retest reliability of key pinch with r being > 0.8[48, 49]. Furthermore, our patients had different surgical and conservative treatment. For that reason, we cannot draw any conclusions about the effect of a specific treatment option, which was, however, beyond the scope of this study. Further comparisons with other hand-specific questionnaires such as the Australian/Canadian Hand Osteoarthritis Index[50], the Patient-Rated Wrist Evaluation[51], and the Patient Evaluation Measure[52] are indicated in order to find the best questionnaire for each purpose and target population.

In conclusion, this study evaluated the measurement properties of the MHQ with the help of the DASH and SF-12. For patients with TMC joint OA who underwent surgery or who were conservatively treated for their condition, our results indicate good reliability and validity. Additionally, the MHQ demonstrated high responsiveness for the patients who underwent surgery. Based on these results, we can recommend the MHQ as a suitable assessment instrument for patients with TMC joint OA.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Ms Marks had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Marks, Audigé, Herren, Schindele, Nelissen, Vliet Vlieland.

Acquisition of data. Marks, Herren, Schindele.

Analysis and interpretation of data. Marks, Audigé, Vliet Vlieland.

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CHAPTER **FIVE**

DETERMINANTS OF PATIENT SATISFACTION AFTER ORTHOPEDIC INTERVENTIONS TO THE HAND: A REVIEW OF THE LITERATURE

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Miriam Marks
Daniel B Herren
Thea PM Vliet Vlieland
Beat R Simmen
Felix Angst
Jörg Goldhahn

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ABSTRACT

Treatment effectiveness is increasingly evaluated from the patients' perspective. However, the interpretation of satisfaction is complex because the patient's perception of a satisfactory outcome is influenced by numerous factors. The objective of this study was to identify which factors are associated with patient satisfaction after orthopedic interventions to the hand. A literature review was conducted, including studies on determinants of satisfaction with treatment outcome or unspecified overall satisfaction of patients with hand problems. The results indicate that patient satisfaction is determined by multiple factors. There is moderate evidence that pain/symptoms, activities of daily living/function, aesthetics, and embodiment influence patient satisfaction. Furthermore, data indicate a correlation of strength, range of motion, fulfillment of expectations, deformity, workers' compensation, and length of follow-up with satisfaction. Knowledge about these determinants may lead to a more detailed decision-making process, thus contributing to improved treatment outcomes and cost-effectiveness.

Level of Evidence V

INTRODUCTION

After orthopedic interventions to the hand, objective parameters, such as range of motion (ROM), strength, and radiological findings, have often been assessed to quantify the outcome of the intervention. In recent years, subjective results based on self-assessment of function, activities of daily living (ADL), quality of life, and patient satisfaction have emerged as increasingly important outcome variables after orthopedic interventions. However, numerous studies have shown that objective parameters do not necessarily correlate with the patient's perception of treatment success. Several researchers have described the discrepancy between objective and subjective outcome assessments after orthopedic interventions to the hand[1-5]. For example, Mandl et al.[1] revealed that objectively quantified outcomes in patients after metacarpophalangeal (MCP) arthroplasty are not necessarily associated with the satisfaction of the patient. Specifically, strength and ROM showed only low-to-moderate nonsignificant correlations with patient satisfaction. MacDermid et al.[3] support Mandl et al.[1] in that they found no significant correlations between strength, ROM, radiographic findings, and patient satisfaction in patients after trapezial arthroplasty. Additionally, in patients with distal radius fractures, no significant correlation between ROM and the patient-rated wrist evaluation[4] could be shown. van Oosterom et al.[2], furthermore, could not prove a strong correlation between impairment ratings in patients with multiple finger fractures and function measured with the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire. However, Chung and Haas[6] found a significant correlation between strength, ROM, and satisfaction with strength and ROM, respectively. According to these findings, the use of patient-reported outcome for assessing the individual function of patients in their daily life is emphasized[2]. This statement is supported by Goldhahn et al.[5] who recommended using both objective and subjective outcome assessments in patients with distal radius fracture.

Although the value of measuring patient satisfaction has been increasingly emphasized, its interpretation is complex because of the potential influence of a variety of, so far, poorly defined factors on the patients' perception of a satisfactory outcome[7]. Weaver et al.[8] defined treatment satisfaction as ''a recipient's rating of or report on salient aspects of the process and the results of his or her treatment experience according to predetermined criteria.'' Hall and Dornan[9] defined 11 dimensions of care that patients evaluate when they are asked about their satisfaction. These dimensions include aspects of processes, such as facilities, continuity of care, humaneness, and competence, as well as the aspect of satisfaction with the outcome of care.

PURPOSE OF THE STUDY

Although assessing patient satisfaction is becoming more and more important, evidence about factors that determine the subjective treatment success is still insufficient. For that reason, the objective of this narrative review was to identify factors that are associated with patient satisfaction after orthopedic interventions to the hand.

METHODS

A literature search was conducted using MEDLINE, the Cochrane Library, OTseeker, PEDro, CINAHL, PsycINFO, and EMBASE until November 2009. The search comprises the terms patient

satisfaction, treatment satisfaction, subjective outcome, and patient reported outcome in combination with determinant or influence or predictor or predict. All terms were combined with hand or wrist or finger or thumb (Figure 1). Limits were set for English, German, and Humans.

All studies investigating determinants of satisfaction with treatment outcome or unspecified overall satisfaction after orthopedic interventions for hand problems were included in the review.

Studies about satisfaction with aspects of processes, such as facilities, continuity of care, humaneness, and competence, as well as studies assessing satisfaction with a treatment without investigating the relationship between outcomes and satisfaction, were excluded.

All studies meeting these criteria were considered, regardless of their methodological quality. The search and article selection were done by the main author. For the article selection, the titles and abstracts were firstly screened to ascertain that they were relevant for the review. If so, the full texts were analyzed, and the decision for inclusion or exclusion was made. References were checked for additional relevant studies.

The resulting articles were reviewed for independent variables, which have a correlation to or predict patient satisfaction. The quality of each study was rated according to the Structured Effectiveness Quality Evaluation Scale (SEQES)[10]. The SEQES scores range from 0 to 48 with higher scores indicating higher methodological quality.

Concerning the strength of the association of independent variables and patient satisfaction, correlation coefficients were extracted, if available. $r \leq 0.25$: little to no correlation; $0.26 \leq r \leq 0.5$: mild correlation; $0.51 \leq r \leq 0.75$: moderate correlation; and $r \geq 0.76$: good correlation[11].

The statistical methods used in the studies for assessing variables and their relationship to patient satisfaction were quite heterogeneous, thus making it impossible to compare the data quantitatively for a meta-analysis. For this reason, the results are displayed descriptively.

RESULTS

The literature search yielded 296 articles in different databases (Figure 2). Of these, 263 were excluded after reading the title and abstract. After reading the full texts, 17 articles[1, 3, 12-26] were included in the final analysis.

The 17 articles examined the association of 25 independent variables with patient satisfaction. In 12 articles, the aim of the study was to investigate the factors influencing patient satisfaction, whereas in the remaining five studies, the investigation of factors influencing

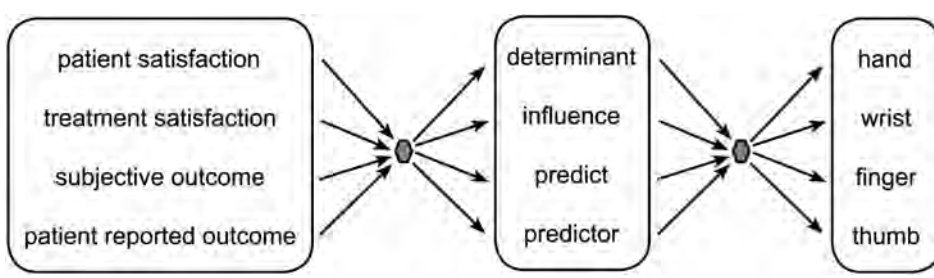

Figure 1 Search strategy. All terms of the three boxes were combined with AND

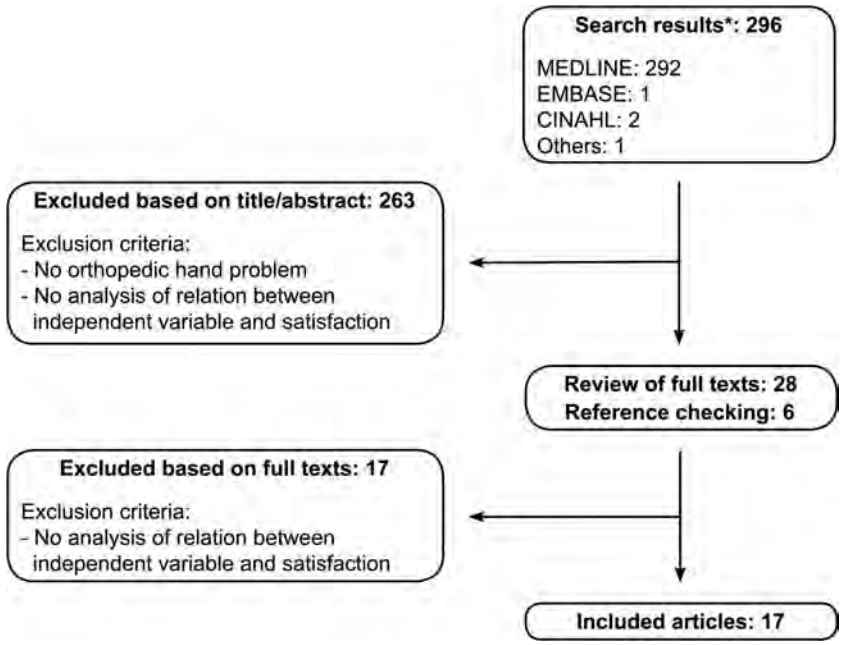

Figure 2 Quorum diagram of article selection process
*Inclusion criteria: satisfaction with treatment outcome or not specified overall satisfaction and studies involving patients with any orthopedic hand problem

satisfaction was not the primary objective. The methodological quality of the studies ranged from 10 to 32 points of 48 on the SEQES scale.

In the studies, 918* subjects were investigated overall, receiving the following interventions: carpal tunnel release (546 patients), elective hand surgery (122 patients), MCP arthroplasties (80 patients), conservatively managed distal radius fractures (74 patients), hemiresection interposition arthroplasties of the distal radioulnar joint (52 patients), trapezial arthroplasties (25 patients), and partial wrist denervation (19 patients).

The correlation coefficients between the investigated factors and satisfaction are shown in Table 1. The factor most related to satisfaction is pain/symptoms showing low-to-good correlation coefficients (r = 0.01 - 0.87) followed by ADL/function (r = 0.14 - 0.86) and aesthetics (r = 0.6 - 0.7). For the factor "alcohol use," only the regression coefficient with $\beta = 3.1$ ($p = 0.002$) is given[26].

The factors studied among the greatest populations were age, pain/symptoms, and psychological factors. The least studied factors were number of hand problems and length of follow-up. A detailed description of each study and an appraisal of the level of correlation can be found in Appendix 1.

* The following studies investigated patients from the same population: Katz et al. 2001[26]; Bessette et al. 1997[23, 25]; Hobby et al. 2005[12, 22]; Anzarut et al. 2004[20] and Jaremko et al. 2007[19]; for calculation of the total sample size, the population of these studies was only taken once. Regarding the studies of Katz et al. 2001[26] and Bessette et al. 1997[23, 25], the number of 250 subjects was taken, reflecting the surgical cohort of the Maine carpal tunnel study.

Table 1 Studies investigating the influence of different factors on patient satisfaction

	Study	Number of Subjects	Correlation Coefficient (r)	SEQES
Pain / symptoms	Bain et al.[17]	52	0.87	18
	MacDermid et al.[3]	25	0.78**	14
	Kadzielski et al.[18]	49	0.63***	27
	Mandl et al.[1]	26	0.46*- 0.67**	10
	Katz et al.[26]	241	0.01 - 0.18*	24
	Lozano Calderón et al.[16]	49	/	17
	Hansen & Larsen[24]	101	/	17
ADL / function	Goldfarb et al.[15]	36	0.86***	18
	Bain et al.[17]	52	0.69	18
	MacDermid et al.[3]	25	-0.02 to 0.81**	14
	Mandl et al.[1]	26	0.12 - 0.56	10
	Katz et al.[26]	241	0.14 - 0.22**	24
	Weinstein & Berger[21]	19	/	11
Aesthetics	Mandl et al.[1]	26	0.60**- 0.70**	10
	Goldfarb et al.[15]	36	0.69***†	18
Strength	Bain et al.[17]	52	0.71	18
	Mandl et al.[1]	26	0.03 - 0.37	10
	MacDermid et al.[3]	25	0.11 - 0.29	14
	Katz et al.[26]	241	0.21	24
	Lozano Calderón et al.[16]	49	/	17
Fulfillment of expectations	Hudak et al.[13]	122	0.53 - 0.69	21
	Kadzielski et al.[18]	49	0.36**	27
ROM	Bain et al.[17]	52	0.60	18
	MacDermid et al.[3]	25	0.19 - 0.35	14
	Mandl et al.[1]	26	0.20 - 0.24	10
	Burgess et al.[14]	18	/	17
Embodiment	Hudak et al.[13]	122	-0.54***	21
Deformity	Mandl et al.[1]	26	0.30 - 0.50	10
	Goldfarb et al.[15]	36	/	18
	Burgess et al.[14]	18	/	17
Workers´ compensation	Bessette et al.[25]	202#	0.37***†	24
	Hudak et al.[13]	122	0.09	21
	Katz et al.[26]	241#	/	24
Length of follow-up	MacDermid et al.[3]	25	-0.38	10
Radiographic findings	Bain et al.[17]	52	-0.31 to 0.05	18
	MacDermid et al.[3]	25	-0.30 to 0.22	14
	Jaremko et al.[19]	74#	/	32
	Anzarut et al.[20]	74#	/	30
Reasons for surgery	Bessette et al.[23]	220	0.16* - 0.31*	23
Psychological factors	Lozano Calderón et al.[16]	49	-0.25*	17
	Katz et al.[26]	241#	-0.24**	24
	Hudak et al.[13]	122	-0.07 - 0.11	21
	Hobby et al.[12]	97	/	22
	Bessette et al.[25]	202#	/	24
Physical health	Katz et al.[26]	241	-0.22**	24

(Continued on next page)

Table 1 (continued)

	Study	Number of Subjects	Correlation Coefficient (r)	SEQES
Age	Katz et al.[26]	241	-0.18*	24
	MacDermid et al.[3]	25	0.06	14
	Hudak et al.[13]	122	0.06	21
	Lozano Calderón et al.[16]	49	/	17
	Hobby et al.[22]	97	/	21
Number of hand problems	MacDermid et al.[3]	25	0.18	14
Social status	Hudak et al.[13]	122	-0.13	21
	Lozano Calderón et al.[16]	49	/	17
	Katz et al.[26]	241	/	24
Sensibility	Katz et al.[26]	241	-0.02 to -0.04	24
Comorbidities	Katz et al.[26]	241	0.02	24
Disease	Katz et al.[26]	241	/	24
Intervention	Katz et al.[26]	241	/	24
Marital status	Lozano Calderón et al.[16]	49	/	17
	Katz et al.[26]	241	/	24
Physical signs	Katz et al.[26]	241	/	24
Gender	Lozano Calderón et al.[16]	49	/	17
	Hansen & Larsen[24]	101	/	17
	Bain et al.[17]	52	/	18
	Hobby et al.[22]	97	/	21
	Katz et al.[26]	241	/	24
Drinking / smoking	Katz et al.[26]	241	β = 3.1** (alcohol use)	24

DISCUSSION

The results indicate that a number of factors play a role in determining patient satisfaction, with some of them beyond the influence of the hand surgeon and therapist and others guidable through the physician/therapist. However, as can be seen from Table 1 and Appendix 1, only a small number of studies can prove a good correlation between a factor and patient satisfaction. This might be because of methodological issues of some studies, such as small sample sizes, and indicates that more research is needed in this field.

In the context of assessing the patient's view of an intervention, the International Classification of Functioning, Disability and Health (ICF) has gained increasing relevancy. The ICF offers a comprehensive understanding of the individual health condition based on body functions and structures, activities, participation, personal and environmental factors and provides a scientific base for studying health, health-related states, outcomes, and the related determinants[27]. Not only the health condition of an individual but also his/her satisfaction with treatment is influenced by factors relating to all these categories mentioned above. The determinants revealed in this literature review could be effectively classified into five ICF categories. The results show that factors of every dimension may have an impact on treatment satisfaction, although most of them are related to body functions/body structures (Figure 3).

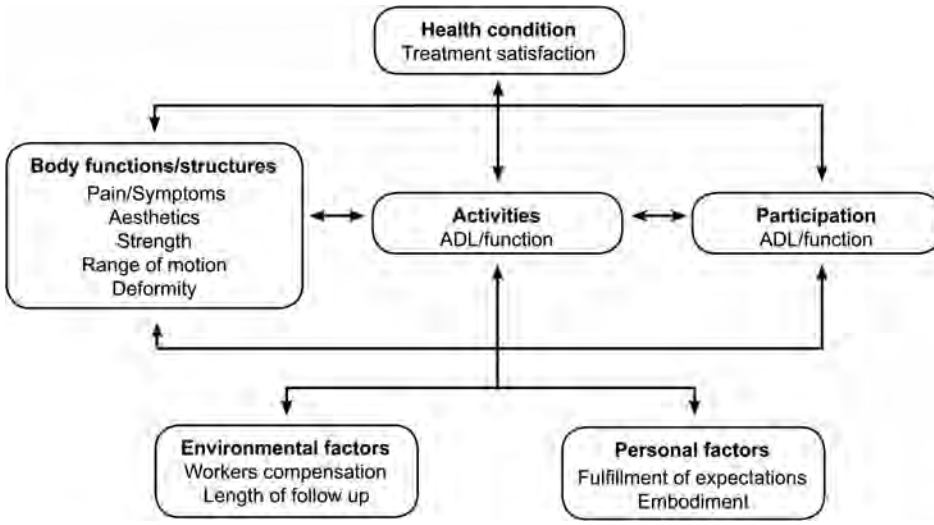

Figure 3 Categorization of all factors according to the International Classification of Functioning, Disability and Health concept[27] where at least mild correlations between the factor and satisfaction could be shown. Graph was adapted with agreement from the World Health Organization. ADL = activities of daily living.

This may be because of the fact that these factors are the ones studied most often, whereas others such as environmental and personal factors are less investigated. Further research assessing the influence of factors related to these categories is needed.

According to the ICF, the factors' symptom or pain improvements could be classified into the category of body functions/body structures. Their correlation with patient satisfaction is rated differently with a trend toward increased satisfaction with pain/symptom improvement. These findings are supported by Jackson et al.[28] who established that symptom improvement increased satisfaction in patients presenting a physical symptom. Another factor, which could be classified into the ICF category body functions/body structures, the postoperative aesthetics, is also regarded as an important parameter that may contribute to satisfaction[1,15]. These findings are confirmed by Mandl et al.[29] and Synnott et al.[30] who found that a very important expectation of patients after MCP joint replacement was to improve the appearance of their hand.

Deformity, which mildly correlates with satisfaction, might also be associated with aesthetics. Synnott et al.[30] hypothesized that the correction of the MCP deformity may be the cause for improved appearance of the hand, which in turn, influences patient satisfaction.

Strength and ROM seem to have a correlation with patient satisfaction although there is a great diversity in the correlation coefficients ranging from 0.11 to 0.71 and 0.19 to 0.6, respectively. Chung and Hass[6] defined cutoff points for grip strength, key pinch strength, ROM, and satisfaction with these objective parameters after surgery for distal radius fractures. They found these points to be at 65%, 87%, and 95%, respectively, of the function of the other unaffected hand. These findings highlight the importance of measuring objective outcomes and defining values for distinguishing between satisfied and dissatisfied patients also for other hand problems.

The role of functional improvements, measured by different assessments, is discussed differently in the investigated articles. A reason of these different results might be the various measurement methods of ADL/function, highlighting the need for standardized, valid, and reliable methods for assessing function. However, a trend toward greater satisfaction with increased function could be seen. This is supported by Jackson et al.[28] who revealed that functional status had an independent effect on satisfaction. Another study[31] that determined the reasons why patients seek MCP joint arthroplasty could show that impaired function was the most significant predictor of choosing MCP reconstruction.

In the ICF category of environmental factors, the impact of receiving money during disability can be confirmed by Weinstein and Berger[21] who found that a need for subsequent procedures for pain relief after partial wrist denervation was significantly associated with workers' compensation claims. Further studies also indicate that patients receiving workers' compensation were less satisfied with the results of a revision trapeziometacarpal joint arthroplasty[32] and that the most influential predictor of pain and disability was third-party compensation[33].

Another factor belonging to the ICF category of environmental factors is the time between treatment and assessment. There is mild evidence that a longer follow-up is associated with a poorer outcome[3]. However, it remains unclear, if the worse rating corresponds to an effective worse condition of the patients or just a worse perception of the condition.

Besides satisfaction, the fulfillment of preoperative expectations is an increasingly important assessment of treatment success. The conclusion that patients seem to be more satisfied if preoperative expectations are fulfilled[13, 18] is further confirmed in other studies with patients with orthopedic and abdominal surgeries[34], patients seeking out-of-hours care[35], adults presenting a physical symptom[28], and patients undergoing total hip and knee arthroplasty[36, 37]. In the field of hand surgery and therapy, sufficient evidence about the importance of expectations is still rare. Patients are often unaware of the severity of an injury and the complexity of treatment[38]. They expect that if just a small part of the body is injured that it can be quickly managed with a simple surgical procedure or conservative treatment. O'Brien and Presnell[38] highlight the importance of detailed patient education about the injury and the resulting intervention to lead to a better adherence to the treatment. The correlation between expectations and satisfaction substantiate the relevance of the decision-making process before an intervention. The physician and therapist have to be aware of the patients' expectations and should guide them to realistic assumptions of the treatment outcome. There is a need for developing a standardized assessment tool that can be routinely used in daily practice for evaluating patients' expectations before the treatment and their fulfillment when the treatment is finished.

A phenomenological concept, not widely known in the field of hand surgery, was investigated by Hudak et al.[13, 39, 40]: Embodiment ''serves to de-emphasize the physical body with its assumed subject-object split and instead to create an understanding of our bodies as they are given to us: agents of our consciousness that are capable of action on the plane of our experience that we have to call the ''physical" world[41]. Gadow[42] elucidated four different states of embodiment representing the unity or disunity between the body and self. Hudak et al.[39] suggested that patients satisfied with their treatment had a relative lack of consciousness of the affected hand, leading to a unity of body and self. A body-self unity means that a person takes his body for granted without thinking of it because the body or parts of it are unproblematic[39]. If

body-self unity can be achieved after surgery, even when the clinical outcome is poor, a patient could be satisfied. Nevertheless, the authors stated that it remains unclear whether body-self unity leads to satisfaction or whether satisfaction facilitates body-self unity. However, they recommend consideration of the patient's embodiment as an important aspect of treatment outcome and suggest interventions to facilitate body-self unity[13].

The influence of different psychological factors is discussed diversely in the investigated articles. Several authors[13, 25] could not find an association between measures of psychological state and functional improvement or satisfaction after surgery. By contrast, Lozano Calderon et al.[16] could show that depression significantly affected satisfaction, accounting for 25% of the variance in the satisfaction score. Furthermore, depression and ineffective coping skills combined with static numbness accounted for 54% of the variability of perceived disability (DASH score). Articles other than hand studies have also confirmed the effect of psychological factors. Ineffective coping skills, lower personal control, somatization, serious illness worries, depression, and anxiety are shown to have an impact on the functional outcome or on satisfaction[43-45]. Awareness of the influence of the psychological state may help the physician and hand therapist achieve a better treatment outcome, probably by considering accompanying psychological therapies.

Factors that cannot be influenced by the health care provider, such as age and gender, are discussed diversely. Although significant correlations could not be proved, the included articles, as well as studies dealing with other patients, suggest that age has at least a slight influence on patient satisfaction with older people being more satisfied than younger ones[9, 13, 28, 46-48]. This is in contrast to the study of Hobby et al.[22], who found out that satisfaction appeared to be lower in patients older than 70 years. Moreover, in hand surgery and therapy, it is not proven that gender affects patient satisfaction, although results of other studies indicate that it influences patient satisfaction[28] and independently predicts the DASH score with females having higher scores than males[43].

Furthermore, aspects of social status, such as education and income, did not predict satisfaction in the included articles, whereas other authors have shown an influence of income[47] and education[13, 48, 49] on patient satisfaction.

In areas other than hand surgery and therapy, some other factors influence patient satisfaction, such as shared decision making[50] and the information given to the patient[28, 48]. Furthermore, the influence of hospital-related factors, such as friendliness of the staff[46, 48, 51, 52], duration of waiting times[46], time spent with the provider[46, 53], state of facilities[48], and food[48, 52], have to be kept in mind. These aspects may also affect patient satisfaction, but the investigation of them was beyond the scope of this study. Nevertheless, in daily practice, the treatment environment and the behavior of the staff should be considered to make patients more satisfied. A scientific investigation of these factors in the field of hand surgery and therapy remains to be done.

Jackson et al.[28] suggested a model to explain patient satisfaction in patients presenting a physical symptom. The authors showed that fulfillment of expectations, age older than 65 years, better functioning, symptom improvement, and no need for another clinical visit for the symptom could explain 38% and 40% of the variance in patient satisfaction at two weeks and three months postvisit, respectively. Another model was proposed by Katz et al.[26] for patients after carpal tunnel release. By including functional limitations, mental and physical health status, tobacco and alcohol use, day pain, and bilateral symptoms, they found an explained variance of 15%. Adding work-related factors (attorney involved, forceful, repetitive work) to this model,

the variance increased to 27%. Besides these very helpful approaches, there is a need for assessing patient satisfaction in the field of hand surgery and therapy more comprehensively.

Some limitations have to be acknowledged: Due to the heterogeneous measurement of the variables, an analytical approach was impossible, limiting the validity of this review. Satisfaction, for example, was measured using various approaches, such as different Likert scales, a visual analog scale, or the Michigan Hand Questionnaire satisfaction subscale, which precluded statistical comparisons. Further issues are the different approaches for calculating correlation coefficients and the lack of correlation coefficients in some studies complicating an evident conclusion. Given that most of the studies are observational studies without comparison group, the quality of some studies is quite low with SEQES scores of eight studies being below 20 points of 48 points. Therefore, caution is advised in generalizing the results without proving the evidence in further studies.

CONCLUSIONS

To conclude, the findings of the current narrative review provide moderate evidence that the factors pain/symptoms, ADL/function, aesthetics, and embodiment have an influence on patient satisfaction. Furthermore, the data indicate a correlation of strength, ROM, fulfillment of expectations, deformity, workers' compensation, and length of follow-up with patient satisfaction. For daily practice, it can recommend that a treatment goal should be relief of pain or symptoms, restoration of the individual's important functions while taking the appearance of the hand and the body-self unity into account. In addition, restoration of strength, ROM, and deformity should be addressed. However, besides evaluating these objective outcomes, the impact of the patients' individual expectations, if they are involved in workers' compensation, and the time between treatment and follow-up have to be considered.

Knowledge about these factors may lead to a more detailed decision-making process and higher patient adherence, thus contributing to improved treatment outcomes and cost-effectiveness[7]. Nevertheless, further well-designed prospective trials are needed to quantify the influence of possible determinants on satisfaction in patients with hand problems and to establish a standardized method of assessing patient satisfaction.

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APPENDIX 1

Table A-1 Description of studies investigating correlations between independent variables and satisfaction

Factor	Author	Methods
Pain / symptoms	Bain et al.[17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint Postoperative pain and overall satisfaction rated on a VAS Pearson's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction and self-reported improvement of Pain measured by a VAS Pearson's correlation coefficient
	Kadzielski et al.[18]	49 patients with carpal tunnel release Modified DASH to assess symptom relieve, satisfaction measured by a VAS Spearman's correlation coefficient
	Mandl et al.[1]	26 RA patients with 160 MCP joint replacements MHQ postoperative pain subscale Spearman's correlation coefficient
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale, Postoperative symptoms measured on the Symptom Severity Scale Spearman's correlation coefficient
	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
	Hansen & Larsen[24]	101 patients with carpal tunnel release, Boston questionnaire, Satisfaction measured by a VAS
ADL/ function	Goldfarb et al.[15]	36 RA patients with 208 MCP arthroplasties MHQ functional and satisfaction subscale Simple regression analysis
	Bain et al.[17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint Daily activities and satisfaction rated on a VAS Pearson's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Hand function measured by JTHF and PPT satisfaction, improvement of ADL ability, hand and wrist movement and strength measured on a VAS Pearson's correlation coefficient
	Mandl et al.[1]	26 patients with RA received 160 MCP joint replacements, MHQ, JTHF Spearman's correlation coefficient
	Katz et al.[26]	241 patients with carpal tunnel release Functional Limitation Scale, Satisfaction measured by a 5-point Likert scale Spearman's correlation coefficient
	Weinstein & Berger[21]	19 patients received 20 partial wrist denervations Functional outcome measured by the DASH

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Results	SEQES	Correlation
Change of pain correlated with satisfaction: r=0.87, No information about significance	18	Good
Correlations with satisfaction: r=0.78**	14	Good
Relieved symptoms correlated with satisfaction: r=0.63***	27	Moderate
Correlation with satisfaction: r=0.46*-0.67**	10	Mild to moderate
Correlation between dissatisfaction and Symptom Severity Score r=0.18* and day pain r=0.15*. No correlation between night pain r=-0.06 and duration of symptoms r=0.01	24	None
Absent distal motor and sensory latencies, presence of atrophy, static numbness and EMG findings at follow up do not correlate significantly with satisfaction. No correlation coefficient given.	17	None
Postoperative symptom score determines patient satisfaction: OR=3.05** No correlation coefficient given	17	/
Function correlated with satisfaction: r=0.86*** †	18	Good
Correlation between satisfaction and change of daily activities: r=0.69, No information about significance	18	Moderate
Correlation between satisfaction and JTHF subtest ´checkers` r = -0.68*, movement r=0.81**, strength r=0.73**, ADL ability r=0.73**. No correlation with JTHF subtests r=-0.35 - -0.02 and PPT r=-0.19- -0.16	14	None to Good
Correlation with satisfaction: r=0.12-0.56; ´hold large light objects` correlates with satisfaction*	10	None to moderate
Correlation between dissatisfaction and functional limitation r=0.22** , exposure to physical stressors at work r=0.19*, no correlation with exposure to keyboard activities r=-0.14	24	None
No correlations between DASH results and satisfaction No correlation coefficient given	11	None

Table A-1 (continued)

Factor	Author	Methods
Aesthetics	Mandl et al.[1]	26 RA patients with 160 MCP joint replacements, MHQ postoperative aesthetic Spearman's correlation coefficient
	Goldfarb et al.[15]	36 RA patients with 208 MCP arthroplasties MHQ postoperative aesthetic and satisfaction subscale Simple regression analysis
Strength	Bain et al.[17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint Strength and overall satisfaction rated on a VAS Pearson's correlation coefficient
	Mandl et al.[1]	26 RA patients with 160 MCP joint replacements Grip strength; Key grip; three-point pinch Spearman's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS, tip and key pinch, grip strength Pearson's correlation coefficient
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale Spearman's correlation coefficient
	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
Fulfillment of expectations	Hudak et al.[13]	122 patients with hand surgery Satisfaction measured by a 9-item questionnaire. Spearman's correlation coefficient
	Kadzielski et al.[18]	49 patients with carpal tunnel release Modified DASH to assess postoperative met expectations; satisfaction measured by a VAS Spearman's correlation coefficient
ROM	Bain et al.[17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint ROM and overall satisfaction rated on a VAS Pearson's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS, thumb extension and abduction, wrist extension and flexion Pearson's correlation coefficient
	Mandl et al.[1]	26 RA patients with 160 MCP joint replacements Sum of active MCP ROM Spearman's correlation coefficient
	Burgess et al.[14]	18 RA patients with 62 revision MCP arthroplasties Patients were asked if they would have surgery again pleased or not displeased
Embodiment	Hudak et al.[13]	122 patients with hand surgery Embodiment assessed by a questionnaire Satisfaction measured by a 9-item questionnaire Spearman's correlation coefficient

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Results	SEQES	Correlation
Correlation with satisfaction: r 0.60**-0.70**	10	Moderate
Aesthetics correlated with satisfaction: r=0.69*** †	18	Moderate
Change of strength correlated with satisfaction: r=0.71 No information about significance	18	Moderate
Correlation with satisfaction: r=0.15-0.29; r=0.18-0.37; r=0.03-0.19	10	None to mild
Correlation with satisfaction: r=0.11; r=0.11; r=0.29	14	None to mild
Grip strength correlates with dissatisfaction: r=-0.21*	24	None
Thumb abduction weakness does not correlate significantly with satisfaction. No correlation coefficient given	17	None
Expectations correlate with global satisfaction: r= 0.53-0.69	21	Moderate
Postoperatively met expectations correlated with satisfaction: r=0.36**	27	Mild
Change of range of motion correlated with satisfaction: r=0.60, No information about significance	18	Moderate
Correlation with satisfaction: r=0.35; r=0.19; r=-0.22; r=0.28	14	None to mild
Correlation with satisfaction: r=0.20-0.24	10	None
Pleased patient showed less residual extensor lag after surgery than displeased patients 17° versus 30°** No difference between the groups for flexion, No correlation coefficient given	17	/
The state of embodiment correlates with satisfaction with care: r=-0.54***	21	Moderate

Table A-1 (continued)

Factor	Author	Methods
Deformity	Mandl et al.[1]	26 RA patients with 160 MCP joint replacements Sum of postoperative ulnar deviation of the 4 MCP Spearman's correlation coefficient
	Goldfarb et al.[15]	36 RA patients with 208 MCP arthroplasties Degree of postoperative MCP ulnar drift, MHQ satisfaction subscale
	Burgess et al.[14]	18 RA patients with 62 revision MCP arthroplasties Patients were asked if they would have surgery again pleased or not displeased
Workers ´ compen-sation	Bessette et al.[25]	202 patients with CTS Satisfaction measured by a 10-item questionnaire Multiple linear regression
	Hudak et al. [13]	122 patients with hand surgery Satisfaction measured by a 9-item questionnaire. Spearman's correlation coefficient
	Katz et al.[26]	241 patients undergoing carpal tunnel release Satisfaction measured on a 5-point Likert scale
Length of follow-up	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS Pearson's correlation coefficient
Radio-graphic findings	Bain et al.[17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint Satisfaction measured by a VAS Pearson's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS, assessment of prosthetic position and wear Pearson's correlation coefficient
	Jaremko et al.[19]	74 patients with distal radius fractures Difference in satisfaction between patients with acceptable and unacceptable values of radiographic deformities
	Anzarut et al.[20]	74 patients with distal radius fractures Radiographic evaluation of dorsal and volar tilt 2 Questions about satisfaction with medical care
Reasons for surgery	Bessette et al.[23]	220 patients with carpal tunnel surgery Patients were asked for reasons for having carpal tunnel surgery and their satisfaction 6 months after surgery Spearman's correlation coefficient
Psycho-logical factors	Lozano Calderón et al.[16]	49 patients with carpal tunnel release CES-D depression, PASS anxiety, PCS ineffective coping skills Pearson's correlation coefficient
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured by a 5-point Likert scale, SF-36 mental subscale score Spearman's correlation coefficient

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Results	SEQES	Correlation
Correlation with satisfaction: r=0.30-0.50	10	Mild
A greater degree of ulnar drift was associated with decreased satisfaction** No correlation coefficient given	18	/
Pleased patient showed less ulnar deviation after surgery than displeased patients 9° versus 30°*** No correlation coefficient given.	17	/
Increased variance of satisfaction by 10% by adding workers compensation to baseline variables r=0.37***†	24	Mild
Workers compensation status does not correlate with satisfaction with care: r=-0.09	21	None
Receiving workers compensation plus an attorney had significantly higher dissatisfaction scores than patients without an attorney or without workers compensation** No correlation coefficient given	24	/
Correlation between the time of follow up since surgery and satisfaction: r=-0.38	10	Mild
No radiographic parameter correlated well with satisfaction: r=-0.31-0.05	18	None to mild
Correlation with satisfaction: r=0.22; r=-0.30	14	None to mild
No significant difference in satisfaction between patients with acceptable and unacceptable radiographic deformities No Correlation coefficient given.	32	None
No significant difference between patients with acceptable and patients with unacceptable dorsal/volar tilt No correlation coefficient given	30	/
Correlation between satisfaction and importance to improve strength r=0.31*, performance at work r=0.25*, ability to grasp and use small objects r=0.21*, sensation in hand and fingers r=0.19*, performance at household tasks r=0.16* and relief of day pain r=0.18*	23	None to mild
CES-D: r= -0.24*; Neither PASS-score nor PCS score present significant predictors of satisfaction	17	None
Mental health correlated with dissatisfaction: r=-0.24**	24	None

Table A-1 (continued)

Factor	Author	Methods
	Hudak et al.[13]	122 patients with hand surgery MHLC beliefs of health-related behaviors, LOT optimism, SCS self-consciousness, CHA depression; global satisfaction question Spearman's correlation coefficient
	Hobby et al.[12]	97 patients with CTS HAD anxiety and depression, Satisfaction measured by a 7-point Likert scale
	Bessette et al.[25]	202 patients with CTS Satisfaction measured by a 10-item questionnaire, MHI
Physical health	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale, Physical health measured with SF-36 Spearman's correlation coefficient
Age	Katz et al.[26]	241 patients undergoing carpal tunnel release Satisfaction measured by a 5-point Likert scale Spearman's correlation coefficient
	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS Pearson's correlation coefficient
	Hudak et al.[13]	122 patients with hand surgery Satisfaction measured by a 9-item questionnaire Spearman's correlation coefficient
	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
	Hobby et al.[22]	97 patients with CTS PEM satisfaction subscale
Number of hand problems	MacDermid et al.[3]	25 patients with 30 trapezial arthroplasties Satisfaction measured by a VAS Pearson's correlation coefficient
Social status	Hudak et al.[13]	122 patients with hand surgery Satisfaction measured by a 9-item questionnaire. Spearman's correlation coefficient
	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale
Sensibility	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale Spearman's correlation coefficient

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	Results	SEQES	Correlation
	No significant correlations between all measures of psychological state and global satisfaction: r=-0.067-0.108	21	None
	No difference in satisfaction between depressed and normal patients, Anxious patients were slightly less satisfied than normal patients** No correlation coefficient given	22	/
	No correlation between MHI score and satisfaction. No correlation coefficient given.	24	/
	Correlation with dissatisfaction: r=-0.22**, Physical health status determines dissatisfaction: β=-3.3***	24	None
	Higher age significantly correlates with dissatisfaction: r=-0.18*	24	None
	Patients >60 years reported higher satisfaction than younger ones*, correlation with satisfaction: r=0.06	14	None
	Age does not correlate with satisfaction r=0.06	21	None
	Age does not correlate significantly with satisfaction. No correlation coefficient given	17	None
	Patients <70 years reported higher satisfaction with treatment* as well as satisfaction with hand outcome* No correlation coefficient given	21	/
	Correlation with satisfaction: r=0.18	14	None
	Education has no correlation with satisfaction with care: r=-0.13	21	None
	The obtained academic degree, numbers of years of education and the occupation do not correlate significantly with satisfaction. No correlation coefficient given	17	None
	Labourers were less satisfied than managers or patients with other occupations*, no difference in dissatisfaction between high school and college No correlation coefficient given	24	/
	No correlation between satisfaction and 2-point discrimination r=-0.04, numbness r=-0.03, tingling r=-0.02	24	None

Table A-1 (continued)

Factor	Author	Methods
Co-morbidities	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale Physical health measured with SF-36 Spearman's correlation coefficient
Disease	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale
Intervention	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale
Marital status	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured by a 5-point Likert scale
Physical signs	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured on a 5-point Likert scale
Gender	Lozano Calderón et al.[16]	49 patients with carpal tunnel release Satisfaction measured by a VAS
	Hansen & Larsen[24]	101 patients with carpal tunnel release Satisfaction measured by a VAS
	Bain et al. [17]	52 patients with 55 hemiresection interposition arthroplasties of the distal radioulnar joint Satisfaction measured by a VAS
	Hobby et al.[22]	97 patients with CTS PEM satisfaction subscale
	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured by a 5-point Likert scale
Drinking / Smoking	Katz et al.[26]	241 patients with carpal tunnel release Satisfaction measured by a 5-point Likert scale

SEQES = Structured Effectiveness Quality Evaluation Scale[10]; VAS = visual analog scale; DASH= Disabilities of the Arm, Shoulder, and Hand Questionnaire; RA = rheumatoid arthritis; MCP = metacarpophalangeal; MHQ = Michigan Hand Questionnaire; EMG = electromyographic; OR = odds ratio; JTHF = Jebsen's Test of Hand Function; PPT = Purdue Pegboard Test; ADL = activities of daily living; ROM= range of motion; CTS = carpal tunnel syndrome; CES-D = Center for the Epidemiological Study of Depression instrument; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophizing Scale; SF-36 = Short Form 36; MHLC= Multidimensional Health Locus of Control Scale; LOT = Life Orientation Test; SCS = Self-Consciousness Scale; CHA = Current Health Assessment;

	Results	SEQES	Correlation
	No correlation with dissatisfaction: r= 0.02	24	None
	No difference in dissatisfaction between diabetic and non-diabetic patients No correlation coefficient given	24	None
	No difference in dissatisfaction between Endoscopic and open release No correlation coefficient given	24	None
	Marital status does not correlate significantly with satisfaction. No correlation coefficient given	17	None
	No difference in dissatisfaction between married and non-married patients or between patients living alone and with others No correlation coefficient given	24	None
	No difference in dissatisfaction between present/absent tinels sign, phalens sign, thenar athrophy	24	None
	Gender does not correlate significantly with satisfaction. No correlation coefficient given.	17	None
	Gender determines patient satisfaction OR=6.30** with males being less satisfied than females. No correlation coefficient given	17	/
	Female patients were more satisfied mean 79% on the VAS than male patients mean 46%** No correlation coefficient given	18	/
	No difference in treatment satisfaction between males and females No correlation coefficient given	21	/
	No difference in dissatisfaction between males and females No correlation coefficient given	24	/
	Drinkers* and Smokers* have higher dissatisfaction scores than non-drinkers and non-smokers, Drinking determines dissatisfaction: β=3.1** No correlation coefficient given	24	/

HAD = The Hospital Anxiety and Depression Scale; MHI = Mental Health Inventory; PEM = Patient Evaluation Measure.

$r \leq 0.25$: no correlation; $0.26 \leq r \leq 0.5$: mild correlation; $0.51 \leq r \leq 0.75$: moderate correlation; $r \geq 0.76$: good correlation[11].

*$p \leq .05$; **$p \leq .01$; ***$p \leq .001$.

† Calculated from R^2.








CHAPTER **SIX**

OUTCOMES OF SURGICAL AND CONSERVATIVE TREATMENT IN PATIENTS WITH TRAPEZIOMETACARPAL OSTEOARTHRITIS AND DETERMINANTS OF PATIENT SATISFACTION – RESULTS OF A PROSPECTIVE COHORT STUDY

Submitted

Miriam Marks
Laurent Audigé
Lisa Reissner
Daniel B Herren
Stephan Schindele
Thea PM Vliet Vlieland



ABSTRACT

Objective To analyze the outcomes of surgical and conservative treatment in patients with trapeziometacarpal osteoarthritis (TMC OA) and to evaluate determinants of treatment satisfaction.

Methods Prospective cohort study of patients with TMC OA who received surgical or conservative treatment. Patients filled out the Michigan Hand Questionnaire (MHQ) at baseline and at 3, 6, and 12 months after the intervention. On a 5-point Likert scale, they reported baseline expectations, expectation fulfillment at each follow up, and satisfaction with the results of treatment. To identify determinants of patient satisfaction at 1 year, we entered these variables at baseline and 1 year, together with sociodemographic variables, into one ordered logistic regression model for surgical patients and another for conservative patients.

Results We included 165 patients, 97 of whom were treated surgically. Surgical patients improved continuously from an MHQ score of 47 ± 15 at baseline to 80 ± 16 at 1 year ($p \leq 0.001$). In the conservatively treated group, an improvement was found between baseline (61 ± 13) and 6 months (68 ± 15; $p \leq 0.001$), but not at 1 year (66 ± 17; $p = 0.055$). Expectations being fulfilled at 1 year was an important determinant of satisfaction in both groups.

Conclusion Surgery leads to a significantly improved outcome up to 1 year. Conservative treatment is significantly effective for 6 months. As fulfillment of expectations was an important determinant of satisfaction in both groups, we emphasize the need to provide comprehensive information prior to any intervention, so that the patient's expectations of treatment outcome are realistic.

INTRODUCTION

After the distal interphalangeal joints, the trapeziometacarpal (TMC) joint is the hand joint most frequently affected by osteoarthritis (OA)[1]. Treatment strategies consist of either surgical or conservative management[2]. Surgical interventions include trapeziectomy alone or in combination with ligament reconstruction (LR), tendon interposition (TI), or both (LRTI). Other surgical options are arthrodesis of the TMC joint, implant arthroplasty, arthroscopic or open debridement of the TMC joint, metacarpal osteotomy, and partial trapeziectomy with or without interposition[3, 4]. Trapezium resection with LRTI is the primary choice for 62% - 68% of American hand surgeons who perform surgery for TMC OA[3, 4]. In terms of pain reduction and restoration of hand function, however, evidence on the superiority of one procedure over another is limited[5-7].

Conservative management includes injections, thumb orthoses, hand exercises, and analgesics[2, 8, 9]. In the conservative treatment of TMC OA, 89% of American hand surgeons prefer corticosteroid injections, while the rest use hyaluronic acid or do not usually give injection[3]. Corticosteroid injections can significantly reduce pain in the short term, with a single injection being effective for about 4 weeks or even up to 6 months[10-13]. There is evidence that thumb orthoses decrease pain and improve hand function in patients with TMC OA[14, 15]. In contrast, exercise therapy seems to have only a minor effect on pain and hand function, although it might increase grip strength for a short time in patients with hand OA[14-16]. In the long-term, however, pain relief from various conservative treatment strategies (drug therapy, physiotherapy, orthoses, and corticosteroid injections) has not been observed[17].

Guidelines for the management of patients with TMC OA suggest conservative treatment initially. Surgery should be considered for patients with severe TMC OA, including severe pain and disability, for patients with high functional demands, and in cases where conservative treatment has failed[2, 17, 18]. However, exactly when patients should undergo surgery has not yet been defined. Deciding on a specific treatment strategy differs between patients, because each case requires a tailor-made approach[2].

Irrespective of the type of intervention, an evaluation of patient satisfaction is becoming increasingly important in assessing treatment outcomes. Satisfied patients are more compliant with treatment and are more likely to return to the same healthcare provider[19, 20]. In hand surgery, it has been shown that pain and function are associated with treatment satisfaction. Furthermore, the appearance of the hand, its strength, range of motion, and expectations fulfilled seem to influence the satisfaction of patients with various hand disorders[21]. A retrospective study including patients with TMC OA after implant arthroplasty found that pain, movement, strength, and functional ability were moderately correlated with satisfaction[22], but no prospective studies investigating the determinants of patient satisfaction after surgical and conservative management of TMC OA are currently available.

The objective of this study was to analyze the outcomes of surgical and conservative treatment in patients with TMC OA and to evaluate the determinants of treatment satisfaction in both groups.

METHODS

This monocenter, prospective cohort study was carried out in the department of hand surgery of an orthopedic hospital and was approved by the local ethics committee.

Patients

Patients were eligible for the study if they had a radiographically confirmed diagnosis of TMC OA and if they underwent either conservative or surgical treatment for that condition in the months from September 2011 to November 2012. Exclusion criteria were: TMC OA was not the main problem at the time of consultation, rheumatoid arthritis, concomitant surgery on other fingers, legal incompetence, poor general condition precluding study participation, previous inclusion in this study for the other hand, and insufficient knowledge of the German language to complete the questionnaires. All eligible patients were asked to participate by their hand surgeon, and were consecutively enrolled in the study after they had given written informed consent.

Treatment strategies

In each case, the surgeon chose the treatment strategy in discussion with the patient. Surgery included trapeziectomy with LRTI or arthrodesis of the TMC joint. Trapeziectomy with LRTI was carried out according to Epping[23], Weilby[24], or Sigfusson and Lundborg[25], whichever method was preferred and routinely performed by each surgeon. In some cases, the surgeon chose a GraftJacket as interpositional material[26]. Additional procedures such as carpal tunnel release and arthrodesis of the metacarpophalangeal (MCP) joint I were also performed, if required. Conservative treatment comprised corticosteroid injections, prescription of analgesics, hand therapy, or splinting.

Some patients were initially treated conservatively but later decided on surgery. Data available until such time were used for the analysis of conservatively treated patients. If patients were operated on during the enrollment phase, they were enrolled again in the surgical group but excluded from this group in the present analysis to prevent confounding from double inclusion.

Outcome measures

An independent examiner assessed patients at baseline, and 3, 6, and 12 months after the start of treatment. Sociodemographic and disease-related data were gathered at baseline. At each study visit, patients underwent a clinical assessment and completed a questionnaire set consisting of the Michigan Hand Questionnaire (MHQ) and the Short Form (SF) 12, version 2.0.

The *MHQ*, developed by Chung et al.[27], is a hand-specific questionnaire which yields results for each hand separately. It consists of 37 items divided into six subscales: hand function, activities of daily living (ADLs), pain, work performance, aesthetics, and satisfaction with hand function. The psychometric properties of the MHQ have been assessed in patients with TMC OA and show overall good reliability, validity and responsiveness[28]. The total score and all six subscale scores are normalized and range from 0 to 100; higher scores indicate better performance, except for the pain subscale, where a higher score denotes more pain. The German version[29] was used for this study and the data for the affected hand were analyzed.

The *SF-12* is a short version of the SF-36 for assessing quality of life. Its twelve questions give two component summary measures of physical health and mental health. The scores range from 0 to 100, with higher scores representing better health, and the norm value being 50 ± 10[30]. Although the full version (SF-36) has been investigated in patients with TMC OA, the SF-12 itself has not[31].

Expectations were recorded at baseline. Patients gave their most important reason for seeking treatment. They indicated whether they expected treatment to deal with the problem, rating

their expectations on a 5-point Likert scale ranging from 'totally fulfilled' to 'not at all fulfilled'. At each follow up, patients were asked if their expectations had been fulfilled and again they answered on a 5-point Likert scale.

At every follow-up visit, we also asked about *satisfaction with the treatment result*, which patients answered on a 5-point Likert scale ranging from 'very satisfied' to 'very dissatisfied'.

Key pinch was assessed in a standardized sitting position using a digital pinch gauge (ELINK, Biometrics Ltd., Gwent, UK). We took the average of three measurements on the affected hand for further analysis.

The evaluation of *active thumb opposition* was based on the Kapandji index, ranging from 1-10[32]. Patients try to touch their fingers with the tip of the thumb. The score is 1 when patients are able to touch only the lateral side of the index finger and 10 when they can reach the volar crease of the hand.

Active MCP I extension was measured with a digital goniometer (ELINK, Biometrics Ltd., Gwent, UK).

Standard a/p radiographs of the hand were taken at baseline, and the severity of OA was graded from stage I (normal articular contours with joint widening due to ligament laxity) to stage IV (complete TMC joint deterioration and narrowed, sclerotic scaphotrapezial joint) using the Eaton classification[33].

Statistics

Differences between the two treatment groups at baseline were evaluated with an independent, 2-tailed *t*-test for continuous variables. For nominal data, we used the two-group test of proportions. Within-group changes regarding the MHQ total score over one year were calculated using an analysis of variance for repeated measures (ANOVA) with Scheffé's post-hoc adjustment for multiple comparisons.

We used ordered logistic regression to identify determinants of patient satisfaction. All the outcome measures previously mentioned, at baseline and 1 year were possible candidates for the regression model, as well as the baseline variables of gender, age, presence of OA at other joints, duration of thumb complaints, number of previous injections, insurance type, and whether the dominant hand was affected. These variables were first checked for collinearity using the variance inflation factor (VIF). A VIF of 5 indicates moderate collinearity and a VIF of 10 indicates severe collinearity[34]. We excluded variables with a VIF > 7. The remaining variables were entered into one ordered logistic regression model for surgical patients and another for conservatively treated patients, with treatment satisfaction at 1 year being the dependent variable. Stepwise backward elimination removed all variables with $p > 0.05$, until only variables with $p \leq 0.05$ were left. In order to prevent bias due to missing data, we imputed such data for the dependent variable "treatment satisfaction at 1 year", based on the assumption that values were missing at random (MAR). A multiple imputation model was built containing relevant baseline data. We created 20 imputed datasets and pooled them using Rubin's combination rules. All analyses were done with Stata 12.1.

RESULTS

After screening 260 patients, we included 177 patients in our study (Figure 1). Nine patients in the surgical group were subsequently excluded from this analysis, because they had already been

enrolled in the conservatively treated group before they decided on surgery. A further three patients were excluded because they cancelled their operations, giving a final analysis of 165 patients. At 1 year, data were available from 132 patients, which corresponds to a follow-up rate of 80%. Surgery was performed on 97 (59%) patients, while 68 (41%) patients received conservative treatment. Fourteen (21%) patients in the conservatively treated group had surgery during the follow-up period, on average 7 ± 2.1 months after conservative treatment had started (Figure 1).

Trapeziectomy with LRTI was performed in 80 (82%) of the surgical patients (Table 1). Steroid injection was the primary intervention in 58 (85%) of the patients in the conservatively treated group. At baseline, conservatively treated patients had a lower Eaton stage of OA than patients who underwent surgery, and fewer of them took pain killers. Furthermore, patients in

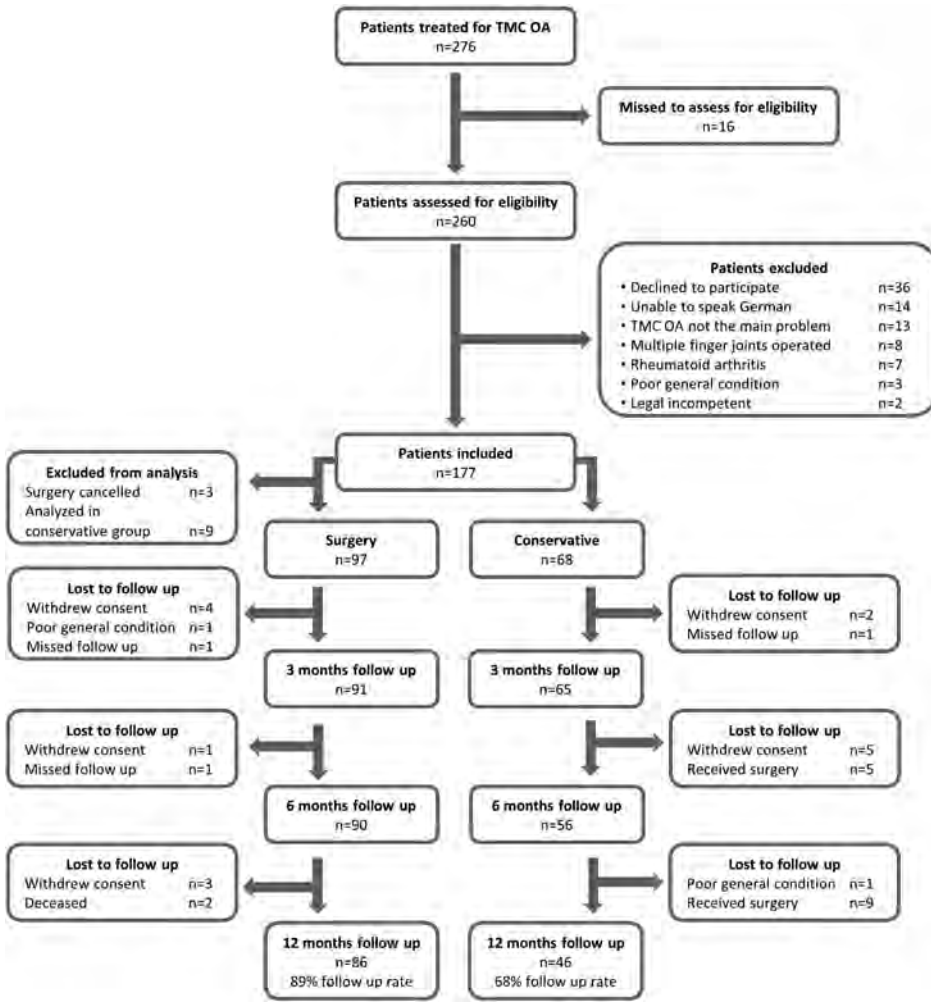

Figure 1 Patient recruitment diagram

the conservative treatment group had significantly better hand function as measured with the MHQ, a higher Kapandji index, and greater key pinch strength (Table 1).

Regarding the outcome measured with the MHQ total score, surgical patients improved continuously from 47 ± 15 at baseline to 80 ± 16 at 1 year ($p \leq 0.001$; Figure 2). In the conservatively treated group, an improvement was found only between baseline (61 ± 13) and 6 months (68 ± 15; $p \leq 0.001$; Figure 2). Compared with baseline, the change in the MHQ total score in this group at 1 year was not significant (66 ± 17 at 1 year; $p = 0.055$).

Complications affecting the flexor carpi radialis tendon occurred in three patients after surgery. Two patients needed surgical revision but were satisfied or very satisfied with the treatment result at 1 year. The third patient was treated with analgesics and was still dissatisfied after a year.

With respect to treatment satisfaction at 1 year, 76 (88%) surgical patients were somewhat or very satisfied with the treatment result, whereas only 19 (41%) of the conservative patients reported that they were somewhat or very satisfied with the result (Figure 3). The regression

Table 1 Baseline characteristics of 165 patients and differences between the surgical and conservatively treated groups. If not otherwise indicated, the mean ± standard deviation is given. Values $p \leq 0.05$ are shown in bold.

Characteristics	Surgery (n = 97)	Conservative (n = 68)	p-value
Female: no. (%)	87 (90)	51 (75)	**0.012**
Age in years	63.7 ± 8.9	64.0 ± 9.6	0.806
Patients taking drugs for thumb pain: no (%)	44 (45)	14 (21)	**≤ 0.001**
Number of drugs per week for thumb pain	7.6 ± 5.8	7.8 ± 7.3	0.935
Duration of complaints in months	50 ± 61	31 ± 62	0.063
Eaton stage of osteoarthritis	2.9 ± 0.7	2.6 ± 0.5	**0.015**
Intervention: no. (%)[1]			
Trapeziectomy and LRTI	80 (82)		
Trapeziectomy and LRTI and CTS release	6 (6)		
Trapeziectomy and LRTI and MCP I arthrodesis	9 (9)		
Trapeziectomy and LR and interposition with GraftJacket	2(2)		
Injection		58 (85)	
Hand therapy		5 (7)	
Analgesic medication		4 (6)	
Splinting		1 (1)	
MHQ total score (0-100, 100 = best)	47 ± 15	61 ± 13	**≤ 0.001**
SF-12 Physical Health (0-100, 100 = best, 50 = norm)	38 ± 8.0	41 ± 8.9	**0.022**
SF-12 Mental Health (0-100, 100 = best, 50 = norm)	50 ± 12	50 ± 11	0.946
Kapandji Index (0-10, 10 = best)	8.5 ± 1.8	9.0 ± 1.1	**0.019**
Key pinch in kg	2.9 ± 1.8	4.5 ± 2.2	**≤ 0.001**

LRTI = Ligament reconstruction and tendon interposition; CTS = Carpal tunnel syndrome; MCP I = metacarpophalangeal joint I; MHQ = Michigan Hand Questionnaire; SF-12 = Short Form 12 questionnaire

[1] % the sum of the percentages is unequal to 100, due to rounding of the figures

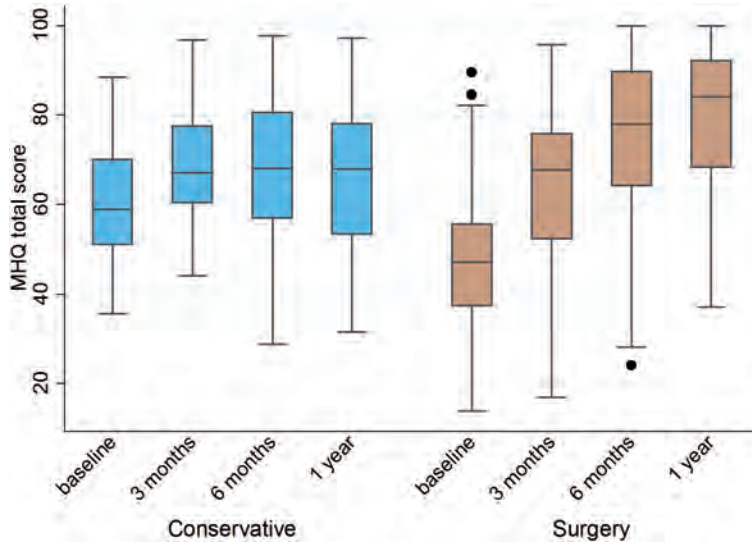

Figure 2 Boxplot showing the distribution of the MHQ total score of both groups at baseline, 3, months, 6 months, and 1 year

analyses showed that expectations being fulfilled was an important determinant of treatment satisfaction at 1 year in both groups. Furthermore, greater MCP extension at 1 year determined higher patient satisfaction in the surgical group, while greater pain at 1 year reduced satisfaction in these patients (Table 2). In the conservatively treated group, a more advanced Eaton stage was associated with reduced satisfaction whereas older age and a better baseline MHQ ADL score determined higher satisfaction (Table 3). The regression coefficients of the latter two variables, as well as of MCP extension and MHQ pain, were relatively small in the surgical group, indicating that a change in these variables leads to only minor changes in satisfaction.

DISCUSSION

The results of this cohort study on the outcomes of surgical and conservative treatment for TMC OA showed that patients scheduled for surgery had a significantly worse hand-related health status at baseline than patients treated conservatively. Surgery led to a significantly improved outcome at one year as measured with the MHQ, whereas conservative treatment seemed to be most effective in the first six months. Of the surgical patients, 88% were satisfied with treatment at 1 year, whereas only 41% of the conservatively treated patients were satisfied at this time. The fulfillment of expectations was an important determinant of treatment satisfaction in both groups. A more advanced stage of OA was associated with less satisfaction in the conservatively treated group.

The findings that patients treated conservatively showed less severe disease at baseline than surgical patients and that the effects of conservative treatment lasted about 6 months, have been confirmed by other studies. Patients with stage I or II TMC OA obtain greater and

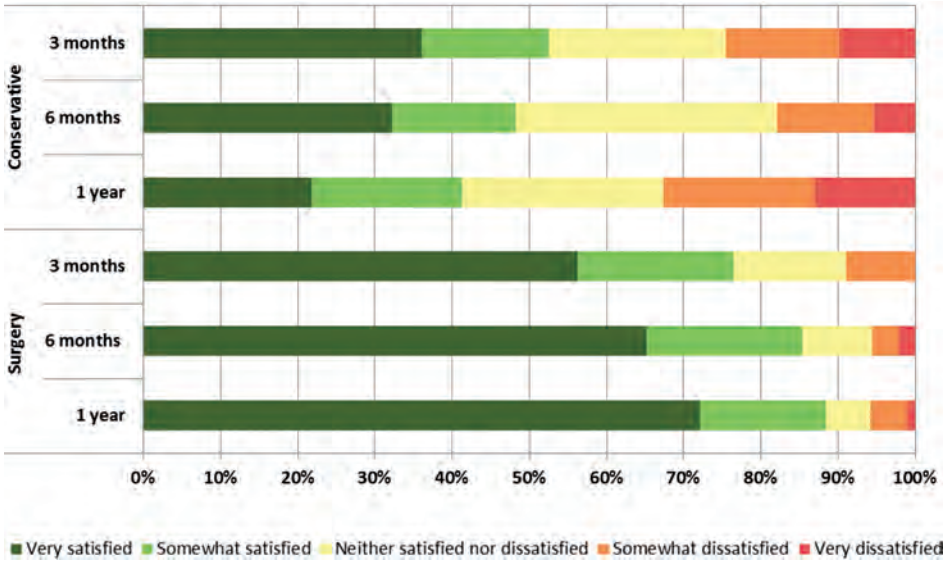

Figure 3 Treatment Satisfaction of surgical and conservatively treated patients at different times of follow up

Table 2 Results of the ordered logistic regression on treatment satisfaction at 1 year for surgical patients.

	Coefficient	Standard Error	p-value	95% Confidence Interval
Expectations fulfilled at 1 year	1.76	0.5	≤ 0.001	0.78 - 2.75
Extension of MCP I at 1 year	0.12	0.05	0.005	0.03 - 0.21
MHQ pain at 1 year	-0.06	0.02	≤ 0.001	-0.1 - -0.02

MCP I = Metacarpophalangeal joint I; MHQ = Michigan Hand Questionnaire

Table 3 Results of the ordered logistic regression on treatment satisfaction at 1 year for conservatively treated patients.

	Coefficient	Standard Error	p-value	95% Confidence Interval
Eaton stage of osteoarthritis	-1.95	0.6	0.001	-3.13 - -0.78
Expectations fulfilled at 1 year	0.98	0.32	0.002	0.36 - 1.60
Age	0.09	0.04	0.012	0.02 - 0.17
MHQ ADL score at baseline	0.04	0.02	0.008	0.01 - 0.08

MHQ ADL = Michigan Hand Questionnaire, subscale activities of daily living

more sustained benefit from conservative treatment than patients with more severe TMC OA[13, 35]. Steroid injections have been shown to be effective for 4 to 18 months in patients with TMC OA stage I or II[13, 35]. These findings are also in keeping with our regression analysis showing

that conservatively treated patients with a more advanced Eaton stage are less satisfied with the results of treatment. However, conservative treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), physiotherapy, analgesics, splints, or intra-articular corticosteroid injections has not demonstrated any long-term effectiveness[13, 17, 35]. At the group level, the MHQ values for conservatively treated patients were indeed higher after 1 year than at baseline, but did not quite reach the significance level. These results indicate that the patient's condition could at least be kept stable with conservative management. At one year, the hand function of these patients was still above the baseline MHQ values of the surgical patients, suggesting that conservative treatment may postpone surgery.

The decision for the treatment strategy was made individually for each of our patients. Our hand surgeons usually prefer to treat patients with only mild complaints conservatively, but suggest surgery to patients with severe pain and restrictions in their daily life. This approach is similar to that in other studies recommending surgery in cases where pain limits the activities of daily living or when conservative treatment fails[2, 17, 18]. A steroid injection might still be useful in cases of severe TMC OA, however, in order to reduce the patient's complaints during the waiting time for surgery[13, 17, 18].

In the surgical group, we found an improvement of 31 points in hand function between baseline and 1 year, as measured with the MHQ. As this change is above the value of 17 points for the minimum important change (MIC)[28], we can assume that this result is not only statistically significant but also clinically meaningful for the patients. Similar changes were found for patients after abductor pollicis longus suspension arthroplasty[36] and after basal thumb metacarpal osteotomy[37], with patients in the latter study having an improvement of 28 points after 3 years. This result indicates that the outcomes of surgery for TMC OA remain stable over time. Whether one type of surgery is superior to another in the long term has been discussed in the literature, but the evidence is still insufficient[5, 7].

Regarding satisfaction, the present study shows that expectations play a major role in predicting treatment satisfaction in both groups. An association between expectations fulfilled and patient satisfaction has also been reported for patients after MCP arthroplasty[38]. In patients after carpal tunnel release, it has been shown that expectations being met and a generally optimistic view of health accounted for 31% of the variability in postoperative Disabilities of Arm, Shoulder and Hand questionnaire (DASH) scores. The association between expectations and satisfaction revealed in our study substantiates the relevance of the decision-making process (i.e. shared decision making) prior to an intervention. It is important that the physician is aware of the patient's expectations in order to ensure that the patient makes realistic assumptions about the possible treatment outcome[39].

Although showing a small regression coefficient, MCP extension at 1 year was another determinant of patient satisfaction in surgical patients. The finding that a bigger range of motion in this direction is associated with greater satisfaction can be interpreted in that patients need a certain amount of mobility to grasp large objects. Despite the statistically significant result, however, we should be careful with the interpretation that more MCP extension leads to greater satisfaction. Too much MCP extension might cause pain and limit the patient's functional abilities. Another study investigating patients after surgery for TMC OA showed that hyperextension of the MCP was associated with a worse functional outcome[40]. Our results suggest that MCP extension is an important function for patients, but with neither too little nor too much mobility.

In the conservatively treated group, the results showed that older age is associated with greater treatment satisfaction, although the regression coefficient is quite small. The correlation between age and satisfaction is variously discussed in the literature. It has been suggested that age has at least a slight influence on patient satisfaction, with older people being more satisfied than younger ones[21].

When assessing patient satisfaction it must be remembered that several dimensions contribute to the individual perception of satisfaction. Satisfaction with the treatment outcome is only one aspect. Other aspects include facilities, service features, continuity of care, humaneness, competence, and the treatment process itself[19, 41]. Furthermore, patient satisfaction is influenced by specific personal characteristics comprising expectations, demographics, and personal preferences[42].

The present study has some limitations: due to its nonrandomized design, we cannot make any firm recommendations that one procedure is superior over another. We have, in fact, described the outcomes of two different treatment strategies in two groups of patients with different characteristics. Making any direct comparison between the two interventions would be prone to confounding by indication. Furthermore, our patients received different conservative or surgical management within the groups, because the treatment strategy was chosen individually in each case. This precludes any conclusions for or against a specific intervention. Nine patients were initially treated conservatively but decided to have surgery during the enrollment period and were therefore enrolled in both groups. For the purposes of this paper, however, we excluded them from the surgical group in the analysis, in order to avoid confounding by patients being included in the study twice. As some data were missing, we were forced to impute them. The regression models for satisfaction are therefore estimations rather than real data. Further research is needed to address the issue of assessing patient satisfaction and expectations. As these outcomes have previously been measured using various approaches such as Likert scales, visual analog scales, or self-developed questionnaires, statistical comparisons between studies are not possible[21]. One focus should be the development of a standardized assessment tool for routine use in clinical practice to evaluate patients' expectations prior to treatment, fulfillment of expectations, and satisfaction at the end of treatment.

Based on our results, we can conclude that patients with mild complaints may benefit from conservative treatment with an effective duration of about 6 months. We suggest surgery in cases where pain limits the patient's daily life or when conservative treatment fails. Surgery gave high treatment satisfaction one year after the operation. Expectations being fulfilled was an important determinant of treatment satisfaction in both groups. This highlights the need to evaluate expectations and provide patients with comprehensive information prior to any intervention, in order to ensure that their expectations of the treatment outcome are realistic.

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CHAPTER **SEVEN**

HEALTHCARE COSTS AND LOSS OF PRODUCTIVITY IN PATIENTS WITH TRAPEZIOMETACARPAL OSTEOARTHRITIS

Submitted

Miriam Marks
Thea PM Vliet Vlieland
Laurent Audigé
Daniel B Herren
Rob GHH Nelissen
Wilbert B van den Hout

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ABSTRACT

Purpose To analyze the economic aspects of conservative and surgical treatment of patients with trapeziometacarpal osteoarthritis (TMC OA) with regard to costs associated with healthcare and loss of productivity.

Methods Prospective cohort study including patients with TMC OA who received either surgical or conservative treatment. Healthcare costs were measured using our clinic's earnings in Swiss francs (CHF). Patients were assessed at baseline and 3, 6, and 12 months after the intervention. Employed patients filled out the Work Productivity and Activity Impairment Questionnaire (WPAI) to assess absenteeism, presenteeism, and overall costs due to loss of productivity.

Results We included 161 patients, 58 of whom were in employment Healthcare costs were CHF 10,303 in the surgery group and CHF 622 in the conservatively treated group. The total productivity loss in the surgical group increased from baseline to 3 months (50% versus 64%) but decreased significantly to 25% at 1 year. Total productivity loss in the conservative group was more stable over time (52% at baseline to 48% at 1 year). Estimated annual healthcare and productivity costs were higher in the surgical group (CHF 20,210) compared with the conservatively treated group (CHF 6,877).

Discussion With respect to both healthcare and loss of productivity, surgery was associated with considerably higher costs than conservative treatment. However, we cannot make any treatment recommendations, because the indications for conservative management and surgery are different. The extent of improved productivity after more than one year and its related economic consequences should be the subject of further research.

INTRODUCTION

In recent years, economic evaluations have become increasingly important because of the growing emphasis on cost containment. The evaluation of both costs and benefits allows more comprehensive consideration of the value of a particular intervention[1]. In addition to direct healthcare expenses, the costs associated with loss of productivity lead to substantial economic consequences for the patient, the employer, and society[2, 3].

People with hand osteoarthritis (OA) report limitations in daily life which may also affect their working ability[2]. Loss of productivity arises from two sources: absenteeism and presenteeism[4]. Absenteeism can be quantified by the time absent from work due to illness[4]. Presenteeism is defined as the reduction in productivity while at work because of an individual's state of health[5]. Costs due to absenteeism are quite straightforward to record, while the costs of presenteeism often remain hidden[4].

Absenteeism in patients with trapeziometacarpal (TMC) OA may be due directly to their condition, but surgical intervention may also lead to a relatively long period of sick leave. Full work incapacity of eight weeks can be expected after trapezium resection with tendon interposition, followed by another eight weeks with a working ability of only 50%[6]. Despite these postoperative limitations, 90% of the patients can expect to return to the same level of occupation as before their illness[6].

Studies investigating presenteeism for patients with OA of any joint[7, 8] and patients with rheumatoid arthritis[9, 10] showed that the costs associated with presenteeism were considerably higher than those for absenteeism.

Economic evaluations in orthopedics, especially for the hand, are scarce. Economic studies have been published only for the treatment of Dupuytren's disease[11-13], hand and wrist injuries[3, 14], and for ganglia and trigger fingers[13, 15], with only limited information about the economic consequences due to absenteeism and presenteeism.

The objective of this study was to analyze the economic aspects of conservative and surgical treatment of patients with TMC OA, with regard to the costs associated with healthcare and loss of productivity.

MATERIALS AND METHODS

Study design

This economic evaluation is part of a mono-center prospective, cohort study on the outcomes of conservative and surgical treatment in patients with TMC OA. It was conducted in the Department of Hand Surgery in an orthopedic clinic in Switzerland. This clinic is a non-profit organization, administered by a private foundation, in which 8,700 elective inpatient and outpatient operations on the musculoskeletal system are performed each year. This study was approved by the local ethics committee.

Patients

The parent study included all patients, with a radiographically proven diagnosis of TMC OA, who underwent either conservative or surgical treatment for that condition in the months from September 2011 to November 2012. Exclusion criteria were: TMC OA was not the main problem

at the time of consultation, rheumatoid arthritis, concomitant surgery on other fingers, legal incompetence, poor general condition precluding study participation, previous inclusion in the study for the other hand, and insufficient knowledge of the German language to complete the questionnaires. All eligible patients were asked to participate by their treating hand surgeon, and were consecutively enrolled in the study after they had given written informed consent.

For the present economic analysis, the surgical group included patients who received the following treatment: trapeziectomy with LRTI or arthrodesis of the TMC joint. Trapeziectomy with LRTI was carried out according to Epping[16], Weilby[17], or Sigfusson and Lundborg[18] whichever method was preferred and routinely performed by each surgeon. Additional procedures, such as carpal tunnel release or arthrodesis of the metacarpophalangeal (MCP) joint I were also performed, if required. In the conservatively treated group, the analysis included patients given corticosteroid injections into the TMC joint by their treating hand surgeon. In each case, the decision for the treatment strategy was made by the treating surgeon in discussion with the patient. Physical or occupational therapy might have been prescribed additionally in both groups, if it was indicated.

Assessments

Baseline assessments were made at the preoperative consultation for surgical patients and on the day of injection for the conservatively treated patients. Sociodemographic and disease-related data were gathered at this visit. Follow-up assessments were scheduled at 3, 6, and 12 months after treatment. If routine medical care did not require a checkup at these times, patients came for a study visit with an independent examiner, for which they were not charged.

At each study visit, patients completed a questionnaire set consisting of the Michigan Hand Questionnaire (MHQ)[19] and the Work Productivity and Activity Impairment Questionnaire (WPAI)[20]. Additionally, we asked about the duration of sick leave due to the TMC OA, work status, and income.

The *MHQ,* developed by Chung et al.[19], is a hand-specific questionnaire which yields results for each hand separately. The psychometric properties of the MHQ have been assessed in patients with TMC OA and show overall good reliability, validity, and responsiveness[21]. The total score ranges from 0 to 100 with a higher score indicating better performance. The German version[22] has been used for this study and the data for the affected hand were analyzed.

The *WPAI*[20] is a quantitative assessment of absenteeism, presenteeism, and overall productivity loss attributable to a specific health problem during the previous 7 days. There are several versions available. We used the Swiss-German translation of the WPAI Specific Health Problem version 2.0 with the generic term "problem" being replaced by the word "Daumensattelgelenksarthrose" [osteoarthritis of the thumb saddle joint]. The WPAI is the instrument most frequently used to measure health-related productivity and its psychometric properties have been assessed for various medical conditions[23]. It consists of six questions regarding employment status (Q1), hours absent from work due to TMC OA (Q2), hours absent from work due to other reasons (Q3), hours actually worked (Q4), the extent to which the person was limited at work due to TMC OA (Q5), and the extent to which TMC OA affected daily activities other than work (Q6). WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity[24, 25].

Healthcare costs

Healthcare costs were measured by the clinic's earnings, as extracted from the hospital accounting system for the following treatment events: preoperative consultations, intervention, follow-up consultations, and treatment of complications. Earnings from the baseline date until the date of the 1 year follow-up were recorded. All monetary numbers were recorded and reported in Swiss francs (CHF). One Swiss franc is equivalent to 0.72 United States dollars, 0.56 euro and 0.50 pounds sterling[26].

Furthermore, the length of hospital stay for postoperative patients, as well as the type of insurance, was extracted from the hospital accounting system. There are three types of inpatient hospital care in Switzerland, depending on whether the patient has general, semi-private, or private health insurance. All outpatient treatment (conservative treatment and consultations) is covered by the general insurance, so the insurance type was not specified for these patients. The earnings of the clinic for patients with a general insurance are based on flatrate payments. For patients with additional (semi-) private insurance, the hospital charges additional fees.

Loss of productivity

Loss of productivity over one week was calculated for employed patients. We chose the human capital (HC) method, because the duration of absenteeism is typically less than 6 months and patients usually return to work following treatment for TMC OA. The HC method counts any hour not worked as an hour lost. Other methods, such as the friction-cost method, only count as lost those hours not worked until another employee takes over the patient's work[27]. Using the WPAI data, we calculated the percentage of absenteeism, presenteeism and overall work productivity loss for one week[24, 25]: Absenteeism = Q2 / (Q2 + Q4); Presenteeism = Q5 / 10; Overall work productivity loss = Absenteeism + [(1 - absenteeism / 100) x presenteeism]. The costs associated with loss of productivity were calculated by multiplying the corresponding score with the weekly working hours and the hourly wage. For the wages, we used norm values for monthly income of the Swiss population, stratified by sex and age group[28]. Hourly wages were calculated from the monthly wage (divided by 21.75 x 8, with 21.75 being the average monthly working days and 8 being the daily working hours)[29], resulting in values of CHF 29 to CHF 43 per hour for our patients.

Statistics

Baseline differences between the treatment groups were evaluated with a two-group, two-tailed t-test for continuous variables. For nominal data, we used the two-group test of proportions. We used one-way ANOVAs to determine any differences in the earnings of the clinic, the length of hospital stay, and the MHQ total score between patients with different types of insurance. Loss of productivity was compared between the treatment groups using a two-group, two-tailed t-test. Within-group changes regarding productivity over the year were analyzed using an ANOVA with Scheffé's post-hoc adjustment for multiple comparisons.

The WPAI provides data on loss of productivity for only one week. As we were interested in the annual costs, we made a linear extrapolation of each measurement time point for absenteeism and presenteeism and calculated the area under the curve. For this analysis, the value for absenteeism at baseline in the surgical group was set at 100%, because all patients were on full sick leave during the first day after surgery. This analysis was not feasible if follow-up data for a patient were missing. Based on the assumption of values missing at random (MAR), we substituted missing data for

absenteeism and presenteeism by multiple imputation. An imputation model for each follow-up was built containing the absenteeism / presenteeism data of the other follow-ups. We created 20 imputed datasets and pooled them using Rubin's combination rules. The annual healthcare and productivity costs were estimated with these data for all patients irrespective of their working status. For non-working patients, loss of productivity was set at 0.

RESULTS

This study included 161 patients, mean age 64 years, 103 of whom had surgery and 58 were managed conservatively (Table 1). Forty-one percent of the patients treated surgically had only a general insurance, while 59% had additional (semi-) private insurance. At one year, data were available from 130 patients, corresponding to a follow-up rate of 81%.

Healthcare costs

Average earnings of the clinic were CHF 10,303 and CHF 622 for the surgical and conservatively treated group, respectively ($p \leq 0.001$). In three patients, complications affecting the M. Flexor Carpi Radialis tendon occurred after surgery. Overall, average costs for complications were CHF 58 per operated patient (Table 2).

Table 1 Sociodemographic baseline data of 161 included patients with TMC OA. Values $p \leq 0.05$ are marked in bold.

Characteristics	Total group (n = 161)	Surgery (n = 103)	Conservative (n = 58)	p-value
Sex female; no. (%)	136 (84)	90 (87)	46 (79)	0.175
Age in years; mean ± SD	63.9 ± 9.1	63.6 ± 8.8	64.4 ± 9.8	0.590
MHQ total score; mean ± SD	52 ± 16	48 ± 15	59 ± 13	**≤ 0.001**
Insurance for surgery; no. (%)				
General		42 (41)		
Semi-private		34 (33)		
Private		27 (26)		
Employment status; no. (%)				
Employed, fully able to work	46 (29)[1]	31 (30)	15 (26)	
Employed, partly unable to work due to TMC OA	4 (2)	4 (4)	0 (0)	
Employed, partly unable to work due to other reasons	6 (4)	2 (2)	4 (7)	
Employed, unable to work due to TMC OA	1 (1)	1 (1)	0 (0)	
Employed, unable to work due to other reasons	1 (1)	1 (1)	0 (0)	
Unemployed/retired/housewife	101 (63)	64 (62)	37 (64)	
No information	2 (1)		2 (3)	
Contractual weekly working hours; mean ± SD[2]	31 (12)	31 (12)	31 (13)	0.968

TMC OA = Trapeziometacarpal osteoarthritis
MHQ = Michigan Hand Questionnaire
[1] due to rounding errors, the sum of the percentages is higher than 100
[2] among employed patients

Comparing the different types of insurance, patients with only general insurance provided significantly lower earnings for the clinic and had shorter hospital stays, although no difference in the outcome could be detected (Table 3).

Loss of productivity

At baseline, 58 patients in both groups had paid work. Employed patients had an average of 10 weeks complete sick leave following surgery. In addition, nine patients also had partial sick leave (50-80%, for 3 to 4 weeks). Three patients reported that they had no sick leave at all.

Overall, except for the 3-month follow-up in the surgical group, costs for loss of productivity due to presenteeism were considerably higher than costs for absenteeism (Table 4). The total productivity loss in the surgical group increased from baseline to 3 months (50% versus 64%) but decreased significantly to 25% at 1 year. Total productivity loss in the conservative group was more stable over time (52% at baseline to 48% at 1 year. Regarding the weekly costs of overall loss of productivity, there was a significant decrease in both groups over one year, with a significant decrease in the surgical group between 3 and 6 months ($p \leq 0.001$), and a decrease in the conservative group between baseline and 3 months ($p = 0.027$).

No differences regarding absenteeism, presenteeism, and overall costs due to productivity loss were found between the two groups at baseline and 6 months. At 3 months, the overall loss

Table 2 Average earnings of the clinic in Swiss Francs (CHF) by treatment event and intervention group. Mean values ± standard deviations are given.

	Earnings	
	Surgery (n = 103)	**Conservative (n = 58)**
Preoperative consultation	317 ± 144	
Treatment	8,868 ± 3,622	622 ± 337[b]
Follow up consultations	1,061 ± 538	
Complications[a]	58 ± 395	
Total earnings	10,303 ± 3,730	622 ± 337

[a] mean calculated for all 103 surgical patients, of whom 3 actually had complications
[b] includes follow up consultations for conservative patients

Table 3 Average among surgically treated patients (n = 103) for earnings of the clinic in Swiss Francs (CHF), length of inpatient stay, and health status measured with the Michigan Hand Questionnaire (MHQ) by insurance type. Mean values ± standard deviations are given. Values $p \leq 0.05$ are marked in bold.

	General Insurance (n = 42)	**Semi-private Insurance (n = 34)**	**Private Insurance (n = 27)**	**p-value**
Surgery earnings (CHF)	5,412 ± 1,657	10,288 ± 1,910	12,455 ± 2,683	**≤ 0.001**
Length of inpatient stay (days)	1.7 ± 0.7	2.1 ± 0.5	2.1 ± 0.5	**0.012**
MHQ total score baseline	45 ± 15	48 ± 17	51 ± 161	0.223
MHQ total score 1 year	78 ± 16	79 ± 17	81 ± 16	0.771

Table 4 Absenteeism, presenteeism, overall productivity loss and associated costs for one week at the different study time points for employed patients (n = 58). Mean values ± standard deviations are given; p-values are given for the comparison between both intervention groups and within the groups. Values p ≤ 0.05 are marked in bold.

	Surgery (n = 39 at baseline)	Conservative (n = 19 at baseline)	p-value (between group comparison)
Absenteeism (%)			
Baseline (n = 58)	7 ± 19	3 ± 7	0.421
3mo follow up (n = 56)	43 ± 47	6 ± 23	**0.002**
6mo follow up (n = 47)	8 ± 22	1 ± 2	0.226
1 year follow up (n = 41)	2 ± 10	4 ± 11	0.560
p-value (within-group comparison)	**≤ 0.001**	0.525	
Costs of absenteeism per week (CHF)			
Baseline	78 ± 193	45 ± 98	0.485
3mo follow up	431 ± 529	43 ± 144	**0.003**
6mo follow up	99 ± 295	8 ± 32	0.262
1 year follow up	22 ± 84	34 ± 87	0.688
p-value (within-group comparison)	**≤ 0.001**	0.815	
Presenteeism (%)			
Baseline	45 ± 28	50 ± 24	0.544
3mo follow up	24 ± 29	33 ± 22	0.284
6mo follow up	28 ± 24	40 ± 27	0.151
1 year follow up	24 ± 21	46 ± 23	**0.006**
p-value (within-group comparison)	**≤ 0.001**	**0.003**	
Costs of Presenteeism per week (CHF)			
Baseline	478 ± 360	548 ± 364	0.492
3mo follow up	239 ± 296	316 ± 312	0.369
6mo follow up	261 ± 200	415 ± 329	0.055
1 year follow up	268 ± 274	366 ± 341	0.339
p-value (within-group comparison)	**≤ 0.001**	**0.010**	
Overall work productivity loss (%)			
Baseline	50 ± 29	52 ± 23	0.742
3mo follow up	64 ± 37	38 ± 26	**0.010**
6mo follow up	33 ± 28	40 ± 27	0.403
1 year follow up	25 ± 23	48 ± 23	**0.007**
p-value (within-group comparison)	**≤ 0.001**	0.051	
Costs of overall work productivity loss per week (CHF)			
Baseline	556 ± 400	593 ± 359	0.736
3mo follow up	670 ± 469	359 ± 315	**0.012**
6mo follow up	360 ± 346	423 ± 334	0.565
1 year follow up	290 ± 300	400 ± 376	0.330
p-value (within-group comparison)	**≤ 0.001**	**0.025**	

of productivity was 64% for patients who had undergone surgery, while the figure was 38% for conservatively treated patients. At 1 year, however, patients treated conservatively reported 48% loss of productivity, which is significantly more than in the surgical group with only 25%.

The estimated costs due to loss of productivity for one year showed that surgery was about CHF 13,000 more expensive than conservative treatment (Table 5). Costs from absenteeism were higher in the surgical group while costs from presenteeism were higher for those managed conservatively.

DISCUSSION

The results of this economic analysis showed that healthcare costs for conservative treatment of TMC OA were much lower than for surgery. Patients with private insurance provided the clinic with more earnings than patients with general insurance, although we found no differences in the treatment outcome. Between baseline and the 1-year follow-up, there was at first an increase and then a significant decrease in loss of productivity in the surgical group, whereas productivity loss was more stable over time in the conservatively treated group. Estimated combined annual healthcare and productivity costs were considerably higher in the surgical group.

As expected, the clinic earns significantly more money from patients with additional (semi-) private insurance. This is not only due to a higher charge per day, but also to a significantly longer stay. People with (semi-) private insurance pay more in insurance premiums and, in return, get more benefits, such as treatment by a senior physician, double- or single-room accommodation in the hospital, and complementary and alternative medical (CAM) treatment, none of which are covered by the general insurance. Despite these additional benefits, we did not see a better treatment outcome in these patients. This may be because trapeziectomy with LRTI is a straightforward operation that provides good overall results and patient satisfaction[30-32], irrespective of whether the senior surgeon or another consultant performs the surgery. Another study in our clinic, investigating patients who underwent total shoulder replacement, confirms that the insurance status has only weak association with the outcome[33]. Further studies are needed to determine whether these results can be extrapolated to other medical facilities and other countries. In the United States, for example, where a different health insurance system exists, patients with private insurance have been shown to have lower risk-adjusted mortality rates than patients in other payer groups[34].

Regarding absenteeism, we found that patients have an average of 10 weeks sick leave after surgery, leading to high productivity losses. The relevance of costs associated with absenteeism

Table 5 Estimated average annual costs for surgery and conservative treatment (CHF) for all patients (n = 161).

	Surgery	Conservative	p-value
Healthcare costs	10,303	622	**≤ 0.001**
Loss of Productivity costs			
Absenteeism	5,750	217	**≤ 0.001**
Presenteeism	4,157	6,038	0.269
Total annual costs	20,210	6,877	**≤ 0.001**

in patients with hand and wrist injuries is substantiated by data from the Netherlands, where these costs were found to be considerably higher than the health-care costs[3].

In our patients, the costs associated with presenteeism were considerably higher than for absenteeism at all points in time, except 3 months after surgery when some patients were still on sick leave. Higher loss of productivity while at work than when absent from work has also been shown in studies investigating employees with arthritis[35, 36], patients with OA at any joint[7, 8], and patients with rheumatoid arthritis[9, 10]. Goetzel et al.[36] concluded that 77% of the total costs for arthritis are attributable to presenteeism.

In contrast to absenteeism, the quantification of presenteeism remains a complex task[5]. Several questionnaires for loss of productivity are available, but there are no clear guidelines on which one to choose[5, 37, 38]. Furthermore, the way to quantify the economic burden from the various questionnaires is not standardized, making it impossible to compare the results of different studies[5]. We choose the WPAI to assess loss of productivity, because the answers can be easily converted into numbers for absenteeism and presenteeism[5]. In our opinion, however, the WPAI has some shortcomings in that it estimates loss of productivity for only one week. This short recall period is useful from a methodological point of view, in order to minimize recall bias, but it necessitates interpolation to estimate costs over the entire year[23]. Additionally, presenteeism in the WPAI was reported on a numeric rating scale ranging from 0 to 10. If patients gave a score of 8 out of 10, would that necessarily mean that they were only able to work 20%, leading to an 80% loss for the employer[39]? We would question that interpretation and suggest that the high costs of presenteeism may be overestimated, which has also been indicated in other studies[9].

This study has some limitations: On the basis of our data, we cannot make any treatment recommendations, as the two patient groups are not comparable regarding either indication or outcome. We have, in fact, described the outcomes of two different treatment strategies in two groups of patients with different characteristics. Making any direct comparison between the two interventions would be prone to confounding by indication. Future studies, preferably with a randomized design, should focus on the cost-utility analysis of comparable interventions in order to provide treatment recommendations, bearing in mind the economic consequences[1, 40]. Additionally, many of our patients were not willing to report their income, so we used norm data for the hourly income of the Swiss population when calculating the costs associated with loss of productivity. Missing values for absenteeism and presenteeism forced us to impute these data, so that the results are more of an approximation than actual figures. Our data regarding costs due to loss of productivity should be extrapolated carefully. The monetary values are strongly dependent on the income, contractual weekly working hours, and ratio of the employed to and non-working patients in the study population.

In summary, we can conclude that surgery was associated with considerably higher costs than conservative treatment, with respect to both healthcare and loss of productivity. However, we cannot make any treatment recommendations, because the indications for conservative management and surgery are different. Moreover, treatment recommendations also have to consider the clinical and subjective outcome, which is beyond the scope of this paper. The extent of the improved productivity of surgical patients after more than one year and its related economic consequences should be the subject of further research.

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CHAPTER **EIGHT**

SUMMARY AND GENERAL DISCUSSION



SUMMARY

Osteoarthritis (OA) is the most prevalent joint disorder leading to serious functional limitations and reduced quality of life, as well as to considerable social and economic costs[1-3]. In the hand, the distal interphalangeal (DIP) joints are most often affected by OA, followed by the trapeziometacarpal (TMC) and the proximal interphalangeal (PIP) joints[4-6].

Patients affected by hand OA usually report significant restrictions in their daily lives[3, 7, 8]. Pain combined with reduced finger joint mobility and decreased grip strength forces them to reduce their daily hand-related activities or even to avoid specific tasks. The tasks most commonly described as difficult are wringing out washcloths, and opening jars and bottles[9]. Treatment options for patients with hand OA include pharmacological, non-pharmacological, and surgical procedures[1, 10, 11].

The aim of this thesis, which is divided into two parts, was to investigate the limitations in daily life, outcome measures, clinical outcomes with the emphasis on patient satisfaction, and economic aspects of the treatment of hand OA, focussing on patients suffering from TMC OA.

Part ONE, comprising **chapters two, three,** and **four,** describes patients' limitations in daily life and relevant outcome measures. **Part TWO** contains **chapters five, six,** and **seven** and investigates the outcomes of surgical and non-surgical management of hand OA, with respect to patient satisfaction and economic aspects.

Part ONE

Chapter two addressed patients' limitations in daily life and investigated the particular problem of opening food containers. The aim was to develop guidelines for the industry on how to produce easy-to-open packaging. In a cross-sectional study, we investigated the forces that patients can apply to tear tabs and compared the results with normative data from a healthy age- and gender-matched population. We included 100 patients with different hand disorders. The pinch pull force (PPF) applied to tear tabs of different lengths and materials (aluminium, plastic) was measured with a specially designed device. Key pinch was measured with a pinch gauge. Normative data were taken from another study on 402 healthy adults. The results showed that patients were able to apply most force to the longest aluminium tab, using the key grip, but this was still only 53% of the force exerted by healthy people. Furthermore, we found that key pinch strength determines PPF ($R^2 = 0.548$, $p \leq 0.001$). When asked about difficulties with different types of packaging, 82% of the patients mentioned jam jars, 78% peelable meat/cheese packaging, and 69% bottles. We therefore recommend the industry to provide long aluminium tear tabs on their packaging. Furthermore, healthcare professionals are encouraged to measure key pinch to detect difficulty in opening packages.

The objective of **chapter three** was to reveal all the outcome measures used in studies on TMC OA and evaluate their measurement properties. In a two-step systematic literature review, we first identified studies including TMC OA patients and extracted all the outcome measures. They were categorised according to the Outcome Measures in Rheumatology (OMERACT) core set for OA, including five dimensions: pain, physical function, global assessment, imaging, and quality of life. First, 316 articles were identified, including 101 different outcome measures, mostly addressing the OMERACT pain and function domains but under-representing quality of life. Secondly, we

retrieved articles on the measurement properties of the outcome measures identified for TMC OA patients and found 12 articles investigating measurement properties of 12 outcome measures. The Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) and the Patient-Rated Wrist Evaluation (PRWE) were the tools most extensively studied. None of the studies examined all measurement properties. Positive ratings were seen for the DASH, the quickDASH, the Australian / Canadian Osteoarthritis Hand Index (AUSCAN), and the Nelson Score. In contrast, the Eaton classification, the carpometacarpal grind test, and the Hand Functional Index of the Keitel Functional Test rated poorly. Ratings for the PRWE and the Short Form 36 (SF-36) were equivocal. The methodological quality of these studies was fair to poor, implying that no recommendations for the use of any of the outcome measures can be made from the literature.

Given the lack of evidence on outcome measures for TMC OA, the reliability, validity, and responsiveness of the Michigan Hand Outcomes Questionnaire (MHQ) was investigated as described in **chapter four**. The prospective cohort study included 177 patients diagnosed with TMC OA, who received either conservative or surgical treatment. At baseline and at one year following the beginning of the treatment, we measured key pinch strength and the patients filled out the MHQ, the DASH, and the Short Form 12 (SF-12). They also completed these questionnaires 2 - 11 days after the last study visit. In order to analyse the measurement properties of the MHQ, we calculated test-retest reliability (intraclass correlation coefficient, ICC), internal consistency (Cronbach's alpha for the six subscales), construct validity (Pearson's correlation coefficient, r), responsiveness (effect sizes), and the minimal important change (MIC). The results showed that the mean MHQ total score for surgical patients increased from 48 ± 14 at baseline to 75 ± 18 at one year ($p \leq 0.001$). In contrast, no treatment effect was observed in the conservatively treated group ($p = 0.74$). The MHQ total score showed excellent test-retest reliability (ICC = 0.95) and correlated strongly with the DASH ($r = -0.77$). Internal consistency of the MHQ subscales ranged between 0.77 and 0.89. A large effect size of 1.7 was found for the surgical patients, with an MIC of 17 points. Based on these results, we concluded that the MHQ demonstrates good reliability, validity, and responsiveness in patients with TMC OA and it can be recommended as a suitable assessment tool in this population.

Part TWO

Chapter five aimed to identify which factors are associated with patient satisfaction after orthopaedic interventions in the hand. Assessing patient satisfaction is becoming more and more important, because it contributes to the continuous evaluation of healthcare, for which the patient and society are paying. Furthermore, satisfied patients show greater compliance and continue to attend for treatment[12, 13]. Quantification is demanding because a variety of factors, as yet poorly defined, influence the patient's perception of a satisfactory outcome. We conducted a literature review including studies on determinants of treatment satisfaction and nonspecific overall satisfaction of patients with hand problems. The results indicated that patient satisfaction is multifactorial. There is moderate evidence that pain/symptoms, activities of daily living/function, aesthetics, and embodiment influence patient satisfaction. Furthermore, data indicated that strength, range of motion, fulfilment of expectations, deformity, workers' compensation, and length of follow-up correlated with satisfaction.

Knowledge of these determinants may lead to a more detailed decision-making process, thus contributing to improved treatment outcomes and cost-effectiveness.

In routine practice, the recommended treatment goals are relief of pain or symptoms and restoration of the important individual functions, while taking the appearance of the hand and body-self unity into account. Restoration of strength, range of motion, and any deformity should also be addressed. In addition to evaluating these objective outcomes, the impact of the patients' individual expectations, whether they are involved in worker's compensation, and the time between treatment and follow-up all have to be considered.

The objective of **chapter six** was to analyse the outcomes of surgical and conservative treatment in patients with TMC OA and to evaluate determinants of treatment satisfaction. We conducted a prospective cohort study on patients with TMC OA who received either surgical or conservative treatment. Patients filled out the MHQ at baseline and 3, 6, and 12 months after the intervention. On 5-point Likert scales, they reported baseline expectations and their fulfilment at each follow-up visit, as well as satisfaction with treatment. These variables at baseline and 1 year, as well as sociodemographic and disease-related variables were entered into one ordered logistic regression model for surgical patients and into another for conservatively treated patients, in order to identify determinants of patient satisfaction at 1 year. This study included 165 patients, 97 of whom received surgery. Surgical patients improved continuously from a MHQ score of 47 ± 15 at baseline to 80 ± 16 at 1 year ($p \leq 0.001$). In the conservatively treated group, an improvement was found between baseline (61 ± 13) and 6 months (68 ± 15; $p \leq 0.001$), but not at 1 year (66 ± 17; $p = 0.055$). Expectations being fulfilled at 1 year was an important determinant of satisfaction in both groups. Based on these results, we concluded that surgery leads to a significant improved outcome up to 1 year. Conservative treatment is significantly effective for 6 months. As the fulfilment of expectations was an important determinant of satisfaction in both groups, we emphasised the importance of providing patients with comprehensive information prior to the intervention, in order to ensure that their expectations of the treatment outcome are realistic.

Chapter seven presented the economic aspects of conservative and surgical treatment of patients with TMC OA, analysing the costs associated with healthcare and with loss of productivity. This prospective cohort study included patients with TMC OA who received either conservative (corticosteroid injection) or surgical treatment (trapeziectomy with ligament reconstruction and tendon interposition or arthrodesis). Healthcare costs were measured using the earnings of our clinic in Swiss francs (CHF). Patients were assessed at baseline and 3, 6, and 12 months after the intervention. Employed patients filled out the Work Productivity and Activity Impairment Questionnaire (WPAI) to assess absenteeism, presenteeism, and overall costs due to loss of productivity. We included 161 patients, of whom 58 were in employment. Healthcare costs were CHF 10,303 in the surgery group and CHF 622 in the conservatively treated group ($p \leq 0.001$). The total productivity loss in the surgical group increased from baseline to 3 months (50% versus 64%; $p = 0.136$) and decreased significantly from 3 to 6 months (64% versus 33%; $p \leq 0.001$). Total productivity loss in the conservatively treated group was more stable over time (52% at baseline to 48% at 1 year, $p = 0.051$). The annual healthcare and productivity costs of CHF 20,210 estimated for the surgical group were higher than the CHF 6,877 estimated for the conservatively treated group ($p \leq 0.001$). In conclusion, surgery was

associated with considerably higher costs than conservative treatment, with respect to both healthcare and loss of productivity. The extent of improved productivity after more than a year and its related economic consequences should be the subjects of further research.

DISCUSSION

The research for this thesis has shown that patients with hand OA report severe limitations in daily life, in particular when opening food packaging. We developed guidelines for the industry on the production of easy-to-open food packaging. A variety of patient-reported outcomes are currently used to measure interventions in patients with TMC OA, but none of them has overall positive ratings. We were able to show that the MHQ demonstrates good reliability, validity, and responsiveness in patients with TMC OA and we recommend it as a suitable assessment tool in this population. Regarding satisfaction we found that many variables determine patient satisfaction with treatment – relief of pain or symptoms and restoration of hand function being the most important determinants in patients with orthopaedic hand conditions. In patients with TMC OA, the fulfilment of expectations was found to be an important determinant of satisfaction. In the analysis of two different treatment strategies, conservative and surgical management, in patients with TMC OA, we showed that surgery leads to significantly improved hand function after one year, while conservative treatment seems to be most effective in the first 6 months. From an economic point of view, however, surgery was associated with considerably higher costs than conservative treatment, with respect to both healthcare and loss of productivity.

Patients' limitations in daily life

So far, several studies have described activity limitations in patients with hand OA. Most of the activities addressed are pinch-related, such as writing, moving small objects, turning keys in locks, as well as grasping and carrying large objects, for example unscrewing jars[14-16]. In recent years, activities of daily living have changed. Although writing by hand was an important activity 20 years ago, people nowadays use computers, laptops, tablets, and smartphones. Besides the many advantages of using computers and mobile devices for work, it also leads to new complaints. Researchers have shown that the time spent using a mobile phone is significantly associated with pain in the base of the thumb, and that excessive texting is related to TMC OA[17, 18]. Another very relevant but under-investigated issue in daily life is the opening of food packaging, which was addressed in **chapter two**. Up to 90% of the over 60s have difficulty opening peelable packaging, such as cheese/meat packaging, or are even unable to do so[19]. In particular, patients with hand disorders experience difficulties in opening food containers due to pain, loss of grip strength, and reduced dexterity[20-22]. As demographic aging in Europe will increase in the coming years, the number of people with hand conditions and thus difficulties in opening packaging will rise correspondingly. The ease of opening food containers will therefore be increasingly important, not only to consumers but also to producers wanting to satisfy their clients' needs and achieve high brand loyalty[23].

More than 30 years ago, in the early 80s, Berns identified the issue of opening food containers for healthy as well as for handicapped people[24]. He also measured the forces that patients were able to apply to different types of food packaging and provided norm data useful for the industry[24]. However, opening packaging requires more than just hand strength. Besides

manual function, sensitivity is important when opening consumer products, as are visual and cognitive aspects[19]. Easy-to-open packaging not only has to be opened without much force but also depends on such factors as the visibility and simplicity of the opening mechanism[20, 25]. Even small changes in the size of the tear tab, the material used, its geometry or the design therefore have a large impact on the ease of opening the packaging[23, 25-27].

Although researchers[23, 25-32] other than Berns[24] have also documented the issue of opening food containers, the industry in Germany and Switzerland has not yet put much effort into the development of easy-to-open packaging.

Based on our results presented in **chapter two**, a Swiss retailer (Coop, Basel) initiated a project to develop easy-to-open food packaging. They aimed to optimise peelable meat packaging. The issue with the old packaging was that it needed a great deal of force to open it because the packs were sealed so strongly. Furthermore, the space provided for holding the tear tab was too small and the plastic cover often tore during opening. The technical optimisation process addressed these issues by ensuring that sealing parameters, including time, temperature, and pressure, were adapted in such a way as to make the packaging easier to open while the contents remained safely wrapped. The sealing seam and its tear contour were changed in order to provide optimal force distribution during opening. Another innovation was an additional notch, the size of a thumb or fingertip, placed laterally in the bottom plastic foil. A notch was put on each side, so that it could be used easily by left-handed as well as right-handed persons. In order to evaluate whether these technical optimisations were successful, we performed a cross-sectional study on 100 patients with hand osteoarthritis[33]. The results provide good evidence that patients with hand OA are significantly more satisfied with the optimised meat packaging than with the old-style packs. When patients with hand disorders are satisfied with the optimised packaging, we can assume that healthy people will also be happy with it. We have shown that it is possible for manufacturers today to produce easy-to-open food packages that afford greater consumer satisfaction[33].

Difficulty in opening packaging is also seen when taking medicines[34]. Efforts were made to produce an easy-to-open screw-cap container, although it had to be withdrawn from the market due to cost-effectiveness issues[34]. In cases where patients report difficulties opening their medicine containers, pharmacists could give the patient some tips and tricks, suggest helpful tools, or even remove tablets from the packs and store them in a user-friendly container[34].

Further research should analyse the difficulties patients with hand disorders experience in opening other kinds of packaging, so that recommendations for optimisation procedures can be made to the industry. However, not all types of packaging can be made easier to open, because the safety of the contents is the retailer's first priority. In such cases, it would be useful to develop special assistive devices which could be sold together with the product.

Outcome measures

Standardised outcome measures are essential to monitor a disease process and to evaluate the outcome of treatment[35]. Nowadays not only patients and health professionals are interested in outcomes but also hospital managers, lawyers, policy-makers, and the media[36]. Which outcome measures should be used for a comprehensive assessment of the health status and treatment outcome in patients with TMC OA has not yet been defined[36].

This topic was investigated in **chapter three**, with a systematic review of the outcome measures used in TMC OA studies**.** We found a wide variety of outcome measures, with pain and function being used most frequently and QoL clearly under-represented. Studies rarely examined the measurement properties of outcome measures specifically for patients with TMC OA, and the methodological quality of those that did so was only fair, so that it is not yet possible to make any recommendations for the use of a particular outcome measure.

Statistical comparison of different interventions remains unfeasible because of the variety of different outcome measures used in the past. This aspect has also been emphasised in systematic reviews on the treatment of TMC OA[37] and hand OA[7]. The finding that numerous tools (some self-developed) have been used to assess the effectiveness of treatment highlights the need to develop standardised and validated outcome measures for patients with TMC OA, in order to facilitate comparisons of patient populations and the outcomes of different surgical and non-surgical procedures.

The observed predominance of objective measures (such as muscle strength and range of motion) shows that many researchers still do not make the subjective patient perspective their primary focus. This implies under-representation of concepts such as the psychological state, appearance of the hand, and leisure activities, which are important to patients with hand OA[38].

Another issue with the current patient-reported outcome measures, most of them developed in the late 1990s or in the early 2000s, is that they sometimes include old-fashioned items. The DASH, for example, includes an item about difficulties with writing. Nowadays, people hardly ever write by hand. They use computers, laptops, tablets, and smartphones instead. However, none of the various patient-reported outcome measures considers these aspects, not even the thumb-specific Nelson score developed in 2007[39]. Questionnaires developed in the late 1990s need to be updated, replacing old-fashioned items with current ones. Patients should be involved in the revision process, to ensure that items relevant to the target population are covered.

Apart from its measurement properties, other characteristics of a questionnaire such as availability and practicability have to be considered[40, 41]. Several questionnaires carry licence fees. Some questionnaires are easy to score, while others need special software. The number of items and the time required to fill out the questionnaire also have to be considered, bearing in mind the burden on the patient. Furthermore, the researcher has to be aware of the aim and content of the outcome measure, in order to determine the right outcome measure for the intended purpose[40, 41].

Other useful tools to describe the patient's condition comprehensively are the International Classification of Functioning, Disability and Health (ICF) core sets. The ICF offers a comprehensive understanding of the individual health condition based on body functions and structures, activities, participation, personal attributes and environmental factors, providing a scientific basis for studying health, health-related states, outcomes, and the related determinants[42]. Three core sets might be relevant to patients with TMC OA: the ICF core set for OA[43], although it focusses more on hip and knee OA; the ICF core set for hand conditions[44]; and the brief ICF core set for hand conditions[45]. The core set for hand conditions covers 117 categories of functioning, potentially relevant to individuals with any hand condition, while the brief core set covers 23 categories[45]. These core sets assist clinicians in planning treatment from a comprehensive perspective, taking into account not only the body functions and structures

but also psychological aspects, difficulties in daily living and participation, and the individual's environment. There is also a rating scale available, the ICF qualifier, which is useful for evaluating the outcome of an intervention[45].

An important point when conducting a systematic literature review, as we did in **chapter three**, is the assessment of the methodological quality of the studies included. However, there are no uniform guidelines for assessing different types of studies. The Cochrane collaboration recommends its risk of bias tool for randomised controlled trials (RCTs)[46]. There are various checklists and scores available for observational studies, but none of them can be recommended as a gold-standard[47]. The Structured Effectiveness Quality Evaluation Scale (SEQES)[48] seems to be useful in determining the quality of both RCTs and observational studies. This checklist consists of 24 items, including the domains of study question and design, subjects, intervention, outcomes, analysis, and recommendations. Each item is scored on a three-point scale (0-2), giving a maximum of 48, with higher scores indicating higher methodological quality. However, one issue with the SEQES tool is that scores for observational studies are considerably lower than those of RCTs, because some items are designed specifically for RCTs[48]. Furthermore, it has not yet been tested for reliability and validity. Other common checklists, such as the Consolidated Standards of Reporting Trials (CONSORT)[49], the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)[50, 51], and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[52] statements, are not intended to serve as quality appraisal tools but to guide authors when reporting RCTs, systematic reviews, and observational studies, respectively. Guidelines for the evaluation of the methodological quality of studies on the measurement properties of health-related patient-reported outcomes are described in the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist[53-55]. This checklist is useful when selecting a measurement tool, peer-reviewing a manuscript, designing or reporting a study on measurement properties, and for educational purposes[55].

The results of **chapter three** indicated that more research is needed on hand-specific questionnaires, to determine which are the most suitable for detecting changes in patients with TMC OA. The next step required is to investigate the measurement properties of hand-specific questionnaires that have not yet been evaluated in patients with TMC OA. The review also emphasised that these studies need to be methodologically sound before we can make any firm recommendations about the use of specific tools.

Our next step towards identifying suitable outcome measures for patients with TMC OA was an evaluation of the MHQ, and this was described in **chapter four.** The results of the study provide evidence that the MHQ is a reliable, valid, and responsive tool for assessing treatment outcomes in patients with TMC OA. Compared with the DASH, the hand-specific MHQ showed more favourable results for internal consistency, responsiveness, and missing items, indicating that it is more suitable for patients with conditions affecting the thumb.

In our study, internal consistency for the MHQ was satisfactory, although item redundancy was apparent in other studies[56]. For that reason, and because patients need a relatively long time to complete the questionnaire[57, 58], a short form of the MHQ has recently been developed[59]. The BriefMHQ shows similar measurement properties to the original version and is highly recommended as a more efficient tool in large studies, as a cross-sectional screening

tool, and for documenting the outcome in routine clinical practice, as it reduces responder burden and increases response rates[59, 60]. Use of the original MHQ is still advocated, however, as it provides a more comprehensive analysis of the patient's condition[59]. In addition, the full MHQ can assess the two hands separately, so that stratification for hand dominance or affected hand is possible[56], something which neither the BriefMHQ nor the DASH allows.

Regarding responsiveness, the lowest effect size related to the MHQ aesthetics subscale. This fact, combined with the relatively high baseline scores and the ceiling effect of this subscale, indicates that the appearance of the hand is not as important to patients with TMC OA as it is to patients with rheumatoid arthritis[56], for example. On average, patients who underwent metacarpophalangeal joint arthroplasty had baseline values in the MHQ aesthetics subscale 40 points lower than our patients, and the standardised response mean (SRM) was very high at 1.2[56].

When interpreting change scores of an outcome measure, it has to be considered whether they are based at a group level or at an individual level[61]. On a group level, smaller changes may be interpreted as important, whereas larger changes are required at an individual level before they are confidently accepted as indicating a meaningful change[61].

The MIC[62], which was introduced by Guyatt et al.[63], facilitates the interpretation of change scores at an individual level. The MIC is the smallest change in score in the construct to be measured that patients perceive as important[54]. Two approaches to calculating the MIC are described in the literature: the anchor-based and the distribution-based method[64, 65].

The anchor-based approach that we used in **chapter four** requires an external criterion, the anchor. This might be a global question about the perceived change in the condition over a certain time, used to identify patients who have changed to a small but meaningful degree and others who have not changed. The MIC can now be calculated using a receiver operating characteristic (ROC) curve, where the optimal cut-off point reflects the MIC. Another method is the mean-change method, where the MIC is defined as the change value of the patients who consider themselves to be slightly improved[62, 64, 65].

The advantage of the anchor-based approach is that patient-related information about the perceived change is explicitly incorporated. However, it fails to take into account the variability of the assessment tool scores in the sample[65].

Distribution-based approaches take the distribution of the tool scores and its variability into account. They express the observed change in a group of patients in a standardised way. Frequently used parameters are standard deviation (SD), effect size (ES), and the standard error of measurement (SEM). Values of 0.5 x SD, or the value corresponding to an ES of 0.5, or 1.96 x SEM, have all been proposed to reflect the MIC. As these are solely statistical measures which do not take the importance from the patient's perspective into account, anchor-based approaches are preferred[64, 65]. Distribution-based calculations are nevertheless useful as supportive information. To combine the characteristics of both approaches, de Vet et al. developed an integrated method[66]; however, this visual method has not yet been used in populations with hand disorders.

MIC values are always determined in groups of patients (e.g. in an RCT or a longitudinal observational study), although this does not say anything about the level on which the MIC is applied[62]. It depends whether the anchor used for determining the MIC is on the group or individual level. An individual-focused approach applies in most clinical trials, which means that the MIC derived from a group of patients can be transferred to the individual[62]. The MIC is also

useful for calculating statistical power and determining sample sizes for a research project[64]. It varies across populations, disease characteristics, and treatments[64].

Apart from our study, there is one other study that has investigated the MIC of the MHQ[67]. Differences in the findings can be interpreted on the basis of different populations and the disparate methods used to calculate the MIC.

Future research should include a comparison of the MHQ with other hand specific questionnaires, such as the AUSCAN[68], PRWE[69], and Patient Evaluation Measure (PEM)[12], in order to find the best questionnaire for each purpose and target population. The calculation of the MIC for these questionnaires is useful to provide a number for sample size calculation and for the interpretation of treatment outcomes.

Patient satisfaction

Assessing patient satisfaction is becoming more and more important, because it contributes to the continuous evaluation of healthcare, for which the patient and society are paying[70]. Satisfied patients show greater compliance with treatment and an increased likelihood of returning to the same healthcare provider[12, 13]. Quantification is demanding because a variety of factors, as yet poorly defined, influence the patient's perception of a satisfactory outcome[12].

In order to identify which factors are associated with patient satisfaction following orthopaedic interventions in the hand, we reviewed the literature, as presented in **chapter five**.

The results indicate that a number of factors play a role in determining patient satisfaction; the hand surgeon or therapist can influence some of these factors, while others are beyond their control. The determinants revealed by this literature review could be effectively classified into the five categories of the ICF[42]. Factors in every category have an impact on treatment satisfaction, though most of them relate to body functions/body structures. This may be due to the fact that these factors are the ones most often studied while others such as environmental and personal factors have been less thoroughly investigated.

In reviewing the literature, we found that the appearance of the hand contributes to patient satisfaction. However, the studies investigated patients with rheumatoid arthritis[71, 72]. Based on the results of chapter four, where we found only a moderate effect size for the aesthetic subscale of the MHQ, we assume that the appearance of the hand is not such an important issue to patients with TMC OA as it is to patients with rheumatoid arthritis.

Strength and range of motion seem to correlate with patient satisfaction, although there is great diversity in the correlation coefficients. Chung and Hass[73] defined cut-off points for grip strength, key pinch strength, and range of motion related to satisfaction with these objective parameters after surgery for distal radius fractures. They found the cut-offs to be 65%, 87%, and 95%, respectively, of the function of the other, unaffected, hand. These findings highlight the importance of measuring objective outcomes and defining values to distinguish between satisfied and dissatisfied patients with any hand problem.

In the ICF category of environmental factors, we showed that patients who receive money during time of disability are less satisfied. Further studies also indicate that patients receiving worker's compensation were less satisfied with the results of a revision trapeziometacarpal joint arthroplasty[74] and had a higher risk of failure of partial wrist denervation[75]; the most influential predictor of pain and disability was third-party compensation[76].

When assessing patient satisfaction, it has to be remembered that several dimensions contribute to the individual perception of satisfaction. Satisfaction with the treatment outcome is only one aspect. Other aspects include facilities, service features, continuity of care, humaneness, competence, and the treatment process itself[12, 77]. Factors such as the friendliness of the staff[78-81], waiting times[79], time spent with the provider[79, 82], state of the facilities[81], and food[80, 81] have to be kept in mind, because they may also affect patient satisfaction. Furthermore, patient satisfaction is influenced by specific personal characteristics comprising expectations, demographics, and personal preferences[83].

Based on the results of this review, we recommend that treatment goals in routine practice should be the relief of pain or symptoms and restoration of the important individual functions, while taking the appearance of the hand into account. In addition, restoration of strength, range of motion, and deformity should be addressed. As well as evaluating these objective outcomes, consideration must be given to the impact of the patient's individual expectations and whether worker's compensation applies.

Further research needs to address the issue of assessing patient satisfaction. To date, satisfaction is measured using various approaches such as Likert Scales, visual analogue scales or the MHQ satisfaction subscale, which precludes statistical comparisons between studies. The focus should be on developing a standardised assessment tool for use in routine clinical practice.

Although we were able to identify several factors which might determine satisfaction in patients with various hand disorders, it was still not clear whether they were also true for patients with TMC OA. A retrospective study on patients after implant arthroplasty of the TMC joint, showed a correlation with satisfaction of $r > 0.7$ for pain, movement, strength, and ability to perform activities of daily living[84]. There is a lack of prospective studies investigating determinants of patient satisfaction after surgical and conservative management of TMC OA. In order to resolve this issue, **chapter six** evaluated determinants of patient satisfaction in the surgical and conservative treatment of patients with TMC OA.

The results of the cohort study revealed that patients' expectations play a major role in predicting satisfaction as the variable 'expectations fulfilled' was an important determinant of treatment satisfaction in both groups. These findings support the results of chapter five, where 'expectations met' has also been identified as associated with patient satisfaction.

In the field of hand surgery and hand therapy, evidence on the importance of expectations is still rare. Patients are often unaware of the severity of an injury and the complexity of treatment[85]. An association between expectations being fulfilled and patient satisfaction has been reported for patients after MCP arthroplasty[86]. It has also been shown that expectations being met and a general optimistic view of health accounted for 31% of the variability in postoperative DASH scores in patients after carpal tunnel release[87]. Our conclusion that patients are more likely to be satisfied if their expectations are fulfilled is confirmed in other studies on patients undergoing orthopaedic and abdominal surgery[88], patients seeking out-of-hours care[89], adults presenting a physical symptom[90], and patients with total hip and knee arthroplasty[91, 92].

In contrast to expectations fulfilled after the intervention, the relevance of the preoperative expectations in hand surgery has not been demonstrated to date[87]. Research on expectations in patients with other musculoskeletal conditions found that positive expectations of the

outcome predicted a favourable outcome and higher satisfaction, whereas negative baseline expectations were associated with a worse outcome[93].

The association between expectations and satisfaction substantiates the relevance of the decision-making process prior to an intervention. Detailed patient education about the injury and the resulting intervention may lead to better adherence to treatment[85]. In areas other than hand surgery and therapy, it has been shown that the information given to the patient and shared decision making can have a positive effect on patient satisfaction[81, 90, 94].

Based on these results, we can conclude that expectations being fulfilled is an important determinant of treatment satisfaction. It highlights the need to evaluate expectations and to provide patients with comprehensive information prior to the intervention, so that their expectations of the treatment outcome are realistic.

As mentioned previously, further research needs to address the issue of assessing patient satisfaction, as well as evaluating individual expectations. Whenever expectations are measured at the present time, which is rarely the case, different non-standardised tools are used for surveying baseline expectations and evaluating their fulfilment. This variety of outcome measures precludes statistical comparisons between studies. The focus should be on developing a standardised assessment tool for routine use in clinical practice to evaluate patients' expectations prior to treatment and to determine their fulfilment and satisfaction when treatment is finished.

Clinical outcomes in the treatment of patients with TMC OA

Besides the determinants for satisfaction, **chapter six** analysed the outcomes of surgical and conservative treatment in patients with TMC OA. The results of this cohort study showed that patients treated conservatively had fewer complaints at baseline and a less advanced stage of OA than patients who had been operated on. Conservative treatment seemed to be most effective in the first six months. Other studies reported similar results: patients with stage I or II TMC OA benefitted more from conservative treatment, and for a longer period, than patients with more severe TMC OA[95, 96]. The effects of a steroid injection in patients with TMC OA stage I or II have been found to last from 4 to 18 months[95, 96]. These findings also support our regression analysis results showing that conservatively treated patients with a more advanced Eaton stage of OA seem to be less satisfied with the treatment result. Conservative treatment, including nonsteroidal anti-inflammatory drugs (NSAIDs), physiotherapy, analgesics, splints, and intra-articular corticosteroid injections, has not been shown to have any long-term effectiveness[95-97].

The decision on the treatment strategy for our patients was made individually in each case. Our surgeons usually prefer to treat patients with only mild complaints conservatively but suggest surgery to patients with severe pain and restrictions in daily life. This approach is confirmed by other researchers, who recommended surgery in cases where pain restricts the patient's daily life or when conservative treatment fails[14, 97, 98]. However, steroid injections might be useful in patients severely affected by TMC OA, in order to reduce the symptoms while waiting for surgery[95, 97, 98].

In the surgical group, hand function measured with the MHQ showed a significant improvement of 31 points between baseline and 1 year. As this change is above the value for the MIC of 17 points[99], we can assume that this result is not only statistically significant but also

clinically meaningful for the patients. Similar changes were found for patients after abductor pollicis longus suspension arthroplasty[100] and after basal thumb metacarpal osteotomy[101], with patients in the latter study improving by 28 points after three years. This result indicates that the outcomes of surgery for TMC OA remain stable with time.

Based on these results, we can conclude that patients with mild complaints may benefit from conservative treatment with an effect lasting about six months. We suggest surgery in cases where pain limits the patient's daily life or when conservative treatment fails.

Further research is needed to compare different surgical treatment strategies. Although trapeziectomy with ligament reconstruction and tendon interposition (LRTI) is the first choice of 2/3 of American hand surgeons[102, 103], there is limited evidence for the superiority of that technique in terms of pain reduction and restoration of hand function[37, 104, 105]. Some studies suggest that trapeziectomy alone results in fewer adverse events than trapeziectomy with LRTI[37, 104, 105]. It still has to be confirmed whether LRTI produces better long-term results because the scaphoid-metacarpal distance is preserved[105]. In addition, the development of an algorithm to identify patients who would benefit from conservative management or from surgery would be useful to assist in making the medical decision prior to an intervention.

Economic aspects

Economic aspects in the treatment of TMC OA were investigated in **chapter seven**. In medicine, the effectiveness of interventions has traditionally been evaluated in terms of mortality, clinical aspects, and patient-related outcomes[106, 107]. In recent years, however, outcome measures have expanded to include economic analyses, due to the increasing costs of healthcare combined with the costs for the employers. Expenses for the employer arise from absenteeism, short-term disability, long-term disability, worker's compensation, and presenteeism[106, 107]. Presenteeism, i.e. reduced productivity at work due to health problems, is not only an issue for employers but also for the workers. From their perspective, going to work when not feeling well is important because it might exacerbate existing medical conditions, reduce the quality of working life, and lead to an impression of inefficiency due to reduced productivity[107]. On the other hand, loyalty to the employer may encourage people to go to work when they are not feeling up to it and can be regarded as productive gain instead of loss due to absenteeism[107].

In contrast to absenteeism, the quantification of presenteeism is complex[106]. Several instruments to measure the impact of illness on productivity have been developed and reviewed[106, 108-112]. Although most of these tools provide sound measurement properties, all of them have some shortcomings[106]. Some of the questionnaires were developed for a specific health condition and are not transferrable to other diseases. Others are intended to be used in clinical settings and are therefore useless for employers. The major issues concern scoring the questionnaires, converting the answers into a usable construct such as lost time, and translating the scores into monetary values[106]. For some questionnaires, such as the WPAI[113] that we used in the work described in **chapter seven**, the answers are easily convertible into figures for absenteeism and presenteeism. Answers to other questionnaires, however, cannot be converted directly or the conversion methods have not been published[106]. Due to the variety of outcome measures and translation methods, research results cannot be compared between different studies at the present time. Awareness of the methods is therefore important when interpreting study

results. The subsequent translation of figures for presenteeism to monetary values can be based on different economic models, such as the human-capital method or the friction-cost method. However, there is no general consensus as to which model is the best. Researchers should be clear and transparent about how they measured presenteeism and how they converted and translated it into monetary values[106]. They are also encouraged to consider the target concept and the purpose of the intended application, as well as the underlying economic model[106, 109].

In the WPAI, presenteeism is calculated by using the answer to question 5 ("How much did your TMC OA affect your productivity while you were working?"). If patients give a score of 8 out of 10, would that necessarily mean that they are only able to work 20%, leading to a 80% loss for the employer[111]? This might be true for some jobs, but it is unlikely in others[111]. The costs of presenteeism may therefore generally be overestimated, something that has also been indicated in a study including patients with rheumatoid arthritis[114].

In **chapter seven**, we found a large difference in total annual costs between surgical and conservatively treated patients, but we cannot make any firm treatment recommendations based on these results. The indications for injection therapy and surgery are different, and any such recommendations have to consider both the clinical and subjective outcomes. In **chapter six**, we found significantly better outcomes for surgical patients than for those treated conservatively.

Bearing in mind both the outcomes and the economic aspects, cost-effectiveness or cost-utility analyses are useful for making treatment recommendations. In these types of study, the costs of two (or more) interventions are put in relation to the clinical outcomes or utility measures, respectively[115]. Utilities are usually expressed as quality-adjusted life-years (QALYs) which can be derived from quality of life questionnaires, such as the SF-36 or the EuroQol-5D (EQ-5D)[115]. It was not worth performing a cost-utility analysis with our patient population, because the two treatment groups were not comparable with respect to either indications or outcomes.

Future studies, preferably with a randomised design, should include economic analyses. It is useful to compare different surgical treatment options with each other or with different conservative strategies. If the indications for the different treatment options are equal, cost-utility studies may assist the healthcare provider to choose the best treatment for the patient, bearing in mind the economic consequences. Ideally, a cost-utility study would also include other healthcare costs, such as those incurred for drugs, physiotherapy, assistive devices, nursing services, and visits to other doctors. The cooperation of health insurers would be required to access the relevant data. Further research should also assess the accuracy and usefulness of different tools in specific settings[108]. Standard presenteeism metrics need to be defined, in order to allow the comparison of study results[111].

CONCLUSIONS

This thesis investigated different aspects relevant to patients with hand OA: patients' limitations in daily life, outcome measures, and treatment outcomes, focussing on patient satisfaction as well as economic aspects.

Regarding limitations in daily life, it can be concluded that patients report severe restrictions, in particular in opening food packaging. In order to make life easier for patients in the future, we defined guidelines for the industry on the production of easy-to-open food packaging.

A systematic literature review of outcome measures for patients with TMC OA found that numerous patient-reported outcome measures are used at present. None of them show overall positive ratings with respect to measurement properties, which is partly due to the lack of methodologically sound studies. In an observational study, we were able to show that the MHQ demonstrates good reliability, validity, and responsiveness in patients with TMC OA and we recommend it as a suitable assessment tool in this population.

With respect to satisfaction, many variables determine patient satisfaction with treatment; relief of pain or symptoms and the restoration of hand function are the most important determinants in patients with orthopaedic hand conditions. In patients with TMC OA, it was found that expectations being fulfilled was an important determinant of treatment satisfaction. Giving patients comprehensive information prior to the intervention is of the utmost importance to ensure that their expectations of the treatment outcome are realistic.

Evaluation of the outcomes of conservative and surgical management in patients with TMC OA showed that surgery leads to significantly improved hand function after one year, while conservative treatment seems to be most effective in the first 6 months. These results suggest that patients with mild complaints benefit from conservative treatment, with the effects lasting about 6 months. Surgery is indicated in cases where pain limits the patient's daily life or when conservative treatment fails. From an economic point of view, however, surgery is associated with considerably higher costs than conservative treatment, with respect to both healthcare costs and loss of productivity.

In medicine, the doctor-patient relationship enters an important dimension when evaluating treatment performance. The use of validated outcome measures should be mandatory for assessing any form of treatment, whether surgical or conservative. The results will further enhance the close interrelationships between patients and their healthcare providers.

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CHAPTER **NINE**

NEDERLANDSE SAMENVATTING



SAMENVATTING

Artrose is de meest voorkomende gewrichtsaandoening, die bij een groot deel van de patiënten leidt tot beperkingen in het functioneren en verminderde kwaliteit van leven, met aanzienlijke maatschappelijke en economische gevolgen[1-3]. In de hand zijn de distale interfalangeale (DIP) gewrichten het vaakst aangedaan door artrose, gevolgd door de carpometacarpale I (CMC I; duimbasis) en proximale interfalangeale (PIP) gewrichten[4-6].

Patiënten met handartrose hebben vaak veel beperkingen in hun dagelijks functioneren[3, 7, 8]. Door de pijn, in combinatie met verminderde beweeglijkheid van de vingers en verminderde knijpkracht, ervaren zij problemen bij bepaalde handelingen en activiteiten. De taken waarbij zij het meest gehinderd worden zijn het uitwringen van bijvoorbeeld washandjes en het openen van potten en flessen[9]. Voor patiënten met handartrose bestaan er verschillende medicamenteuze, niet-medicamenteuze en chirurgische behandelmogelijkheden[1, 10, 11].

Het doel van dit proefschrift, dat uit 2 delen bestaat, is om de beperkingen in het dagelijks functioneren, uitkomstmaten en klinische uitkomsten bij patiënten met handartrose en in het bijzonder CMC I artrose te bestuderen, met de nadruk op patiënt tevredenheid en economische aspecten.

Deel EEN, bestaande de **hoofdstukken twee, drie** en **vier**, beschrijft beperkingen in het dagelijks functioneren en relevante uitkomstmaten bij handartrose. **Deel TWEE** omvat de **hoofdstukken vijf, zes** en **zeven,** en beschrijft de resultaten van chirurgische en niet-chirurgische behandeling van handartrose, inclusief de tevredenheid en economische aspecten.

Deel EEN

Hoofdstuk twee richt zich op de beperkingen van patiënten in het dagelijks leven en in het bijzonder op het specifieke probleem van het openen van levensmiddelenverpakkingen. Het uiteindelijke doel van het onderzoek dat in dit hoofdstuk wordt beschreven was, om richtlijnen voor de productie van gemakkelijk te openen verpakkingen voor de industrie te ontwikkelen. In een dwarsdoorsnede onderzoek werd gekeken welke kracht patiënten konden uitoefenen op scheurstrips en treklipjes van verpakkingen. Deze gegevens werden vergeleken met de resultaten verkregen bij gezonde proefpersonen van dezelfde leeftijd en geslacht. In dit onderzoek werden honderd patiënten met verschillende handaandoeningen geïncludeerd. De knijp-trekkracht die bij het gebruik van de pincetgreep (pinch pull force: PPF) kon worden uitgeoefend op scheurstrips en treklipjes van verschillende lengte en gemaakt van verschillende materialen (aluminium en plastic) werd gemeten met speciaal daarvoor ontworpen meetinstrumenten. De knijpkracht van de pincetgreep werd gemeten met een pincet-knijpkrachtmeter. Normaalwaarden werden verkregen uit een ander onderzoek, waaraan 402 gezonde volwassenen deelnamen. De resultaten van dit onderzoek lieten zien dat de patiënten de meeste knijp-trekkracht konden uitoefenen op de langere treklipjes van aluminium. De gemiddelde kracht die patiënten konden uitoefenen was echter slechts 53% van die van gezonde proefpersonen. Bovendien werd vastgesteld dat de kracht van de pincetgreep een belangrijke determinant van de PPF was (R^2 = 0.548, p ≤ 0.001). Ten aanzien van de in het algemeen ervaren problemen bij het openen van verschillende verpakkingen antwoordde 82% van de patiënten dat het openen van jampotten moeilijkheden opleverde,

78% het openen van verpakkingen van vleeswaren en kaas en 69% het openen van flessen. Concluderend is het advies voor de industrie om lange, aluminium treklipjes te gebruiken voor levensmiddelenverpakkingen. Daarnaast wordt zorgverleners aangeraden om de pincet-knijpkracht te meten en om aandacht te besteden aan problemen die patiënten kunnen ervaren met het openen van verpakkingen.

Hoofdstuk drie belicht de uitkomstmaten en meetinstrumenten die gebruikt worden in onderzoek bij patiënten met CMC I artrose. In een systematisch literatuuronderzoek werden alle uitkomstmaten die werden gebruikt in klinische artikelen over patiënten met CMC I artrose beschreven. Ze werden ingedeeld volgens de Outcome Measures in Rheumatology (OMERACT) core set voor artrose, die vijf dimensies omvat: pijn, fysiek functioneren, algemene beoordeling, beeldvorming en kwaliteit van leven. In totaal werden 316 artikelen gevonden, waarin 101 verschillende uitkomstmaten werden gebruikt, die meestal betrekking hadden op de OMERACT domeinen pijn en fysiek functioneren. Uitkomstmaten voor kwaliteit van leven waren ondervertegenwoordigd. Er waren daarnaast 12 artikelen waarin de klinimetrische eigenschappen van 12 uitkomstmaten voor CMC I artrose werden beschreven. De Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) en Patient-Rated Wrist Evaluation (PRWE) waren de meest onderzochte instrumenten. Er was geen publicatie waarin alle klinimetrische eigenschappen van deze instrumenten onderzocht werden. De DASH, de quickDASH, de Australian / Canadian Osteoarthritis Hand Index (AUSCAN) en de Nelson Score kregen de beste beoordelingen, terwijl de beoordelingen van de Eaton classification, de carpometacarpal grind / duimbasis provocatietest en de Hand Functional Index van de Keitel Functional Test minder gunstig waren. De beoordelingen van de PRWE en de Short Form 36 (SF-36) waren moeilijk te interpreteren. De methodologische kwaliteit van de studies waarin de klinimetrische eigenschappen van meetinstrumenten werden onderzocht was in het algemeen matig tot slecht, wat betekent dat er op grond van de literatuur geen aanbeveling gedaan kan worden over welke van deze uitkomstmaten te gebruiken.

Een onderzoek naar de betrouwbaarheid, validiteit en responsiviteit van de Michigan Hand Outcomes Questionnaire (MHQ) bij patiënten met CMC I artrose wordt beschreven in **hoofdstuk vier.** In een prospectief onderzoek werden 177 patiënten met CMC I artrose onderzocht die een operatieve of conservatieve behandeling kregen. Bij aanvang van het onderzoek en na een jaar werd de pincet-knijpkracht gemeten en de patiënten vulden de vragenlijsten MHQ, de DASH, en de Short Form 12 (SF12) in. Deze vragenlijsten werden 2 tot 11 dagen na het laatste bezoek nogmaals afgenomen.Om de klinimetrische eigenschappen van de MHQ te onderzoeken werden de test-hertest betrouwbaarheid (intra class correlatie coëfficiënt, ICC), de interne consistentie (Cronbach's alfa voor de 6 subschalen), de constructvaliditeit (Pearson's correlatie coëfficiënt, r), responsiviteit (effect sizes), en de minimal important change (MIC) bepaald. Uit dit onderzoek bleek dat de MHQ score van de chirurgisch behandelde patiënten toenam van 48 ± 14 voor de behandeling tot 75 ± 18 na een jaar ($p \leq 0.001$).Daarentegen werd in de conservatief behandelde groep geen behandeleffect gezien ($p = 0.74$). The MHQ totaal score had een excellente test-hertest betrouwbaarheid (ICC = 0.95) en correleerde sterk met de DASH ($r = -0.77$). De interne consistentie van de MHQ subschalen varieerde tussen de 0.77 en 0.89. Een grote effect size van 1.7 werd gezien bij de operatief behandelde patiënten, met een MIC van 17 punten. Gebaseerd op

deze resultaten kan geconcludeerd worden dat de MHQ een betrouwbaar, valide en responsief meetinstrument is, dat kan worden aanbevolen voor gebruik bij patiënten met CMC I artrose.

Deel TWEE

Hoofdstuk vijf had tot doel om vast te stellen welke factoren geassocieerd zijn met patiënttevredenheid na orthopedische ingrepen aan de hand. Het meten van patiënttevredenheid gaat bij het bepalen van de uitkomsten in de gezondheidszorg een steeds belangrijkere rol spelen. Bekend is, dat tevreden patiënten een grotere therapietrouw hebben[12, 13]. Het kwantificeren van tevredenheid is echter moeilijk, omdat er vele factoren zijn op de tevredenheid van invloed zijn. Wij verrichtten een systematisch literatuuronderzoek naar studies waarin tevredenheid en de determinanten daarvan werden onderzocht bij patiënten met handproblematiek. De resultaten lieten zien dat patiënttevredenheid een multifactorieel bepaalde uitkomst is. Er is matig bewijs dat pijn/symptomen, activiteiten van het dagelijks leven, esthetiek en lichaamsbeeld van invloed zijn op patiënttevredenheid. Daarnaast werd gevonden dat kracht, beweeglijkheid, de mate waarin aan verwachtingen werd voldaan, deformiteiten, financiële compensatie bij ziekte en arbeidsongeschiktheid, en duur van de follow-up samenhingen met tevredenheid. Inzicht in deze determinanten kan het proces van besluitvorming over chirurgische ingrepen bij handproblematiek beïnvloeden en daarmee bijdragen aan een grotere kosteneffectiviteit ervan.

In de dagelijkse praktijk betekent dit dat deze ingrepen vooral zouden moeten worden gedaan met het oog op vermindering van pijn en verbetering van activiteiten waarbij de handen zijn betrokken, rekening houdend met het uiterlijk van de hand en het lichaamsbeeld dat de patiënt heeft. Ook moeten verbetering van kracht, beweeglijkheid en deformiteit in beschouwing worden genomen. Naast deze meer objectieve aspecten moeten factoren als verwachtingen die de patiënt heeft, financiële regelingen voor ziekteverzuim en arbeidsongeschiktheid, en de termijn waarop resultaat verwacht mag worden in de besluitvorming worden betrokken.

Het doel van **hoofdstuk zes** was om de resultaten van chirurgische en conservatieve behandelingen bij patiënten met CMC I artrose te beschrijven en determinanten van tevredenheid met de behandeling te bepalen. We voerden hiertoe een prospectieve cohort studie uit bij patiënten met CMC I artrose die ofwel chirurgische of conservatieve behandeling kregen. Patiënten vulden de Michigan Hand Questionnaire (MHQ) in op baseline en 3, 6 en 12 maanden na de interventie. Op 5 punt Likert schalen gaven zij aan wat hun verwachtingen waren en in hoeverre deze waren vervuld bij elk follow-up bezoek, evenals de tevredenheid met de behandeling. Deze variabelen en sociodemografische en ziekte-gerelateerde variabelen werden geanalyseerd in logistische regressiemodellen, apart voor chirurgische en voor conservatief behandelde patiënten, met patiënttevredenheid na 1 jaar als afhankelijke variabele. In totaal werden 165 patiënten geïncludeerd, van wie er 97 werden geopereerd. Chirurgische patiënten toonden een verbetering van de MHQ score van 47 ± 15 voor de behandeling tot 80 ± 16 na 1 jaar ($p \leq 0.001$). In de conservatief behandelde groep werd een significante verbetering gezien tussen de baseline (61 ± 13) en 6 maanden (68 ± 15; $p \leq 0.001$), maar niet na 1 jaar (66 ± 17; $p = 0.055$). De mate waarin verwachtingen van de uitkomst na 1 jaar in vervulling waren gegaan was een belangrijke determinant van tevredenheid in beide groepen. Gebaseerd op deze resultaten

kan worden geconcludeerd dat na operatie een significante verbetering werd gezien na 1 jaar. In de groep met conservatieve behandeling was er een significant effect tot 6 maanden. De mate waarin verwachtingen uitkwamen was een belangrijke determinant van tevredenheid in beide groepen. Dit benadrukt het belang van het verstrekken van goede informatie aan patiënten voorafgaand aan de interventie, om ervoor te zorgen dat hun verwachtingen van de resultaten van de behandeling realistisch zijn.

In **Hoofdstuk zeven** worden de economische aspecten van de conservatieve en chirurgische behandeling van patiënten met CMC I artrose gepresenteerd. In deze prospectieve cohort studie werden patiënten met CMC I artrose geïncludeerd die ofwel conservatieve (injectie met corticosteroïden) of chirurgische behandeling (trapeziectomie met ligament reconstructie en pees interpositie of artrodese) ondergingen. De directe kosten binnen de gezondheidszorg werden gemeten aan de hand van de inkomsten die de kliniek waar de patiënten werden behandeld ontving in verband met hun behandeling, in Zwitserse frank (CHF). Patiënten werden voor de operatie onderzocht en 3, 6 en 12 maanden er na. Patiënten die betaald werk hadden vulden de Work Productivity and Activity Impairment Questionnaire (WPAI) in, om het ziekteverzuim, productiviteit op het werk, en de totale kosten als gevolg van verlies van productiviteit te kunnen bepalen. In deze studie werden 161 patiënten geïncludeerd, van wie er 58 betaald werk hadden. De kosten binnen de gezondheidszorg bedroegen CHF 10.303 in de chirurgisch behandelde groep en CHF 622 in de conservatief behandelde groep ($p \leq 0.001$). Het totale productiviteitsverlies in de chirurgische groep nam toe tussen de preoperatieve situatie en 3 maanden daarna (50% versus 64%; $p = 0.136$) en nam weer significant af tussen 3 en 6 maanden na de operatie (64% versus 33%; $p \leq 0.001$). Het totale productiviteitsverlies in de conservatief behandelde groep was stabiel over de tijd (52 % bij de nulmeting tot 48% na 1 jaar, $p = 0.051$). De jaarlijkse kosten binnen de gezondheidszorg en de kosten van productiviteitsverlies werden geschat op CHF 20.210 in de chirurgische groep, en waren significant hoger dan de geschatte kosten van CHF 6.877 in de conservatief behandelde groep ($p \leq 0.001$). Concluderend waren de geschatte kosten van een operatief ingrijpen aanzienlijk hoger dan die van de conservatieve behandeling, zowel met betrekking tot de kosten binnen de gezondheidszorg als verlies aan productiviteit. De mate van verbetering van de productiviteit na een jaar en de daarmee samenhangende economische gevolgen moeten nader onderzocht worden.

CONCLUSIES

In dit proefschrift werden verschillende aspecten onderzocht die van belang zijn voor patiënten met handartrose: beperkingen in het dagelijks leven, uitkomstmaten en behandelingsresultaten zowel gericht op tevredenheid van de patiënt als op de economische aspecten.

Wat betreft de beperkingen in het dagelijks leven kan worden geconcludeerd dat patiënten ernstige beperkingen kunnen ondervinden, bijvoorbeeld bij het openen van verpakkingen van levensmiddelen. Om het openen van verpakkingen voor patiënten in de toekomst makkelijker te maken hebben we richtlijnen geformuleerd voor de industrie voor de productie van makkelijk te openen verpakking van levensmiddelen

Een systematisch literatuuronderzoek naar uitkomstmaten bij patiënten met CMC I artrose liet zien dat op dit moment tal van verschillende patiënt gerapporteerde uitkomstmaten worden

gebruikt. Geen enkele daarvan bezit optimale klinimetrische eigenschappen, wat deels te wijten is aan het ontbreken van methodologisch betrouwbaar onderzoek hiernaar. In een observationele studie toonden we aan dat de MHQ een betrouwbaar, valide en responsief meetinstrument was bij patiënten met CMC I artrose, en kan worden aanbevolen in deze populatie.

Van de variabelen die bepalend zijn voor de tevredenheid over de behandeling bij patiënten met verschillende orthopedische handaandoeningen, zijn verlichting van pijn of klachten en het herstel van de handfunctie de belangrijkste determinanten. Daarnaast was het al dan niet voldoen aan de verwachtingen een belangrijke determinant voor tevredenheid. Dit geeft aan dat het van het grootste belang is om voorafgaand aan ingrepen uitgebreide informatie te geven, om er zeker van te zijn dat de verwachtingen die de patiënt heeft van de resultaten van de behandeling realistisch zijn.

Uit de evaluatie van de resultaten van conservatieve en chirurgische behandeling bij patiënten met CMC I artrose bleek dat operatie leidt tot een aanzienlijk verbetering van handfunctie na een jaar, terwijl de conservatieve behandeling het meest effectief lijkt in de eerste 6 maanden. Deze resultaten suggereren dat patiënten met milde klachten profiteren van conservatieve behandeling, waarbij de resultaten ongeveer 6 maanden aanhouden. Een operatie is geïndiceerd in gevallen waarin de pijn leidt tot beperkingen in het dagelijks leven van de patiënt of wanneer conservatieve behandeling heeft gefaald. Vanuit economisch oogpunt gaat een operatie gepaard met aanzienlijk hogere kosten dan conservatieve behandeling, zowel met betrekking tot kosten binnen de gezondheidszorg als verlies aan arbeidsproductiviteit.

Het meer en meer inzichtelijk maken van resultaten van behandelingen zal in de gezondheidszorg leiden tot nieuwe dimensies in arts-patiënt relatie. Hiertoe moet gebruik gemaakt worden van gevalideerde uitkomstmaten voor elke vorm van behandeling, chirurgisch of conservatief.

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CHAPTER **TEN**

DEUTSCHE ZUSAMMENFASSUNG



ZUSAMMENFASSUNG

Die Arthrose ist die häufigste Erkrankung der Gelenke. Sie kann zu erheblichen Funktionseinschränkungen sowie verminderter Lebensqualität führen und beträchtliche sozioökomische Konsequenzen mit sich bringen[1-3]. An der Hand sind die distalen Interphalangealgelenke (DIP Gelenke) besonders häufig von Arthrose betroffen, gefolgt von den trapeziometakarpalen und den proximalen Interphalangealgelenken (PIP Gelenke)[4-6]. Die Arthrose des trapeziometakarpalen Gelenks wird auch als Rhizarthrose bezeichnet.

Von Arthrose betroffene Patienten beschreiben in der Regel, dass sie im ihrem täglichen Leben erheblich eingeschränkt sind[3, 7, 8]. Schmerzen in Verbindung mit einer eingeschränkten Fingermobilität und verminderter Greifkraft zwingen die Patienten, ihre täglichen Handaktivitäten zu reduzieren oder sogar bestimmte Aktivitäten zu vermeiden. Die problematischsten Aktivitäten sind meistens das Auswringen eines Lappens sowie das Öffnen von Gläsern und Flaschen[9]. Die Behandlungsmöglichkeiten für Patienten mit Handarthrose bestehen aus medikamentöser, nicht-medikamentöser und chirurgischer Versorgung[1, 10, 11].

Ziel dieser zweiteiligen Dissertation war, die Einschränkungen von Patienten mit Handarthrose im täglichen Leben darzustellen, Messverfahren zu evaluieren, Behandlungsergebnisse mit dem Schwerpunkt der Patientenzufriedenheit aufzuzeigen, sowie die ökonomischen Aspekte der Behandlung von Patienten mit Handarthrose zu untersuchen. Schwerpunkt dieser Analysen war dabei die Rhizarthrose.

Teil EINS, welcher die **Kapitel zwei, drei** und **vier** umfasst, beschreibt die Einschränkungen der Patienten im täglichen Leben sowie relevante Messmethoden zur Erfassung des Behandlungsergebnisses. **Teil ZWEI** enthält **Kapitel fünf, sechs** und **sieben** und untersucht die Ergebnisse der chirurgischen und konservativen Behandlung von Patienten mit Handarthrose in Bezug auf die Zufriedenheit der Patienten sowie in Bezug auf ökonomische Aspekte.

Teil EINS

Kapitel zwei untersuchte die Einschränkungen von Patienten mit Handarthrose im täglichen Leben mit dem Fokus auf dem speziellen Problem des Öffnens von Lebensmittelverpackungen. Ziel war die Erstellung von Leitlinien für die Industrie, wie leicht zu öffnende Verpackungen produziert werden können. In einer Querschnittsstudie wurde untersucht, wieviel Kraft Patienten an einer Aufreisslasche aufbringen können. Diese Werte wurden mit Normwerten von gesunden Personen gleichen Alters und Geschlechts verglichen. Es wurden 100 Patienten mit unterschiedlichen Handerkrankungen in diese Studie eingeschlossen. Die Abzugskraft an Laschen mit verschiedenen Längen und aus unterschiedlichen Materialien (Aluminium, Plastik) wurde mit einem speziell dafür entwickelten Gerät gemessen. Die Kraft im Schlüsselgriff wurde mit einem Pinchmeter gemessen. Normdaten wurden aus einer anderen Studie mit 402 gesunden Erwachsenen übernommen. Die Ergebnisse zeigten, dass die Patienten die höchsten Kräfte an der längsten Aluminiumlasche unter Verwendung des Schlüsselgriffes aufwenden konnten. Allerdings betrug diese Kraft nur 53% der Kraft der gesunden Bevölkerung. Weiterhin wurde festgestellt, dass die Kraft des Schlüsselgriffes die Abzugskraft an den Aufreisslaschen bedingt ($R^2 = 0{,}548$; $p \leq 0{,}001$). Des Weiteren wurden die Patienten nach ihren Schwierigkeiten mit dem Öffnen von Verpackungen im Alltag befragt. Hierbei gaben 82% der Patienten an,

dass Marmeladengläser für sie nicht zu öffnen sind. Peelbare Wurst- und Käseverpackungen wurden von 78% als problematisch betrachtet und 69% der Patienten gaben an, keine Flaschen öffnen zu können. Basierend auf diesen Ergebnissen empfehlen wir der Industrie, an ihren Peelverpackungen lange Aufreißlaschen aus Aluminium anzubringen. Darüber hinaus empfehlen wir Medizinern und Therapeuten die Kraft des Schlüsselgriffs bei ihren Patienten zu messen, um eventuelle Schwierigkeiten beim Öffnen von Verpackungen aufzeigen zu können.

Das Ziel von **Kapitel drei** war, alle Messinstrumente zu ermitteln, die in Studien über Patienten mit Rhizarthrose angewendet werden. Des Weiteren sollten die Gütekriterien dieser Messinstrumente überprüft werden. In einer zweistufigen systematischen Literaturrecherche wurden zunächst Studien über Patienten mit Rhizarthrose identifiziert und alle darin enthaltenen Messinstrumente extrahiert. Diese wurden nach dem Core Set für Arthrose der Outcome Measures in Rheumatology (OMERACT) Gruppe in eine von fünf Kategorien klassifiziert: Schmerzen, Körperfunktion, globale Beurteilung, bildgebende Verfahren und Lebensqualität. In einem zweiten Schritt wurden Artikel über die Gütekriterien dieser identifizierten Messinstrumente gesucht. Im ersten Schritt wurden 316 Artikel mit 101 verschiedenen Messinstrumenten identifiziert. Die meisten konnten in die OMERACT Kategorien Schmerz und Funktion eingeordnet werden, die wenigsten beinhalteten die Evaluation der Lebensqualität. Im zweiten Schritt wurden zwölf Artikel über die Gütekriterien von zwölf Messinstrumenten identifiziert. Der Disabilities of the Arm, Shoulder and Hand (DASH) Fragebogen und der Patient-Rated Wrist Evaluation (PRWE) wurden am häufigsten in Studien untersucht. Keine der Studien untersuchte jedoch alle Gütekriterien. Der DASH, quickDASH, Australian / Canadian Osteoarthritis Hand Index (AUSCAN) sowie der Nelson Score konnten positiv bewertet werden. Im Gegensatz dazu wurden die Eaton Klassifikation, der Grind-Test des Daumensattelgelenks, sowie der Handfunktionsindex des Keitel Funktionstests als schwach bewertet. Die Bewertungen für den PRWE und den Short Form 36 (SF-36) waren nicht eindeutig. Da die methodische Qualität der analysierten Studien lediglich mangelhaft bis moderat war, kann basierend auf der bisher existierenden Literatur keine Empfehlung über die Anwendbarkeit bestimmter Messinstrumente für Patienten mit Rhizarthrose gegeben werden.

Da es an Evidenz über gute Messinstrumente für Patienten mit Rhizarthrose mangelt, wurde in **Kapitel vier** die Reliabilität, Validität und Veränderungssensitivität des Michigan Hand Outcomes Questionnaires (MHQ) untersucht. In dieser prospektiven Beobachtungsstudie wurden 177 Patienten mit Rhizarthrose eingeschlossen, die entweder konservativ oder operativ behandelt wurden. Zu Beginn der Studie und ein Jahr nach der Behandlung wurde die Kraft des Schlüsselgriffes gemessen. Die Patienten füllten jeweils den MHQ, den DASH und den Short Form 12 (SF-12) aus. Diese Fragebögen wurden 2 - 11 Tage nach der letzten Studienuntersuchung ein weiteres Mal ausgefüllt. Um die Gütekriterien des MHQs zu analysieren, wurden die Test-Retest Reliabilität (Intraklassen-Korrelationskoeffizient, ICC), die interne Konsistenz (Cronbach's alpha für die sechs Subskalen des MHQs), die Konstruktvalidität (Pearson's Korrelationskoeffizient, r), die Veränderungssensitivität (Effektstärke) sowie die minimal bedeutsame Veränderung (MIC) berechnet. Die Ergebnisse zeigten, dass der durchschnittliche MHQ Gesamtscore für die operierten Patienten von 48 ± 14 vor der Operation auf 75 ± 18 nach einem Jahr anstieg ($p \leq 0{,}001$). Im Gegensatz dazu konnte kein Behandlungseffekt in der konservativen Gruppe

nachgewiesen werden (p = 0,74). Der MHQ Gesamtscore zeigte eine exzellente Test-Retest Reliabilität (ICC = 0,95) und korrelierte stark mit dem DASH (r = -0,77). Die interne Konsistenz der MHQ Subskalen bewegte sich zwischen 0,77 und 0,89. Eine hohe Effektstärke von 1,7 wurde in der Gruppe der operierten Patienten nachgewiesen. Der MIC in dieser Gruppe lag bei 17 Punkten. Basierend auf diesen Ergebnissen können wir schlussfolgern, dass der MHQ eine gute Reliabilität, Validität und Veränderungssensitivität bei Patienten mit Rhizarthrose zeigt und als geeignetes Messinstrument bei diesen Patienten empfohlen werden kann.

Teil ZWEI

In **Kapitel fünf** sollten Einflussfaktoren auf die Zufriedenheit von Patienten nach orthopädischen Eingriffen an der Hand identifiziert werden. Die Evaluation der Patientenzufriedenheit hat in den letzten Jahren an Bedeutung gewonnen, da sie zur kontinuierlichen Überprüfung des Gesundheitswesens beiträgt, für welches die Patienten und die Gesellschaft bezahlen. Zufriedene Patienten zeigen eine höhere Compliance und kommen zuverlässig zur Behandlung[12, 13]. Die Quantifizierung der Zufriedenheit ist jedoch durch den Einfluss von zahlreichen, bisher mangelhaft beschriebenen Faktoren auf die Wahrnehmung eines zufriedenstellenden Behandlungsergebnisses schwierig. Um Studien über Einflussfaktoren auf die Zufriedenheit mit dem Behandlungsergebnis oder auf die nicht näher definierte Gesamtzufriedenheit von Patienten mit Handerkrankungen zu identifizieren, wurde eine Literaturrecherche durchgeführt. Die Ergebnisse zeigten, dass die Patientenzufriedenheit von zahlreichen Faktoren beeinflusst wird. Es gibt moderate Evidenz, dass Schmerzen/Symptome, Aktivitäten des täglichen Lebens, das Aussehen sowie das Körperverständnis die Zufriedenheit beeinflussen. Ausserdem deuteten die Daten auf einen Zusammenhang der Zufriedenheit mit der Kraft, dem Bewegungsausmaß, der Erwartungserfüllung, der Deformitäten, dem Bezug von Erwerbsausfallentschädigung, und der Dauer des Nachkontrollzeitraums hin. Kenntnis dieser Faktoren kann zu einem detaillierteren Entscheidungsfindungsprozess führen und damit zu einem verbesserten und kosteneffektiven Behandlungsergebnis beitragen.

Für die tägliche Praxis bedeutet dies, dass die Behandlung auf Schmerz- und Symptomlinderung und der Wiederherstellung der individuell wichtigen Handfunktionen ausgerichtet werden sollte unter Berücksichtigung des Aussehens der Hand und des Körperverständnisses. Neben der Evaluation von objektiven Behandlungsergebnissen sollte der Einfluss der individuellen Erwartungen der Patienten, ob sie eine Entschädigung für ihren Arbeitsausfall bekommen sowie die Dauer des Nachuntersuchungszeitraumes berücksichtigt werden.

In **Kapitel sechs** wurden die Ergebnisse nach operativer und konservativer Behandlung von Patienten mit Rhizarthrose untersucht und Einflussfaktoren auf die Zufriedenheit mit dem Behandlungsergebnis analysiert. In einer prospektiven Kohortenstudie wurden Patienten, die aufgrund ihrer Rhizarthrose entweder operiert oder konservativ behandelt wurden, eingeschlossen. Vor der Behandlung, nach 3, 6 und 12 Monaten füllten die Patienten den MHQ aus. Auf einer 5-Punkt Likert Skala gaben sie ihre Erwartungen an die Behandlung an. Bei jeder Nachkontrolle bewerteten die Patienten, ob ihre Erwartungen erfüllt worden waren und ob sie mit dem Behandlungsergebnis zufrieden waren. Diese Baseline- und 1-Jahres Variablen, sowie soziodemographische und krankheitsbezogene Daten wurden in ein ordinales logistisches

Regressionsmodell für operierte Patienten und in ein weiteres für konservativ behandelte Patienten eingegeben, um Einflussfaktoren auf die Patientenzufriedenheit nach einem Jahr zu identifizieren. Insgesamt wurden 165 Patienten, von denen 97 operiert wurden, in die Studie eingeschlossen. Die operierten Patienten verbesserten sich kontinuierlich von einem MHQ Wert von 47 ± 15 vor der Operation zu 80 ± 16 nach einem Jahr ($p \leq 0{,}001$). In der konservativen Gruppe konnte eine Verbesserung zwischen der ersten Messung (61 ± 13) und sechs Monaten festgestellt werden (68 ± 15; $p \leq 0{,}001$), aber nicht nach einem Jahr (66 ± 17; $p = 0{,}055$). Die Regressionsanalysen zeigten, dass „erfüllte Erwartungen" ein wichtiger Einflussfaktor auf die Zufriedenheit nach einem Jahr in beiden Gruppen ist. Aus diesen Ergebnissen können wir schlussfolgern, dass eine Operation zu einem signifikant verbesserten Ergebnis nach einem Jahr führt. Eine konservative Behandlung ist über die ersten sechs Monate effektiv. Da die Erfüllung der Erwartungen der Patienten in beiden Gruppen ein wichtiger Einflussfaktor auf die Zufriedenheit war, möchten wir die Wichtigkeit, dem Patienten vor der Behandlung umfassende Informationen zu geben, betonen. Somit kann dazu beigetragen werden, dass die Erwartungen der Patienten an das Behandlungsergebnis realistisch sind.

In **Kapitel sieben** wurden die ökonomischen Aspekte der konservativen und operativen Versorgung von Patienten mit Rhizarthrose untersucht, mit dem Fokus auf Behandlungskosten und Kosten durch Produktivitätsverlust. In dieser prospektiven Kohortenstudie wurden Patienten, die aufgrund ihrer Rhizarthrose entweder operiert (Resektions-Suspensions-Interpositionsarthroplastik oder Arthrodese) oder konservativ (Steroidinfiltration) behandelt wurden, eingeschlossen. Die Behandlungskosten wurden anhand des Ertrages unserer Klinik in Schweizer Franken (CHF) quantifiziert. Die Patienten wurden vor der Behandlung, nach 3, 6 und 12 Monaten klinisch untersucht. Berufstätige Patienten füllten zusätzlich den Work Productivity and Activity Impairment Fragebogen (WPAI) aus, um Absentismus, Präsentismus und die Gesamtkosten des Produktivitätsverlustes zu erheben. Es wurden 161 Patienten eingeschlossen, von denen 58 berufstätig waren. Die Behandlungskosten betrugen 10.303 CHF pro operiertem Patient und 622 CHF pro konservativem Patient ($p \leq 0{,}001$). Der Produktivitätsverlust in der operierten Gruppe nahm zwischen der präoperativen Untersuchung und der 3-Monats Nachkontrolle signifikant zu (50% versus 64%; $p = 0{,}136$), anschliessend bis zur 6-Monats Nachkontrolle aber wieder signifikant ab (64% versus 33%; $p \leq 0{,}001$). In der konservativen Gruppe war der Produktivitätsverlust über den gesamten Zeitraum relativ stabil (52% vor der Behandlung zu 48% nach 1 Jahr; $p = 0{,}051$). Die geschätzten jährlichen Gesundheits- und Produktivitätskosten waren in der operierten Gruppe mit 20.210 CHF signifikant höher als in der konservativen Gruppe (6.877 CHF; $p \leq 0{,}001$). Daraus lässt sich schlussfolgern, dass eine Operation mit deutlich höheren Kosten verbunden ist als eine konservative Behandlung, sowohl in Bezug auf die Behandlungskosten als auch auf den Produktivitätsverlust. Inwiefern sich die verbesserte Produktivität in dieser Gruppe nach mehr als einem Jahr ökonomisch auswirkt, sollte in weiteren Studien untersucht werden.

SCHLUSSFOLGERUNGEN

Diese Dissertation untersuchte verschiedene für Patienten mit Handarthrose relevante Aspekte: Die Einschränkungen im täglichen Leben, Messverfahren sowie die Ergebnisse verschiedener Interventionen mit dem Fokus auf die Patientenzufriedenheit und auf ökonomische Aspekte.

Patienten sind im täglichen Leben durch ihre Erkrankung eingeschränkt, im Speziellen beim Öffnen von Lebensmittelverpackungen. Um das Leben dieser Patienten in Zukunft zu vereinfachen, wurden Richtlinien für die Industrie zur Herstellung leicht zu öffnender Verpackungen entwickelt.

In einer systematischen Literaturrecherche über Messinstrumente für Patienten mit Rhizarthrose wurde festgestellt, dass heutzutage viele verschiedene patientenbezogene Messinstrumente verwendet werden. Keiner dieser Instrumente konnte bezüglich aller Gütekriterien gute Bewertungen erzielen, was auch durch den Mangel an methodologisch guten Studien zu begründen ist. In einer Beobachtungsstudie konnte gezeigt werden, dass der MHQ eine gute Reliabilität, Validität und Veränderungssensitivität bei Patienten mit Rhizarthrose aufweist und somit als ein adäquates Messinstrument für diese Population eingesetzt werden kann.

In Bezug auf die Patientenzufriedenheit mit dem Behandlungsergebnis wurde herausgefunden, dass diese von zahlreichen Variablen beeinflusst wird. Reduzierte Schmerzen und Symptome sowie die Wiederherstellung der Handfunktion sind die wichtigsten Einflussfaktoren auf die Zufriedenheit bei Patienten mit einer orthopädischen Handerkrankung. Bei Patienten mit Rhizarthrose sind die erfüllten Erwartungen ein wichtiger Einflussfaktor. Daher ist es wichtig, den Patienten vor der Behandlung umfassend zu informieren und ihn zu einer realistischen Erwartungshaltung über das Behandlungsergebnis zu lenken.

Die Evaluation der Ergebnisse von konservativer und operativer Behandlung von Patienten mit Rhizarthrose zeigte, dass eine Operation zu einer signifikant verbesserten Handfunktion nach einem Jahr führt, wohingegen eine konservative Intervention in den ersten sechs Monaten am effektivsten erscheint. Diese Ergebnisse suggerieren, dass Patienten mit leichten Beschwerden von einer konservativen Behandlung profitieren mit einer Effektdauer von etwa sechs Monaten. In Fällen, in denen Schmerzen das alltägliche Leben einschränkt oder wenn eine konservative Behandlung nicht anschlägt, ist eine Operation indiziert. Aus ökonomischer Sicht ist eine Operation in Bezug auf sowohl die Behandlungskosten als auch den Produktivitätsverlust jedoch mit deutlich höheren Kosten verbunden.

In der Medizin erreicht die Beziehung zwischen Arzt und Patient eine wesentliche Bedeutung durch die Evaluation des Behandlungsergebnisses. Die Verwendung von validierten Messinstrumenten sollte obligatorisch werden, um jede, egal ob konservative oder chirurgische, Intervention zu evaluieren. Diese Ergebnisse können eine enge Beziehung zwischen Patient und medizinischem Leistungserbringer weiter stärken.

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APPENDIX

PUBLICATION LIST
CURRICULUM VITAE



PUBLICATION LIST

Marks M, Vliet Vlieland TPM, Audigé L, Herren DB, Nelissen RGHH, van den Hout WB. Healthcare costs and loss of productivity in patients with trapeziometacarpal osteoarthritis. Submitted

Marks M, Audigé L, Reissner L, Herren DB, Schindele S, Vliet Vlieland TPM. Outcomes of surgical and conservative treatment in patients with trapeziometacarpal osteoarthritis and determinants of patient satisfaction - Results of a prospective cohort study. Submitted

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CURRICULUM VITAE

Miriam Marks was born Miriam Bleckert in Achern, Germany, in 1980. In 2000, she passed the *Abitur* [German university entrance qualification] at the *Gymnasium* [grammar school] in Achern.

Physiotherapy

Following four years of studies in physiotherapy at the Fresenius University of Applied Sciences in Idstein, Germany, and at the Hogeschool van Utrecht, The Netherlands, she gained the degree of Bachelor of Health in 2004, and a degree in education. Until 2009, she was employed as a physiotherapist in an outpatient rehabilitation centre (Therapiezentrum Lamprecht) in Kirchheim unter Teck, Germany, where she also held the post of deputy head and head of the physiotherapy department for some time. She specialised in treating patients with musculoskeletal disorders. From 2004 to 2008, she took several training courses in manual therapy according to the Maitland concept and passed the exam in Orthopaedic Manual Therapy (OMT). In addition to working at the centre, she attended lectures at the University of Applied Sciences and Arts in Hildesheim, Germany, for five semesters and graduated in 2009 with the degree Master of Science in Physiotherapy with specialisation in Disciplinary Research.

Research

Following her Master's degree in 2009, Ms Marks started work as a research assistant in the Department of Research and Development, Upper Extremities and Hand Surgery, Schulthess Clinic in Zurich, Switzerland. In 2010, she began her PhD at the Leiden University Medical Centre, in Leiden, The Netherlands, under the supervision of Prof. Dr Rob Nelissen and Prof. Dr Thea Vliet Vlieland. Her PhD research about outcome measures, patient satisfaction, and economic aspects in the treatment of patients with hand osteoarthritis was done mainly in the Schulthess Clinic, where she was promoted to a Research Associate in 2012. Starting in 2011, she took a three-semester course in Applied Statistics at the Swiss Federal Institute of Technology (ETH) in Zurich, Switzerland, gaining the Certificate of Advanced Studies (CAS) in 2012. She also completed several training courses in scientific writing, project management, good clinical practice (GCP), and presentation skills. She has presented her research results at several national and international conferences.








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