Prognostic factors in hand surgery

Studies on prognostic factors for self-reported function and satisfaction after hand surgery

PhD thesis

Sebastian Breddam Mosegaard

Faculty of Health Sciences

Aarhus University

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Correspondence

Sebastian Breddam Mosegaard, cand.scient.san.publ.

University Clinic for Hand, Hip and Knee Surgery, Regional Hospital West Jutland

Laegaardvej 12, Entrance N

DK - 7500 Holstebro

E-mail: sebastianmosegaard@gmail.com

Phone: + 45 31 33 02 88

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Sebastian Breddam Mosegaard

Faculty of Health Sciences

University of Aarhus

and

University Clinic for Hand, Hip and Knee Surgery,

Aarhus University,

Department of Orthopaedic Surgery,

Regional Hospital West Jutland

Supervisors

Torben Bæk Hansen, Professor, MD, PhD *(main-supervisor)*
Head of Department University Clinic for Hand, Hip and Knee Surgery, Department of Orthopedics, Regional Hospital West Jutland, Denmark
Department of Clinical Medicine, Aarhus University, Denmark
Email: torbehns@rm.dk

Maiken Stilling, Professor, MD, PhD
Department of Orthopedics, Aarhus University Hospital, Denmark
Department of Clinical Medicine, Aarhus University, Denmark
Email: maiken.stilling@clin.au.dk

Evaluation committee

Stig Storgaard Jakobsen, Associate Professor, MD, PhD *(Chairman)*
Department of Orthopaedics, Aarhus University Hospital, Denmark
Department of Clinical Medicine, Aarhus University, Denmark
Email: stig.jakobsen@clin.au.dk

Ian Harris, Professor, MD, PhD
Department of Orthopaedics, Liverpool Hospital, University of New South Wales
Institute for Musculoskeletal Health at Sydney University, Australia
Email: ianharris@unsw.edu.au

Magne Røkkum, Professor, MD, PhD
Department of Orthopaedics, Rikshospitalet Oslo, Norway
Email: mrokkum@ous-hf.no

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List of Studies

This thesis is based on the following four studies:

I. Risk factors for limited improvement after total trapeziometacarpal joint arthroplasty
Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen.
Health and Quality of Life Outcomes, 2020 Mar 30;18(1):90
DOI: https://doi.org/10.1186/s12955-020-01333-z

II. Higher preoperative pain catastrophizing increases the risk of low patient reported satisfaction after carpal tunnel release: a prospective study
Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen.
BMC musculoskeletal disorders 2020, 21(1):42
DOI: https://doi.org/10.1186/s12891-020-3058-2

III. Measurement properties of the Danish version of the Boston Carpal Tunnel Questionnaire
Sebastian Breddam Mosegaard, Maiken Stilling, Marianne Breddam, Torben B. Hansen.
Manuscript submitted to Journal of Orthopaedics, April 2020

IV. Pain Catastrophizing Scale as a predictor of low postoperative satisfaction after hand surgery
Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen
Journal of Orthopaedics. 2020 Mar 25;21:245-248
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The papers of this thesis will be referred to in the text by their Roman numerals (I-IV).

Contents

Abbreviations

Abbreviations	Definition
BCTQ	Boston Carpal Tunnel Questionnaire
CTS	Carpal Tunnel Syndrome
CTR	Carpal Tunnel Release
DASH	Disabilities of the Arm, Shoulder and Hand Questionnaire
DRF	Distal Radius Fracture
ECTR	Endoscopic Carpal Tunnel Release
ES	Effect Size
FSS	Function Status Scale – Boston Carpal Tunnel Questionnaire
HADS	The Hospital Anxiety and Depression Scale
ICC	Intraclass Correlation Coefficient
MCID	Minimal Clinical Important Difference
MCP	Metacarpophalangeal
MDC	Minimal Detectable Change
MHOQ	Michigan Hand Outcome Questionnaire
MSD	Musculoskeletal Disorder
OCTR	Open Carpal Tunnel Release
OR	Odds Ratio
PIP	Proximal interphalangeal
PROM	Patient Reported Outcome Measure
SEM	Standard Error of Measurement
SF-MPQ	Short Form–McGill pain questionnaire
SRM	Standardized Response Mean
SSS	Symptom Severity Scale – Boston Carpal Tunnel Questionnaire
TF	Trigger finger
TMCOA	Trapeziometacarpal Osteoarthritis
QDASH	Quick Disabilities of the Arm, Shoulder and Hand Questionnaire

1. English summary

Trapeziometacarpal osteoarthritis, carpal tunnel syndrome, Dupuytren's disease, trigger finger, and wrist ganglia are all common reason for patients to be referred to a hand surgeon. The majority of the surgical treatments of these diseases lead to a positive outcome, but there are still some patients who are without improvement, unsatisfied, or even end up with an outcome that is worse than before the surgery. The Boston Carpal Tunnel Questionnaire (BCTQ) was designed to measure function and symptoms in patients with carpal tunnel syndrome. The measurement properties of this questionnaire have been examined in several countries, but not in Denmark.

There has been an increasing attention on psychological factors as predictors of surgical outcome. Catastrophic thinking about pain, characterized by an exaggerated negative response in relation to anticipated or actual pain experiences, can be measured using the Pain Catastrophizing Scale (PCS).

The overall aim of this thesis was to identify preoperative risk factors for unsatisfactory outcome in patients treated for trapeziometacarpal osteoarthritis with total joint arthroplasty, and examine the predictive effect of PCS score in patients treated surgically for carpal tunnel syndrome, Dupuytren's disease, trigger finger, or wrist ganglia. Further, the aim was to evaluate the measurement properties of the Danish BCTQ.

Study I is a prospective cohort study in 287 patients undergoing total trapeziometacarpal joint arthroplasty. Age; gender; the Disabilities of the Arm, Shoulder, and Hand (DASH) score; pain; and grip strength were used as predictors and outcomes. Lower preoperative DASH score and lower preoperative grip strength increased the risk of a low improvement in pain at activity (VAS<3). Women were at increased risk of low improvement in pain at rest (VAS<3) compared to men. **Study II** is a prospective cohort study in 714 patients treated with decompression surgery for carpal tunnel syndrome. Preoperative age, gender, DASH score, EQ-5D (EuroQol-5d) score, distal motor latency, operation technique, and the Pain Catastrophizing Scale were used as predictors of postoperative satisfaction. Patients improved in both DASH

score (mean=12.29) and EQ-5D (mean=0.14) after median nerve decompression surgery. Preoperative PCS score was the only predictor of 12-month postoperative patient satisfaction, where a higher PCS score increased the risk of low postoperative patient reported satisfaction. **Study III** examined the measurement properties of the Danish BCTQ in 188 patients treated for carpal tunnel syndrome with median nerve decompression surgery. The Danish BCTQ showed high responsiveness, internal consistency, and reliability. Further, the Danish BCTQ was moderate to strongly correlated to the Danish QuickDASH. **Study IV** used postoperative patient satisfaction as outcome, and used preoperative age, gender, DASH score, EQ-5D, dominant hand, civil status, and PCS score as preoperative predictors in 645 patients with Dupuytren's disease, trigger finger, or wrist ganglia. Patients improved in both DASH score (median=10.9) and EQ-5D (median=0.18). The most important preoperative cut-points on the PCS for postoperative patient satisfaction were 27.5 and 2.9. Only 2.9 remained statistically significant after adjustment for demographics and preoperative disability.

Conclusion: It was not possible to identify one preoperative risk factor for all outcomes after total trapeziometacarpal joint arthroplasty. Preoperative score on the PCS was a contributing risk factor for low postoperative patient satisfaction after surgical treatment of carpal tunnel syndrome and Dupuytren's disease, trigger finger, and wrist ganglia. We found satisfactory measurement properties of the Danish BCTQ with special regard to reliability and responsiveness.

Perspectives: In future studies, it would be interesting to examine the predictive value of preoperative PCS score in patients surgically treated for trapeziometacarpal osteoarthritis. To establish a useful risk estimation tool for clinical use, studies should try to build a prediction model with variables known to have predictive abilities, including pain catastrophizing measured with the PCS. Preferably, the guidelines for building prediction models like the "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis" should be followed.

2. Danish summary

Rodledsartrose, karpaltunnelsyndrom, Dupuytrens kontraktur, springfinger og håndledsganglion er alle hyppige årsager til at patienter henvises til en håndkirurg. Størstedelen af de kirurgiske behandlinger giver et positivt resultat, men der er stadig nogle patienter som ikke oplever forbedringer, er utilfredse eller i værste fald ender med et resultat der er værre en udgangspunktet før operation.

"Boston Carpal Tunnel Questionnaire" (BCTQ) blev designet med henblik på at evaluere funktion og symptomer hos patienter med karpaltunnelsyndrom. Spørgeskemaets måleegenskaber er blevet undersøgt i flere forskellige lande, men endnu ikke i Danmark. Opmærksomheden og interessen for psykologiske faktorer som prædiktive faktorer for operationsresultat har været stigende. Smerterelateret katastrofetænkning kan måles med "the Pain Catastrophizing Scale" (PCS), og er karakteriseret ved en overdrevet negativ respons i forhold til forventede eller aktuelle smerteoplevelser.

Formålet med denne afhandling var, at identificere præoperative risikofaktorer for utilfredsstillende resultat efter totalalloplastik for rodledsartrose, samt undersøge den prædiktive effekt af smerterelateret katastrofetænkning hos patienter der bliver behandlet kirurgisk for karpaltunnelsyndrom, Dupuytrens kontraktur, springfinger eller håndledsganglion. Formålet var yderligere, at undersøge måleegenskaberne af BCTQ i en dansk kontekst.

Studie I er et prospektivt kohortestudie af 287 patienter behandlet for rodsledsartrose med totalalloplastik. Alder, køn, "Disabilities of the Arm, Shoulder, and Hand" (DASH) score, smerte og grebsstyrke blev brugt som både prædiktorer og outcome. Lavere præoperativ DASH score og lavere præoperativ grebsstyrke øgede risikoen for lav postoperativ forbedring i smerte ved aktivitet (VAS<3). Sammenlignet med mænd, var kvinder i øget risiko for lav forbedring i hvilesmerter (VAS<3). **Studie II** er et prospektivt kohortestudie af 714 patienter med karpaltunnelsyndrom behandlet med dekompressionskirurgi. Præoperativ alder, køn, DASH score, "EuroQol-5d" (EQ-5D) score, distal motorisk latens, PCS score og operationsteknik blev anvendt som

prædiktorer for postoperativ patientrapporteret tilfredshed. Patienterne forbedrede sig i både DASH score (mean=12.29) og EQ-5D score (mean=0.14) efter dekompressionskirurgi for karpaltunnelsyndrom. Præoperativ PCS score var den eneste prædiktor af patientrapporteret tilfredshed 12 måneder postoperativt, hvor en højere PCS score øgede risikoen for lav postoperativ patientrapporteret tilfredshed. **Studie III** undersøgte måleegenskaberne af BCTQ i en dansk kontekst hos 188 patienter behandlet for karpaltunnelsyndrom med dekompressionskirurgi. BCTQ havde høj følsomhed og reliabilitet. Yderligere var BCTQ moderat til stærkt korreleret til QuickDASH. **Studie IV** er et prospektivt kohorte studie af 645 patienter med Dupuytrens kontraktur, springfinger eller håndledsganglion. Præoperativ alder, køn, DASH score, EQ-5D score, dominant hånd, civil status og PCS score blev anvendt som prædiktorer for postoperativ patientrapporteret tilfredshed. Patienterne forbedrede sig i både DASH score (median=10.9) og EQ-5D (median=0.18). De mest betydende præoperative skæringsværdier for PCS til at prædiktere patienttilfredshed var 27.5 og 2.9. Kun 2.9 forblev statistisk signifikant efter justering for demografi og præoperativ genegrad.

Konklusion: Det var ikke muligt at identificere en præoperativ risikofaktor for alle målte outcomes efter total rodledsalloplastik. Præoperativ score på PCS er en risikofaktor for lav patienttilfredshed efter kirurgisk behandling af karpaltunnelsyndrom, Dupuytrens kontraktur, springfinger og håndledsganglion. Vi fandt at BCTQ havde gode måleegenskaber med hensyn til reliabilitet og følsomhed.

Perspektiver: Det vil være interessant i fremtidige studier, at undersøge den prædiktive værdi af præoperativ PCS score hos patienter med rodledsartrose. For at opbygge risikovurderingsmodel anvendelig i klinisk praksis, bør fremtidige studier forsøge at bygge en prædiktionsmodel indeholdende variabler med kendt prædiktiv effekt samt smerterelateret katastrofetænkning målt med PCS. Dette kan med fordel gøres med afsæt i guidelines for opbygning af prædiktionsmodeller, som "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis".

3. Introduction and background

3.1 Brief introduction

The complexity and outcomes following surgical treatment of hand diseases vary widely. Most of the common operations lead to a positive outcome in relation to pain, function, and general patient satisfaction. Although the majority of these hand operations leads to a positive outcome, there are still some patients who do not improve or end up with an outcome that is worse than the preoperative condition. The purpose of this thesis was to identify patients with increased risk of unsatisfactory improvement following surgical treatment, with focus on five common hand conditions characterized by symptoms of pain and function: trapeziometacarpal osteoarthritis (TMCOA), carpal tunnel syndrome (CTS), trigger finger (TF), Dupuytren's disease, and wrist ganglia.

3.2 Diseases and incidence

3.2.1 Trapeziometacarpal osteoarthritis

Trapeziometacarpal osteoarthritis (TMCOA) (Figure 1) is a common hand disease especially in women and is considered to be a normal part of the aging process [1]. TMCOA causes pain during rest and pinch grip function, i.e. buttoning a shirt or writing with a pencil. Also, TMCOA reduces hand function in terms of lower grip- and pinch strength [2]. The exact prevalence of TMCOA is hard to determine, but a retrospective study from the United States examined 615 consecutive radiographs from patients with distal radius fracture. In this study the authors found that the prevalence of TMCOA increased rapidly with age, with a prevalence of more than 90% in patients over the age of 80 years [1].

Figure 1: Trapezium (red)

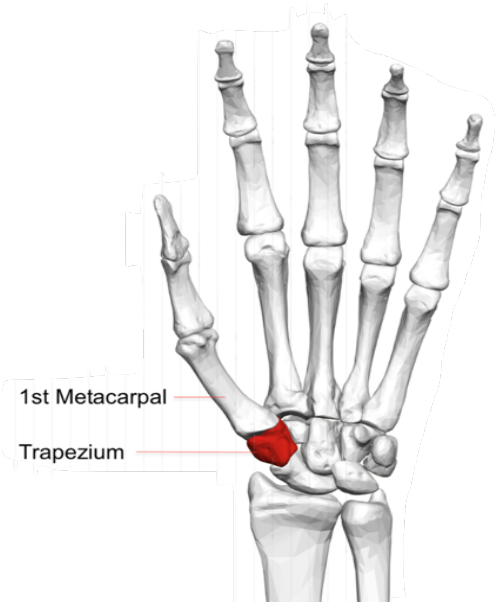
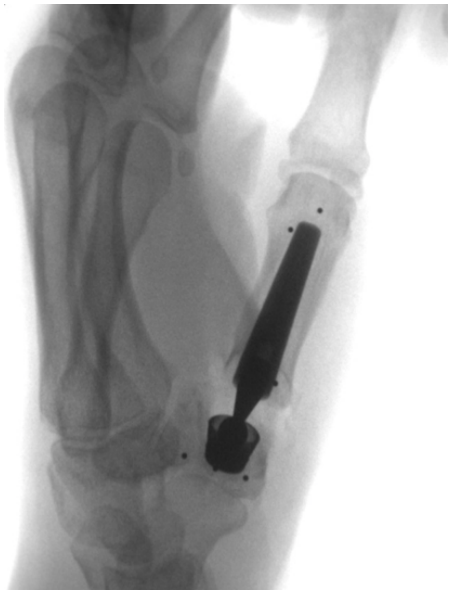


Figure 2: Total trapeziometacarpal joint arthroplasty



If conservative treatment of TMCOA fails, the most common surgical treatment is trapeziectomy, which can be done either with or without interposition arthroplasty [3]. Trapeziectomy generally provides a good outcome regarding both pain and function and up to 86% of patients state that they would have the same surgery done again [4]. Another surgical treatment of TMCOA that has been done for years is trapeziometacarpal total joint replacement (Figure 2). This technique was initially introduced using cemented implants [5]. Cementless implants were introduced 10-15 years ago and design improvements of both the cup and stem have gradually led to increased implant survival [6-9]. Studies have suggested that trapeziometacarpal total joint replacement might be a better option than trapeziectomy with regard to pinch and grip strength [10, 11].

Although trapeziometacarpal total joint replacement might have better outcomes than trapeziectomy, the risk of intra-operative and post-operative complications makes patient selection important [12].

3.2.2 Carpal Tunnel Syndrome

The nerve compression disease, carpal tunnel syndrome (CTS), is a very common reason for patients to be referred to a hand surgeon [13]. CTS causes symptoms like pain, reduced grip strength, and numbness of the hand [14], due to compression of the median nerve (Figure 3). The typical patient is a middle-aged woman [13, 15, 16]. The gender ratio is considered to be 3:1 with females being most common [17]. In the United States alone, approximately one million patients are annually in need of medical treatment for CTS [16].

Figure 3: Anatomy the carpal tunnel

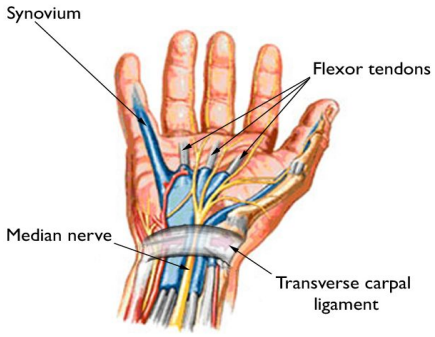
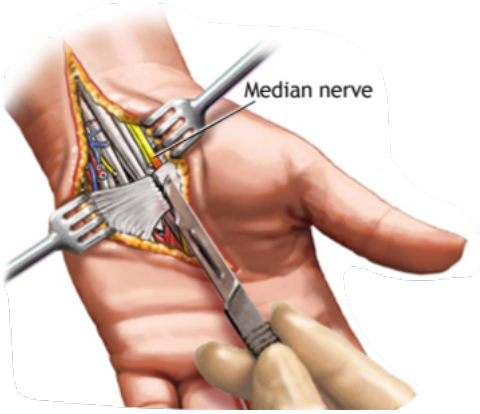


Figure 4: Open carpal tunnel release

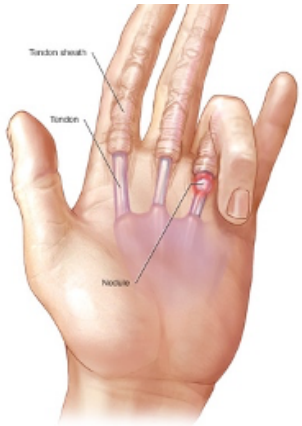


In Europe, the prevalence of CTS is reported to be around 1% to 7% [17, 18], and the incidence is estimated to be 1.8 per 1000 person years [17]. In Germany, the number of patients treated surgically is reported to be 300,000 per year and incidences are reported to be 10 males and 24 females per 10,000 person-years [19]. When conservative treatment is insufficient, surgical treatment is offered to manage symptoms and restore function of the hand [20, 21]. The surgical treatment of CTS is surgical decompression of the median nerve either by open carpal tunnel release (OCTR) (Figure 4) or endoscopic carpal tunnel release (ECTR). In OCTR and ECTR, the transverse carpal ligament is cut to reduce the pressure on the median nerve. The results of surgical median nerve decompression are mostly beneficial, but it is estimated that between 3% and 20% patients do not experience relief of symptoms [22, 23]. In light of the many operations done for CTS, there may also be a high number of patients who are dissatisfied with the postoperative surgical outcome.

3.2.3 Trigger finger

Trigger finger (TF) (Figure 5) is a common hand disease that prompts patients to seek medical treatment. It is caused by an imbalance between the A1 pulley and the diameter of the flexor tendon [24], which leads to both disability of the hand and mild to severe pain [25]. In the general population, TF has a prevalence of 2.6% [24, 26] in the general population and has been reported to be 6.7% in diabetics [27] and estimated to be four to six times as frequent in women [25]. When conservative treatment (steroid injection into the tendon sheath) fails, A1 pulley release surgery is done. This involves a small incision to access and cut the A1 pulley, enabling the flexor tendons to move through the tendon sheath without getting stuck. A1 pulley release surgery has a high rate of success, reported to range from 90% to 100% [24, 28-32]. Although the success rate seems high, there is still a noteworthy number of surgeries with an unsuccessful outcome.

Figure 5: Anatomy trigger finger



3.2.4 Dupuytren's disease

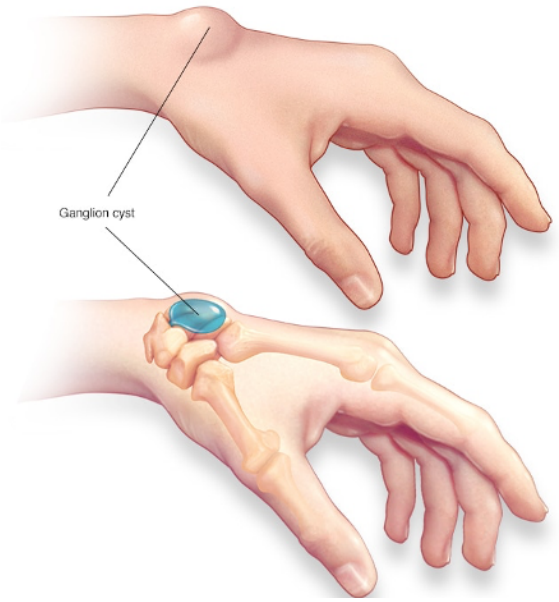
Dupuytren's disease is an inheritable fibroproliferative condition characterized by cord development in the palmar fascia that may cause metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint flexion contractures [33-35]. The prevalence and incidence of Dupuytren's disease is estimated to be around 1%, with a prevalence of 1.35% in men and 0.5% in women in a Swedish study [36], and it is further estimated that two million people in the United Kingdom are affected by Dupuytren's disease [37]. This prevalence might be lower depending on the geographical region, as a nationwide Korean population-based study found a prevalence of 32.2 per 100,000. In the same

Figure 6: Flexion deformation due to Dupuytren's disease

study, the prevalence of Dupuytren's contracture was also reported higher in men, with a prevalence of 41.8 per 100,000 men and 22.5 per 100,000 women [34]. The symptoms of Dupuytren's disease are mainly flexion contracture [33] (Figure 6), typically of the ulnar fingers and impaired hand function due to the extension deficiency of the affected fingers/joints. Pain is not a common symptom of Dupuytren's, except in the beginning of the disease when sore nodules develop, and it is by some called a painless condition [38]. The most common surgical treatment of Dupuytren's disease is fasciectomy, but needle aponeurotomy and collagenase injection are also used [33, 38, 39]. In the collagenase procedure, the cord is softened by the injected enzyme, which enables the surgeon rupture the cord by straightening the finger during local anesthesia. In needle aponeurotomy or percutaneous needle fasciotomy, a needle is used to gradually cut the fibrous bands while the finger is straightened. In the most common treatment, fasciectomy, the layer of tissue called the fascia is surgically removed. However, fasciectomy does not always lead to a good outcome. A systematic review found recurrence rates, in terms of flexion contracture, after needle aponeurotomy ranging from 50% to 58%, after collagenase injection ranging from 10% to 31%, and after open partial fasciectomy ranging from 12% to 39% and overall complication rates ranging from 14% to 67% [40]. Studies further suggest, that the recurrence rate may vary between the PIP and the MCP joint, the recurrence rate being higher after surgery of the PIP joint [41]. However, these rates denote the value of identifying preoperative risk factors that relate to an unsatisfactory outcome after fasciectomy.

3.2.5 Wrist ganglia

Figure 7: Anatomy of wrist ganglia



Ganglia are mucin filled cysts inside a collagenous walled cavity [42] (Figure 7). Wrist ganglia are the most common benign soft tissue tumors of the hand, representing 70% of all such tumors [43]. They are relatively common, with an incidence of 37.2 per 100,000 person-years in females and 10.4 per 100,000 person-years in males [44]. The real incidence might be higher because the study on which these incidences are based only included volar wrist ganglions, and a Swedish study found ganglia of the wrist to be 3.5 times more frequent on the dorsal than on the volar side [43, 45]. Wrist ganglia are not commonly associated with pain, and when it does occur, it is mainly a mild pain [46]. Although preoperative pain is not noteworthy, studies have found postoperative residual pain in 23% and a recurrence rates from 11% to 42% in patients treated with excision (the cyst capsule is removed) [47, 48], and 47% after aspiration treatment (the fluid from the cyst is drained using a syringe) [48].

Due to the prevalence and incidence of CTS, TMCOA, TF, Dupuytren's disease and wrist ganglia, it is of great interest to identify preoperative risk factors able to help predict the patients at risk of having no or only minor improvement after surgical treatment.

3.3 Risk factors for a negative postoperative outcome

Due to the high number of these procedures performed, several studies have tried to identify preoperative predictive risk factors for a negative postoperative outcome following surgical treatment of various hand diseases. Some of the most commonly evaluated risk factors include age, gender, smoking, diabetes, preoperative symptom severity, poor physical health, and poor mental health [49-58]. The results from the different studies show mixed effects of the different potential risk factors, and the defined outcomes are multiple, including change in pain and disability, endpoint in pain and disability, revision surgery, and overall patient satisfaction. This makes it hard to tell whether the different risk factors affect the postoperative outcome.

3.3.1 Age as a risk factor

Age is one of the factors most often accounted for in research. A German study in 71 patients (median age 50.5 years) with CTS investigated the risk of increased time before return to work. In this study the authors did not find a predictive effect of age on the time to return to work [49]. In a larger study in 275 CTS patients, the authors used the Quick Disabilities of the Arm, Shoulder and Hand Questionnaire (QDASH) to monitor changes in disability but did not find age to have a predictive effect on postoperative improvement in QDASH[58]. Rodrigues et al. studied functional outcome and complications following surgery for Dupuytren's disease. They included 432 cases and used the Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH) to define a good postoperative score with DASH ≥ 15 as a poor outcome and a postoperative DASH score < 15 as a good outcome. Once again, the study showed that dichotomized age (age < 50 vs age ≥ 50) did not have a predictive effect on the postoperative outcome after surgical treatment of Dupuytren's disease [54]. On the contrary, a study of 188 patients suffering from CTS found older patients to have less severe symptoms and better satisfaction 18 months after carpal tunnel release (CTR) [53].

3.3.2 Gender as a risk factor

Just like age, gender is almost always included in prediction studies. Although gender is thoroughly investigated as a risk factor, the findings tend to be diverse. In a study in 620 patients, the authors found no difference in self-reported symptom relief between males and females two weeks after OCTR. However, females reported worse self-reported symptom relief six months after OCTR [59]. Females were also found to have worse preoperative QDASH scores than men in a study in 275 CTS patients, but there was no statistically significant difference in postoperative improvement between genders [58]. A study in 71 patients with CTS did not find a difference in time to return work duration between men and women [49]. A study in patients with trigger finger from the United States did not find a difference in outcome between men and women [30]. In a study in Dutch patients with Dupuytren's disease they found women to be at slightly increased risk of low postoperative satisfaction, although this what not statistically significant [33]. This brief introduction to the effect of gender on postoperative outcome in hand surgery indicates that the studies either find no difference with regard to gender or an increased risk for females. It has been suggested that the potential gender difference in postoperative outcome might be due to differences in expectations and pain tolerance [60].

3.3.3 Other potential risk factors

Besides age and gender, several other potential risk factors for a negative postoperative outcome have been examined, such as smoking, diabetes, preoperative symptom severity, poor physical health, and poor mental health [49-58]. Smoking was found to be correlated to a higher pain score using the Short Form–McGill pain questionnaire (SF-MPQ) in a study in 275 CTS patients [58]. Smoking has also been found to be a risk factor for complex regional pain syndrome after upper extremity surgery [61]. In a study in 74 CTS patients, a higher preoperative symptom severity score was associated with less improvement in symptom and function scores after six months [52]. Both smoking and alcohol consumption were identified as risk factors of

more severe symptoms and worse functional outcomes in a review study of CTS patients [62].

During recent years, there has been an increased focus on the mental health as a factor that affects patients' perception of outcome and satisfaction, and several studies have investigated the potential effect of psychological factors on various outcome measures [63-66]. In CTS patients, a poor mental health has been found be a predictor of low postoperative patient-reported satisfaction [53].

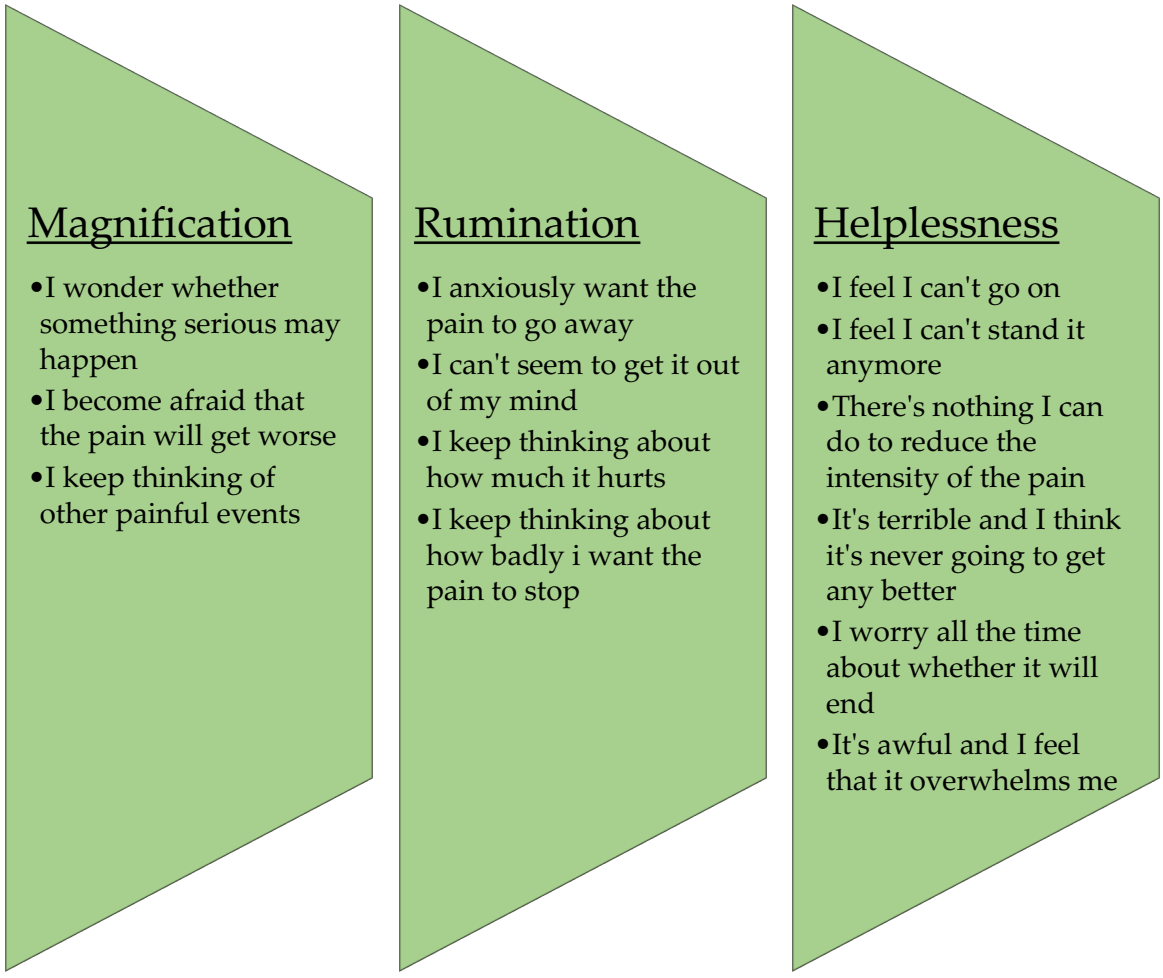
A recent systematic review of CTS patients found a correlation between postoperative patient satisfaction and measures of depression [63] and an association between high preoperative symptom severity and preoperative hospital anxiety [67]. Also, self-reported hand function has been found to be partially influenced by patient-reported depression in patients with trapeziometacarpal arthritis [68]. These studies indicate the effect of psychological factors on different outcome measures including satisfaction. Recently, increasing attention has been given to the Pain Catastrophizing Scale (PCS).

3.4 Pain Catastrophizing Scale

"An exaggerated negative response in relation to anticipated or actual pain experiences" is the definition of pain catastrophizing. This cognitive process can be described as several maladaptive thoughts characterized by a lack of control and confidence connected with the belief that the felt pain will result in the worst outcome [69]. Correlations have been found between pain catastrophizing and both anxiety and neuroticism [70, 71]. The PCS is made up of factors like disproportionate attention to thoughts and rumination on pain, a perceived feeling of helplessness in pain coping and extreme worry.

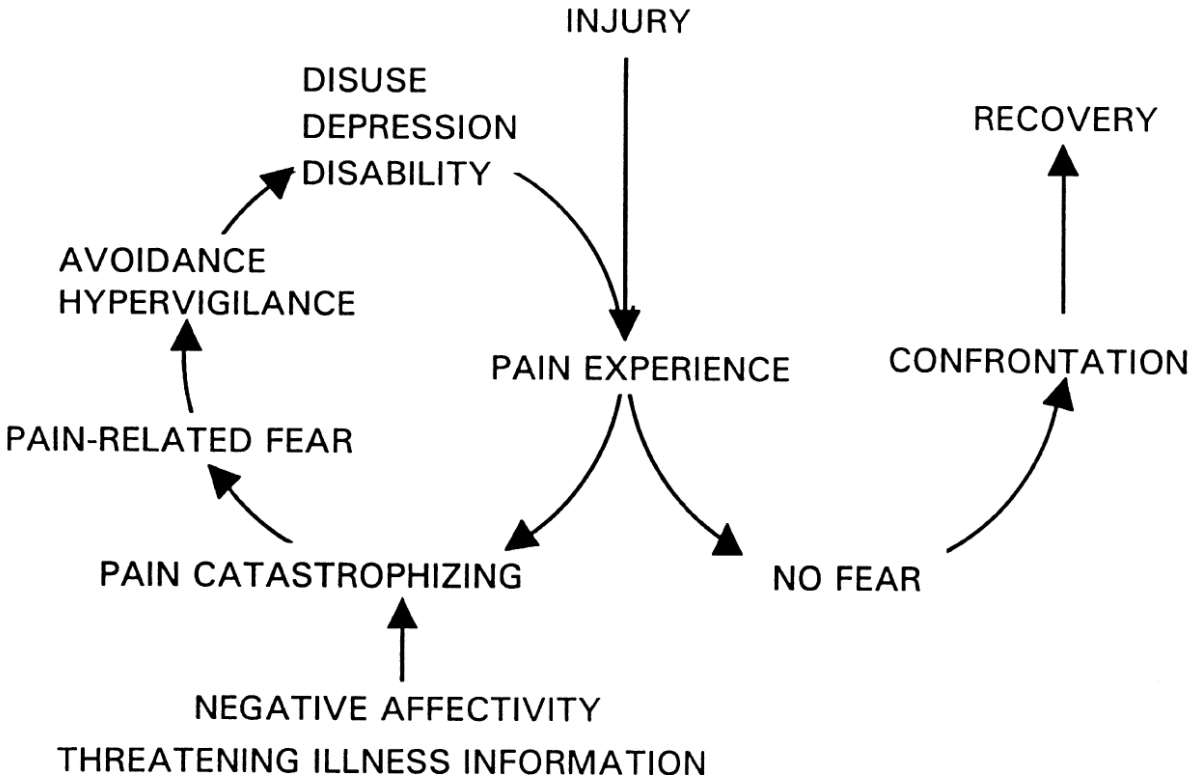
Sullivan et al., developed the PCS in 1995, and it is one of the most used tools to assess pain catastrophizing [72]. The questionnaire is made up of 13 statements, which are each scored from 0 "not at all" to 4 "all the time", making the total PCS score ranging from 0 to 52. The questionnaire can be further divided into three subscales: pain rumination, pain magnification and helplessness (Figure 8).

Figure 8: The three subscales of the Pain Catastrophizing Scale: Magnification, Rumination and Helplessness



Catastrophic thinking about pain might affect the outcome after surgery, because it could affect a patient's behavior. Vlaeyen et al., [73] developed a model called "The fear avoidance model" (Figure 9) that describes how pain catastrophizing can be a part of backbiting circle, where negative thinking due to pain caused by, e.g. surgery, can cause catastrophic thinking about pain. This thinking can cause an avoidance of daily activities if it grows into a fear of pain, which could potentially lead to further pain and disability. In this way, the negative backbiting circle is maintained. On the other hand, patients without catastrophic thoughts about pain will not develop a fear of pain, and thereby maintain daily activities, which could lead to a faster recovery compared to patients with catastrophic thoughts about pain.

Figure 9: The fear avoidance model (Vlaeyen et al.)



3.4.1 Pain Catastrophizing Scale in the existing literature

The Pain Catastrophizing Scale has been used in several studies with different measures of outcome. Some of the studies, their outcome, and conclusion can be seen in Table 1.

Table 1: Studies with the Pain Catastrophizing Scale as predictor

Study	*Design / Patients / Intervention*	*Follow-up Outcome*	*Conclusion*
Papaioannou et al., 2009 [74].	Prospective cohort study: 61 patients undergoing elective instrumented lumbar fusion surgery completed the Pain Catastrophizing Scale the day before surgery.	1 & 2 days: Pain rest Pain activity	"The present study findings suggest that it is possible to preoperatively identify patients at risk for experiencing more severe pain in the postoperative recovery period."
Uckun et al., 2020 [75].	Prospective cohort study: 89 patients with knee osteoarthritis underwent 10 sessions of physical therapy.	2 & 6 weeks: Pain Disability	"This study suggests that the baseline PCS score is a predictive factor for poor response to physical therapy in patients with knee OA."
Granot et al., 2005 [76].	Prospective cohort study: 38 patients scheduled for elective abdominal surgery completed the Pain Catastrophizing Scale on the day of admission.	1 & 2 days: Pain rest Pain activity	"In sum, the study results suggest a simple and quick method for assessing preoperatively the expected postoperative pain experience."
Swinkels et al., 2006 [77].	Experimental cross-sectional study: 96 patients with an episode of acute low back pain performed a dynamic lifting task to measure actual performance. They completed the Pain Catastrophizing Scale and the Tampa Scale for Kinesiophobia.	- Lifting time Lifting bouts Current pain Previous 2-day pain intensity Function	"In sum, the results of the current study are in line with the existing literature concerning pain-related fear, showing that it is significantly associated with perceived disability and actual performance in chronic pain patients."
Wright et al., 2017 [78]	Prospective cohort study: 123 patients undergoing total hip arthroplasty or total knee arthroplasty completed the Pain Catastrophizing Scale 1-2 weeks before surgery.	3 months: Pain Analgesics	"The pain catastrophizing scale is a poor predictor of postoperative pain at 3-month follow-up. However, it may be a risk factor for increased length of stay."
Birch et al., 2019 [79].	Prospective cohort study: 615 patients undergoing total knee arthroplasty or unicompartmental knee arthroplasty completed the Pain Catastrophizing Scale prior to surgery.	4 & 12 months: Oxford Knee Score SF-36 EQ-5D	"Patients with high levels of preoperative pain catastrophizing have lower physical function, more pain and poorer general health both before and after KA than patients without elevated pain catastrophizing."
Coronado et al., 2015 [80].	Prospective cohort study: 68 patients undergoing spine surgery for a degenerative condition completed the Pain Catastrophizing Scale 6 weeks after surgery.	6 weeks 3 & 6 months: Pain threshold Pain intensity Disability Pain interference	"The findings suggest the importance of early postoperative screening for pain sensitivity and pain catastrophizing to identify patients at risk for poor postoperative pain intensity, pain interference, and/or disability outcomes."

3.4.2 Pain Catastrophizing Scale in hand surgery

As mentioned, scores on the PCS have been used in studies on various outcomes in medical research including knee surgery [79, 81], lumbar spine surgery [80], and hand surgery [82, 83]. However, mixed findings are reported in the literature on the potential effect of PCS in hand surgery. A study in patients with either benign tumors, TF, or CTS did not find a correlation between preoperative PCS score and postoperative DASH score [82]. Another study examined the correlation between PCS score and hand disability measured using the Michigan Hand Outcome Questionnaire (MHOQ). In this study, they divided patients into two groups: PCS scores either > 30 or ≤ 30. They found that patients with PCS scores > 30 generally scored worse on the MHOQ than patients with PCS scores ≤ 30, but the patients showed similar absolute improvement both one and three months after surgery [84]. Other studies have suggested that patient satisfaction after surgical treatment of Dupuytren's disease could be influenced by psychological factors [33] and that PCS might affect postoperative outcome in TF patients [24]. A retrospective study of 82 CTS patients examined the potential association between patient satisfaction and PCS in a univariate analysis and did not find an association.

The existing literature using the PCS in prospective cohort studies is sparse. The studies are mainly cross-sectional or retrospective, and the measures used to assess the association between PCS and outcome are measured simultaneously, which reduces their ability to define causality.

3.5 Boston Carpal Tunnel Questionnaire

In order to identify the best possible predictions of patient outcome, it is necessary to use the best possible tools to evaluate symptoms and functional limitations in patients. David W. Levine et al., developed the Boston Carpal Tunnel Questionnaire (BCTQ) in 1993 [85].

The BCTQ was created as a questionnaire to assess the severity of symptoms and functional status in CTS patients. It consists of two subscales: The Symptom Severity Scale (SSS) to measure symptom severity and the Function Status Scales (FSS) to measure the functional status in CTS patients. The BCTQ showed high reproducibility and internal consistency in both subscales in patients in the United States, which was also shown in 2004 in British patients [86]. In 2016, a Taiwanese study found that the Taiwanese BCTQ had high predictive values to evaluate outcome and satisfaction after treatment of CTS using ECTR [87].

Since the release of the BCTQ in 1993, it has been validated and translated into several languages including Swedish [88], Spanish [89], Portuguese [90], Turkish [91], Chinese [92], Greek [93], and Polish [94]. The Danish BCTQ was translated as part of a study performed at our institution more than 20 years ago [95], but the measurement properties of the Danish BCTQ is yet to be assessed.

3.5.1 Other questionnaires used in upper-extremity studies

Traditionally, standard functional measures like range of motion and strength were used to evaluate the quality of hand surgery [96-98]. These measures considered as improvement measures are not necessarily reflective of the experience of the patients themselves [99, 100]. The increasing interest in patients' perceptions has been responsible for an increased use of Patient Reported Outcome Measures. Some of the most used measures in hand surgery include the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH); the Patient-Rated Wrist Evaluation Questionnaire (PRWE); the Michigan Hand Outcomes Questionnaire (MHOQ); and the disease-specific Boston Carpal Tunnel Questionnaire (BCTQ) [85, 101, 102].

In 1996, the DASH was created by Hudak et al. [103] as an overall upper extremity outcome measure, and has been used in upper extremity studies since, and might even be the most used in upper-extremity studies. In CTS patients, both the Quick DASH (QDASH) [58, 104] and DASH [65, 82] are often used to evaluate hand disability. The DASH and QDASH, however, consist of questions related to the arm, shoulder, and hand. This broad content makes it possible to compare outcome and disability in different groups of patients but might also influence the validity when used in a specific patient group such as CTS patients.

The PRWE was published in 1998, and 100 members of the International Wrist Investigators were surveyed to assist in the development. The reliability study was conducted in patients with distal radius fractures and scaphoid fractures, whereas the validity study was conducted in patients with only distal radius fractures, and the PRWE showed reliable and valid measures of patient-rated disability and pain [105]. Later, the PRWE was modified to form the Patient Rated Wrist/Hand Evaluation (PRWHE) questionnaire to allow for evaluation of a broader range of both wrist and hand conditions [106, 107]. Like the DASH, it has also been used in several upper-extremity studies but focuses on the hand and wrist and not on the entire arm and shoulder. Whether it is useful in conditions other than those in the hand and wrist has been studied in patients with distal radius fractures showing good validity and reliability, but the Minimal Detectable Change (MDC) was high making it less useful for individual patients [108].

The MHOQ has been used in studies of hand disease and injuries since 1998 [109]. It was designed to include overall hand function, activities of daily living, pain, work performance, aesthetics, and patient satisfaction with hand function. After a factor analysis of the initial 100 items assessed by patients with hand disorders, hand therapists, and hand surgeons, the questionnaire was reduced to 37 items. The MHOQ showed good measurement properties in a study in 200 patients from a university-based hand clinic [109]. The DASH/QDASH, PRWE/PRWHE, and MHOQ are not disease-specific like the BCTQ. The BCTQ is disease-specific for CTS and has a better responsiveness and faster completion time than MHOQ and DASH in CTS patients

[86, 110, 111]. Further, the BCTQ showed a stronger correlation to total sensation by filament test, grip strength, and key-pinch strength than DASH, in a study in 50 patients surgically treated for CTS, indicating a higher validity [112]. Finally, it has been recommended to use the BCTQ instead of the PRWE when doing research studies in CTS patient [113].

3.6 Design and analysis in research studies

3.6.1 Design

When designing a new study, the randomized controlled trial is often referred to as being above cohort studies in hierarchy of evidence, because the exposure or intervention is randomized accounting for both known and unknown confounders. When it is not possible to randomize the exposure often because it is not manually decided, the cohort studies are used either retrospective or prospective [114]. Unlike the cross-sectional study, the cohort study have the ability to define causality regardless of it being retrospective or prospective [115], as long as there a no other confounders than those adjusted for in the later analyses. The retrospective and prospective design has each their weaknesses and advantages. The biggest advantage of the prospective design is the accuracy in measuring exposure, endpoint, and confounders. This method can be costly and time demanding, especially when the outcome is rare or the follow-up is long. The retrospective design is less time demanding and costly, as it starts at the outcome. From here, a retrospective study will then use existing data or ask patients to answer questions about their past which can lead to recall bias. Because of this, the prospective cohort study is ranked above the retrospective cohort study in the hierarchy of evidence, and both the prospective and the retrospective cohort study is ranked above the cross-sectional study. As mentioned above, the majority of the existing literature on PCS in hand surgery is often either retrospective cohort studies or cross-sectional studies without the ability to define causality.

3.6.2 Analysis in research studies

When the acquisition of the data is done, the next part will be to analyze the data. This part is truly important and the decision made will affect the results. The risk of confounding will always be present, and it is highly recommended to adjust for confounders [115]. However, for a confounder to truly be a confounder, it cannot be an intermediary link in the causal pathway. With this is mind, it would not be appropriate to adjust for lung cancer in a study examining mortality in smokers and non-smokers, because lung cancer is considered a link in the causal pathway between the exposure (smoking) and the outcome (mortality). This type of analysis of the effect of an exposure on a given outcome is often used in cohort studies and randomized controlled trials, where the aim is to examine the possible causality between an exposure and outcome. In these studies, it is important to be aware of whether the potential confounder is a confounder or a link in the causal pathway [116, 117].

Another common study aim is to establish risk prediction tools, where the risk of a given outcome for the individual patient is predicted at baseline. Guidelines for this kind of studies are present. The "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnoses" statement, is a checklist of 22 items to keep in mind when developing or validating prediction models [118, 119], all the way from the title to the funding information. In between these are the analysis and statistics part, which covers both sample-size, predictor selection or deselection, internal validity, model performance, and external validity. These are all important aspects to assess the power of the model, the correct selection or deselection of predictors, the model's ability to discriminate between cases and non-cases, and finally both the internal and external validity of the model. Before the best possible model can be developed it is important to identify the most important predictors of the given outcome.

3.6.3 Properties of health status measurement instruments

In 2010 an article was published aiming to establish a checklist for evaluating the quality of studies on measurement properties under the name "COnsensus-based Standards for the selection of health status Measurement INstruments" (COSMIN) [120]. This was done as a Delphi study with 57 experts agreeing to participate, including psychologists, statisticians, clinicians, and epidemiologists. They agreed with the following overall measurement properties being included in the checklist: reliability, validity, and responsiveness. Reliability reflects the accuracy and consistency where two giving measurements under the same conditions should be as close as possible. In the COSMIN Delphi study, Intraclass Correlation Coefficient (ICC) was recommended to assess the reliability [120, 121]. Standard Error of Measurement (SEM) was the preferred statistical method to asses measurement error, followed by limits of agreement and smallest / minimal detectable change given by the formula $1.96 * \sqrt{2} * SEM$. Validity was divided into content validity, criterion validity, and construct validity. Content validity refers to whether the content is sufficiently covering the measures construct, and should be judged by the relevance and comprehensiveness. They give the example that a statement on shoulder pain would be valid in measuring shoulder disability, but would not be suitable for patients with wrist disability. The Delphi panel discussed whether or not the criterion validity should even be a part of the checklist, and agreed that it would only be useful if a shortened instrument were compared to the original [121]. Finally, the construct validity represents the consistency with hypotheses on relation to other instruments. A hypothesis could in this case be that there would be a strong correlation between the tested instrument and another known instrument.

Responsiveness was defined as the ability to measure change over time [121]. They did not consider measures of responsiveness like Effect Size (ES) to be a measure of validity, but instead a measure of the amount of change due to an intervention or another event.

Before it is even possible to assess the measurement properties of a health measurement instrument, it is often required to translate it from the original language to another language. This is done in various ways, and based on literature studies, it appears that the translation procedure is not standardized, and a study identified 17 different translation processes used in the existing [122]. However, a literature based research study found the most common (79% of studies) translation method to be the forward/backward translation, where the measurement instrument is first translated to the new language and then translated back to the original language [123]. This is done to ensure that the translated instrument reflects the original instrument.
Although the translations are done in various ways, it is still recommended that the translation process should be clearly described [122, 123]

3.7 Summary of background

Due to the high prevalence and incidence of both carpal tunnel syndrome, trapeziometacarpal osteoarthritis, trigger finger, Dupuytren's disease, and wrist ganglia, a large number of patients are treated surgically for these conditions every year. The outcome of these surgeries is mainly good, but studies suggest that 3 to 20% of patients experience unsatisfactory outcome after surgery [4, 22, 23, 40, 47]. Several studies have tried to identify preoperative factors able to predict the postoperative outcome, including general demographics such as age, gender, smoking, and alcohol consumption. Recently, there has been increased attention toward mental health as a possible predictor, which is supported by the existing literature. It has been suggested that the PCS might have a predictive ability regarding postoperative outcomes. However, the existing literature on the predictive abilities of the Pain Catastrophizing Scale regarding postoperative patient-reported satisfaction in hand surgery is sparse.

4. Aims

The general aim of this thesis was to investigate risk factors for unsatisfactory outcome after surgical treatment of five common hand conditions: carpal tunnel syndrome, trapeziometacarpal osteoarthritis, trigger finger, Dupuytren's disease, and wrist ganglia. This was done with special reference to the Pain Catastrophizing Scale as predictor and with postoperative patient-reported satisfaction as outcome. Furthermore, the aim was to examine the measurement properties of the Danish version of the carpal tunnel syndrome-specific questionnaire called the Boston Carpal Tunnel Questionnaire.

The specific aims for each of the four studies were:

Study I:

The aim of this study was to identify preoperative risk factors of no clinical improvement in hand function or symptoms after operative treatment of osteoarthritis with total TMC joint replacement.

Study II:

Based on demographic characteristics, patient-reported outcome measures, and with special attention to the Pain Catastrophizing Scale, the aim of this study was to identify risk factors for low patient-reported satisfaction following surgical treatment of idiopathic, nerve conduction-verified carpal tunnel syndrome with carpal tunnel release.

Study III:

The aim of this study was to assess the measurement properties of the Danish version of the Boston Carpal Tunnel Questionnaire including the Symptom Severity Score and the Functional Status Scale subscales. This was done through validity, responsiveness, and reliability.

Study IV:

The aim of this study was to investigate the effect of the Pain Catastrophizing Scale on postoperative satisfaction in patients with Dupuytren's disease, trigger finger and wrist ganglia. For predictive purpose and better clinical use, we also evaluated the optimal preoperative cut-point on the Pain Catastrophizing Scale to identify patients with increased risk of low postoperative satisfaction.

5. Materials & methods

5.1 Ethical issues

In all studies, the patients were informed about the research study and data collection before they completed the questionnaires and verbal consent was given.

Prior to study initiation, the protocols were reviewed by the local research ethics committee, and no specific approvals were demanded because the studies are quality assurance studies, which according to the Danish law "Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and authorization": Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material.

The Helsinki II declaration was followed, and all data were handled according to the General Data Protection Regulation.

5.1.1 Paper I

The study is a part of an outcome study of the outcome after total joint arthroplasty of the trapeziometacarpal joint registered in Clinicaltrials.gov (NCT01554748) on 15th March 2012.

5.1.2 Papers II, III, & IV

These studies were registered in The Danish Data Protection Agency: jr. nr.: 2007-58-0010.

5.2 Design and patients

5.2.1 Clinical quality assurance databases

Study I, Study II, and Study IV were based on two separate quality assurance databases from our institution. Study I was conducted using data from a hospital-based research database on patients treated for trapeziometacarpal osteoarthritis with total joint arthroplasty. Study II and Study IV were both based on data from a hospital-based research database on upper extremity disorders.

The database for Study I included preoperative data on age, gender, prosthesis type, grip strength, DASH score, VAS pain at rest, and VAS pain at activity. The 12-month postoperative data included grip strength, DASH score, VAS pain at rest, and VAS pain at activity. All the data were used in Study I.

The database for Study II and Study IV included all patients with upper extremity conditions including carpal tunnel syndrome, Dupuytren's disease, trigger finger, wrist ganglia, fractures, de Quervain's tenosynovitis, osteoarthritis, and Kienböck's disease. Patients with CTS were used in Study II and patients with Dupuytren's disease, trigger finger, or wrist ganglia were used in Study IV. Patients in the database with De Quervain's tenosynovitis, Kienböck's disease, fractures, or osteoarthritis were small numbered (<40), and their registration of PCS levels were incomparable, and therefore they were not included in Study IV. The data in the clinical upper extremity database are presented in Table 2.

Table 2: Data in the clinical upper extremity database used in Studies II and IV		
	Preoperative	*12-month postoperative*
Age	+	+
Gender	+	+
Diagnosis	+	
Treatment	+	
Civil status	+	
Dominant side	+	
Operated side	+	
EQ-5D	+	+
DASH	+	+
Pain Catastrophizing Score	+	
Distal motor latency (CTS patients)	+	
Treatment satisfaction		+

5.2.2 Study I

Study I is a prospective cohort study. All patients treated for trapeziometacarpal joint osteoarthritis using trapeziometacarpal total joint arthroplasty at the Department of Orthopaedics at Holstebro Regional Hospital were included. Patients were included in the period from March 2008 to November 2015. A total of 287 patients were enrolled.

5.2.3 Study II

Study II is a prospective cohort study. All patients with nerve conduction-verified carpal tunnel syndrome treated with carpal tunnel release at the Department of Orthopaedics at Holstebro Regional Hospital were included in the period from February 2011 to January 2015. A total of 714 patients were enrolled.

5.2.4 Study III

Study III is a prospective cohort study. All patients with nerve conduction-verified carpal tunnel syndrome treated with carpal tunnel release at the University Clinic at Holstebro Regional Hospital and at the Department of Orthopaedics at Sonderborg University affiliated hospital were included in the period from April 2019 to October 2019 (Holstebro Regional Hospital: 31 patients) and in the period from March 2018 to December 2018 (Sonderborg University Hospital: 157 patients), giving to a total of 188 enrolled patients.

5.2.5 Study IV

Study IV is a prospective cohort study. All patients diagnosed and surgically treated for Dupuytren's disease (133 patients), trigger finger (365 patients), or wrist ganglia (147 patients) at the Department of Orthopaedics at Holstebro Regional Hospital were included in the period from February 2011 to January 2015. A total of 645 patients were enrolled.

5.3 Predictors and outcomes in the four studies

The diagnoses, follow-up time, predictors, and outcomes in the four studies are presented in Table 3.

Table 3: Overview of the predictors and outcomes in Studies I to IV

Diagnoses	*Follow-up*	*Preoperative predictors*	*Outcomes*
Study I			
Trapeziometacarpal joint osteoarthritis	12 months	Age Gender DASH VAS activity VAS rest Grip strength	VAS activity VAS rest DASH Grip strength DASH + VAS activity DASH + VAS rest
Study II			
Carpal tunnel syndrome	12 months	Age Gender DASH EQ-5D Distal motor latency Operation technique PCS	Patient satisfaction with the outcome of the operation
Study III			
Carpal tunnel syndrome	5 days before surgery & 8 weeks after surgery	Age Gender BCTQ FSS BCTQ SSS QDASH	BCTQ FSS BCTS SSS QDASH
Study IV			
Trigger finger, Dupuytren's disease & Wrist ganglia	12 months	Age Gender DASH EQ-5D Dominant hand Civil status PCS	Patient satisfaction with the outcome of the operation

DASH: Disabilities of the Arm, Shoulder, and Hand; QDASH: Quick Disabilities of the Arm, Shoulder and Hand; VAS activity: Visual Analogue Scale on pain at activity; VAS rest: Visual Analogue Scale on pain at rest; EQ-5D: EuroQol-5D; BCTQ FSS: Boston Carpal Tunnel Questionnaire Functional Status Scale; BCTQ SSS: Boston Carpal Tunnel Questionnaire Symptom Severity Scale; PCS: Pain Catastrophizing Scale.

5.3.1 DASH – Disabilities of the Arm, Shoulder, and Hand

The DASH is a questionnaire used to assess disability in patients with upper extremity disorders. The questionnaire consists of 30 statements scored on a 5-point Likert scale, where a score of 0 represents no disability and a score of 100 represents maximum disability [103]. The Danish DASH has been validated [124]. A MCID of 12 points was used for the DASH [125].

5.3.2 QDASH – Quick Disabilities of the Arm, Shoulder and Hand

The QDASH is a shortened version of the above-mention original DASH questionnaire. Instead of 30 statements, the QDASH consists of 11 statements scored on a 5-point Likert scale, where a score of 0 represents no disability and a score of 100 represent maximum disability. QDASH has been found to be highly related to the original DASH ($r = 0.98$) with equally good responsiveness and construct validity[126-128]. The Danish QDASH has been validated [129]. A MCID of 13.6 was used for the QDASH [130].

5.3.3 EQ-5D – EuroQol-5d

The EQ-5D is a questionnaire used to assess quality of life and general health. It is made up of five dimensions: self-care, usual activities, mobility, anxiety/depression, and pain/discomfort, where a higher score represents better general health[131]. The Danish EQ-5D has been validated [132, 133], and Danish population norms have been estimated [134]. A MCID of 0.10 was used for the EQ-5D [135].

5.3.4 BCTQ – Boston Carpal Tunnel Questionnaire

The Boston Carpal Tunnel Questionnaire is used to access symptom severity and functional status in patients with carpal tunnel syndrome. It is made up of two subscales, the Functional Status Scale and the Symptom Severity Scale. On both subscales, a higher score reflects more severe functional status and more severe

symptom severity [85]. The Danish BCTQ was translated as part of a study performed at our institution more than 20 years ago [95]. The measurement properties of the Danish translated BCTQ was assessed in Study III from this thesis.

5.3.5 PCS – Pain Catastrophizing scale

The PCS is used to assess how patients handle feelings and thoughts related to experiencing pain. It consists of three subscales: rumination, magnification, and helplessness, making a total of 13 statements each scored on a 5-point Likert scale from 0 "not at all" to 5 "all the time". The total score ranges from 0 to 52, where 52 represents the most severe catastrophic thinking about pain [70-72]. The Danish PCS has been validated in 113 patients with rheumatoid arthritis and 110 headache patients [70]. No MCID was used in association with the PCS because it was only used as a preoperative predictor.

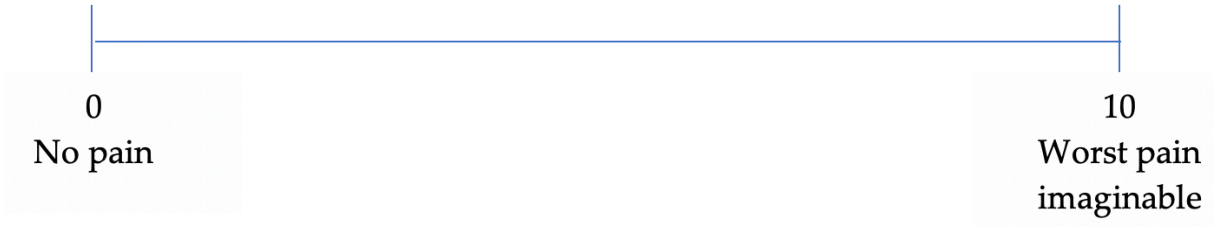
5.3.6 Self-reported patient satisfaction

In Study II and Study IV, self-reported satisfaction was used as the outcome, assessed using one single question on patient satisfaction, with a score ranging from 1 "I am dissatisfied" to 4 "I am very satisfied."

5.3.7 VAS – Visual Analogue Scale

The VAS can be used to assess information on various items. In this thesis it is used to measure pain at rest and pain during activity. It is scored by drawing a vertical line across a 100-mm horizontal line ranging from 0 "no pain" to 100 "worst imaginable pain" [136] Figure 10). A MCID of 3 points was used for pain measures using the VAS scale [137].

Figure 10: Overview of the Visual Analogue Scale



5.4 Statistics

In all studies, we used a significance level of 0.05, and quantile-quantile plots were used to determine whether data were normally distributed.

In Study I and Study II, variance inflation factors were used to test for collinearity in the regression models.

In Study I, Study II and Study III, all statistical analyses were made using STATA, version 15 IC (Stata Corp, College Station, TX, USA). In Study IV, STATA and R (R Core Team (2013), R Foundation for Statistical Computing, Vienna, Austria) were used.

5.4.1 Study I

Post hoc calculation:

We used the rule of 10 to define the sample-size for the logistic regression models, which Peduzzi et al.,[138] have described with the formula *"N = (10 * covariates / smallest proportion of success or failures)*. Assuming 28% of patients would experience improvements below the MCIDs, the required sample size would be (10*7)/0.28 = 250 patients.

Statistics:

To test for difference in preoperative and postoperative measurements, paired Student's t-test was used when data were normally distributed, and Wilcoxon matched-pairs signed-rank test was used when data were not normally distributed.

Both logistic regression models and linear regression models were used to examine the predictors. Linear regression models were used when the outcome variables were kept continuous, and logistic regression models were used when the outcome variables were dichotomized. Improvement in DASH score was dichotomized as improvement >15 points, which is more than the Minimal Clinical Important Difference (MCID) of 12 [125] but is recommended by the DASH organization website. VAS pain at activity and rest was dichotomized at improvement >2 because it was found to be the MCID

[137]. We dichotomized improvement in grip strength at an improvement >19% because it was defined as the MCID in a previous study [139].

5.4.2 Study II

Post hoc calculation:

We used the rule of 10 for sample size calculation as in study I. Assuming 85% of patients would be satisfied postoperatively, this would leave 15% as unsatisfied. According to the formula by Peduzzi et al.,[138] the required sample size with 8 predictors would be: (10*8)/0.15 = 533 patients.

Statistics:

Due to non-normality, Wilcoxon matched-pairs signed-rank test was used to test statistically significant improvement in DASH and EQ-5D score.

The outcome used is this study was postoperative patient-reported satisfaction. The patients were asked to evaluate their satisfaction on a scale ranging from 1 "I am dissatisfied" to 4 "I am very satisfied." Answers 1 and 2 were then pooled as low satisfaction and answers 3 and 4 as high satisfaction.

To test the predictive properties of PCS on postoperative satisfaction after CTR, a logistic regression model was used. This was modelled in three steps. Step 1 was an unadjusted logistic regression model with postoperative satisfaction as outcome and preoperative PCS as predictor. Step 2 was to adjust PCS for age, gender, surgical technique, and civil status. In step 3, PCS was further adjusted for preoperative EQ-5D, DASH, and distal motor latency.

5.4.3 Study III

Statistics:

To evaluate the measurement properties of the FSS and the SSS of the BCTQ and QDASH, we examined acceptability, responsiveness, construct validity, and reliability using the checklist in the Consensus-Based Standards for the Selection of Health Status Measurement Instrument (COSMIN) as guideline and inspiration [120, 121].

Acceptability was evaluated using floor and ceiling effects, with an acceptance level of 15% [140], and skewness with an acceptable range of -1 to 1 [141].

Responsiveness was evaluated using standardized response mean (SRM) and Effect Size (ES) using Cohen's D. A value between 0.2 and 0.5 was considered small, a value between 0.5 and 0.8 moderate, and a value above 0.8 as large[142].

Construct validity was evaluated with the convergent validity using Pearson's correlation between the BCTQ FSS / SSS subscales and QDASH.

Reliability was evaluated using the ICC for the relative reliability, and the SEM and MDC for the absolute reliability. Cronbach's alpha was used to evaluate internal consistency of the BCTQ FSS and SSS.

5.4.4 Study IV

Post hoc calculation:

As in study II, we used the rule of 10 for sample size calculation as in study I. Assuming 85% of patients would be satisfied postoperatively, this would leave 15% as unsatisfied. According to the formula by Peduzzi et al., [138] the required sample-size with 7 predictors would be: (10*7)/0.15 = 467 patients.

Statistics:

Wilcoxon matched-pairs signed-rank test was used to test the improvement in DASH and EQ-5D score because data were not normally distributed. The correlation between preoperative PCS, DASH and EQ-5D was examined using Pearson's correlation.

Missing data in the final study cohort were imputed using "missForest" in R because it is able to impute both continuous and categorical data.

A classification tree was used to define two cut-points on the preoperative PCS to predict postoperative patient satisfaction. These two cut-points as well as the 75th percentile [143] and the PCS kept continuous were then used in four separate logistic regression models.

The modeling of these four models was done through the same three steps as in study II. Step 1 was an unadjusted logistic regression model with postoperative satisfaction as outcome and preoperative PCS as predictor. Step 2 was to adjust PCS for age, gender, civil status, and dominant hand. In step 3, PCS was further adjusted for preoperative EQ-5D and DASH.

6. Results

This section will provide the main results from the four studies included in this thesis.

Table 4 shows the patient demographics for each of the four studies.

6.1 Patient demographics

Table 4: Patient demographics in Studies I, II, III, and IV

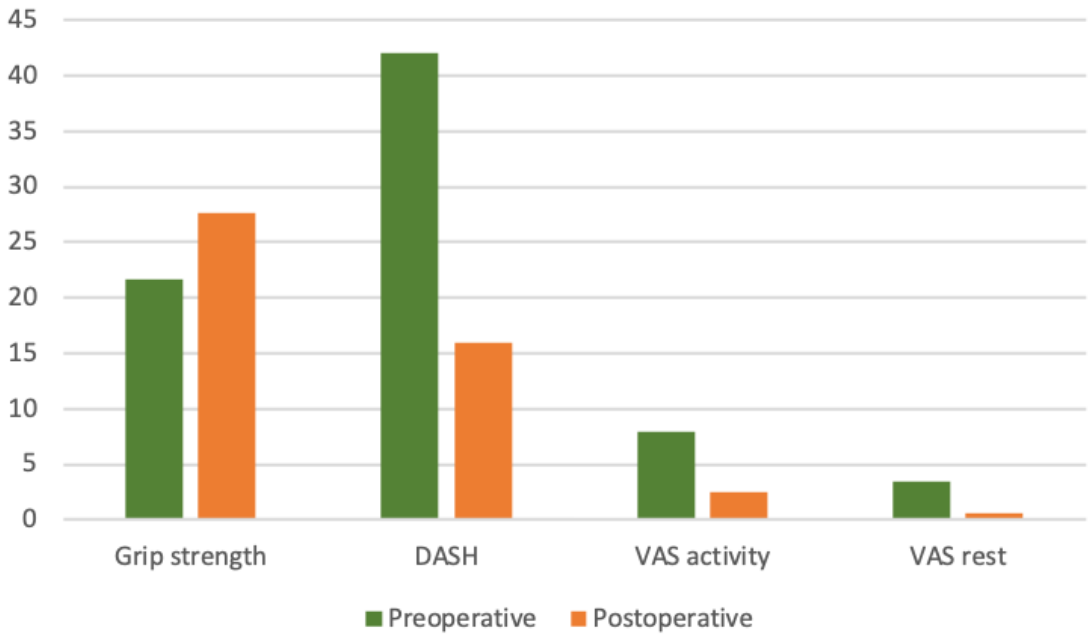
Studies	*Units*	*Value*	
Study I, N = 287			
Age	Mean years (range)	58.9 (41-78)	
Gender	Female %	78	
DASH	Mean score (SD)	42.0 (18.6)	
VAS activity	Mean VAS (SD)	7.9 (1.8)	
VAS rest	Mean VAS (SD)	3.5 (2.4)	
Grip strength	Mean kg (SD)	21.6 (12)	
Study II, N = 417			
Age	Mean years (range)	58.0 (18-92)	
Gender	Female %	64.5	
DASH	Mean score (95% CI)	25.4 (23.5 – 27.4)	
EQ-5D	Mean score (95% CI)	0.74 (0.72 – 0.76)	
Distal motor latency	Mean m/s (95% CI)	5.7 (5.5 – 5.9)	
PCS	Mean score (95% CI)	13.0 (11.9 – 14.1)	
Study III, N = 119 (31 / 88)		*Holstebro*	*Sonderborg*
Age	Mean years (range)	57.0 (21 – 85)	60.0 (22-88)
Gender	Female %	58	53
BCTQ FSS	Mean score (95% CI)	2.7 (2.3 – 3.0)	2.6 (2.4 – 2.8)
BCTQ SSS	Mean score (95% CI)	2.9 (2.6 – 3.2)	3.0 (2.8 – 3.2)
QDASH	Mean score (95% CI)	44.0 (35.8 – 52.2)	43.1 (38.2 – 48.0)
Study IV, N = 413			
Age	Mean years (range)	58.8 (57.4 – 60.3)	
Gender	Female %	52.8	
DASH	Mean score (95% CI)	14.8 (13.2 – 16.4)	
EQ-5D	Mean score (95% CI)	0.8 (0.8 – 0.9)	
Dominant hand	Dominant %	58.0	
Civil status	Living alone %	22.3	
PCS	Mean score (95% CI)	7.6 (6.5 – 8.5)	

6.2 Study I

A total of 287 patients were included in this study. Six different prosthesis types were used, and there was no difference in outcome between these different prosthesis types. The prosthesis distribution was as follows:

- Motec cemented polyethylene cup = 41 patients
- Motec cementless titanium cup = 20
- Moovis press-fit dual-mobility cementless cup = 142 patients
- Elektra Bimetal cementless (generation two) cup = 62 patients
- Elektra cemented polyethylene cup = 10 patients
- Elektra cementless (generation one) cup = 12 patients

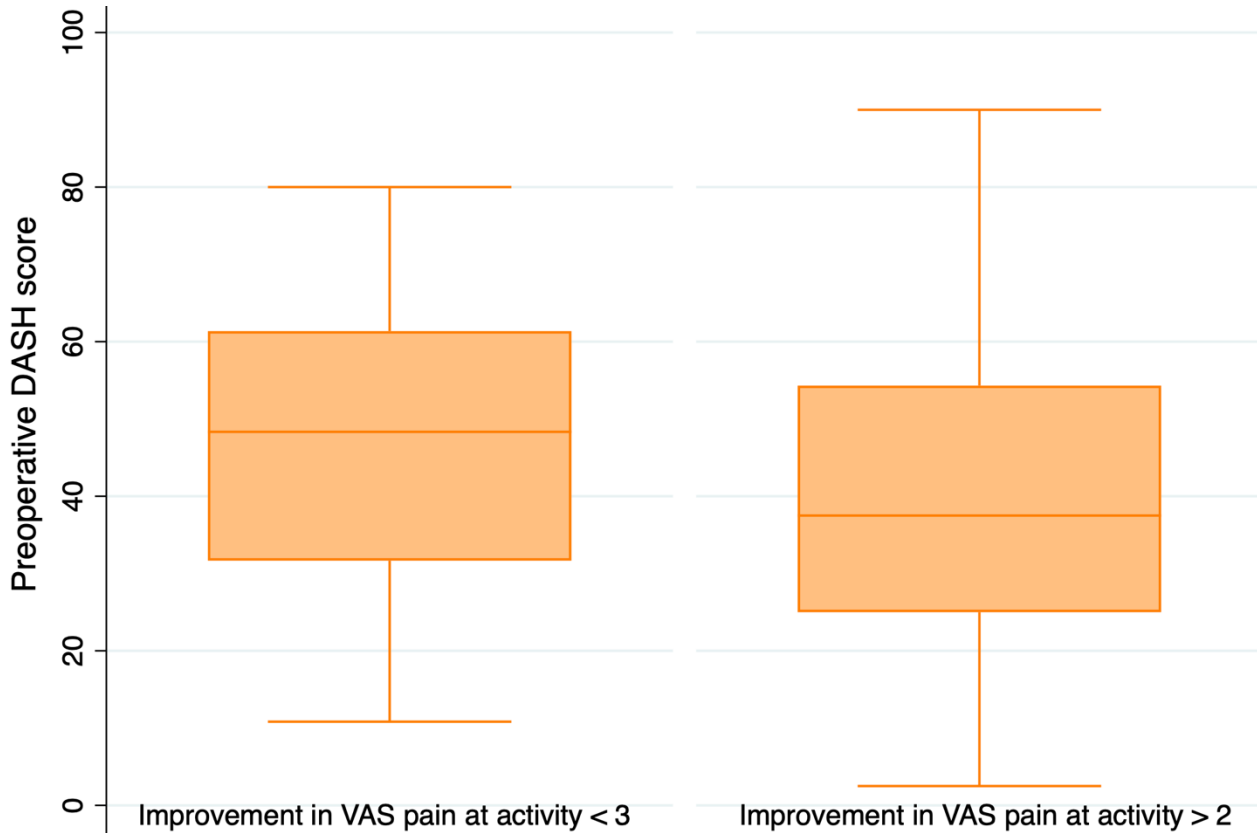
Figure 11: Preoperative and postoperative scores after total trapeziometacarpal joint arthroplasty



There was an overall improvement in both DASH, VAS pain at activity, VAS pain at rest, DASH and grip strength (Figure 11).

We examined six different outcome measures or combinations of outcome measures: VAS pain at activity, VAS pain at rest, DASH, grip strength, DASH + VAS pain at activity, and DASH + VAS pain at rest. When using VAS pain at activity as outcome, lower preoperative DASH score ($p = 0.001$) and lower preoperative grip strength ($p = 0.048$) increased the risk of a VAS improvement < 3. Using VAS pain at rest as outcome, women ($p = 0.025$) were more likely to experience a VAS improvement < 3. For DASH + VAS pain at activity and DASH + VAS pain at rest a lower preoperative grip strength ($p = 0.044$) increased the risk of a postoperative improvement in DASH < 15 and VAS < 3. None of the included variables had a statistically significant effect on postoperative outcome when DASH or grip strength improvement was used as outcome. There was no single predictor with a significant association with all outcomes.

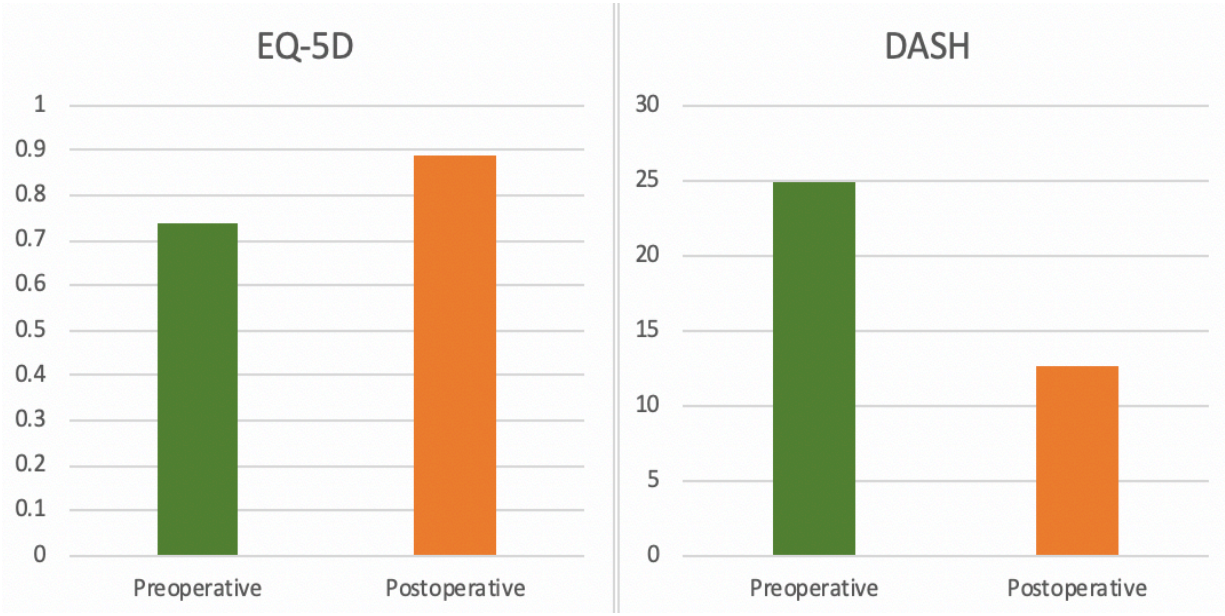
Figure 12: Boxplot of the preoperative DASH score for patients with improvement in VAS pain at activity below 3 and patients with improvement of 3 or more



6.3 Study II

A total of 417 patients with nerve conduction-verified CTS (64.5% females) with a mean age of 58 years were included in the final study cohort. The mean improvement in DASH score was 12.29 ($p < 0.001$), representing an improvement above the MCID for the Danish validated DASH score of 12 points [125]. The mean improvement in EQ-5D score was 0.14 ($p < 0.001$), representing an improvement above the MCID for the EQ-5D of 0.10 [135] (Figure 13).

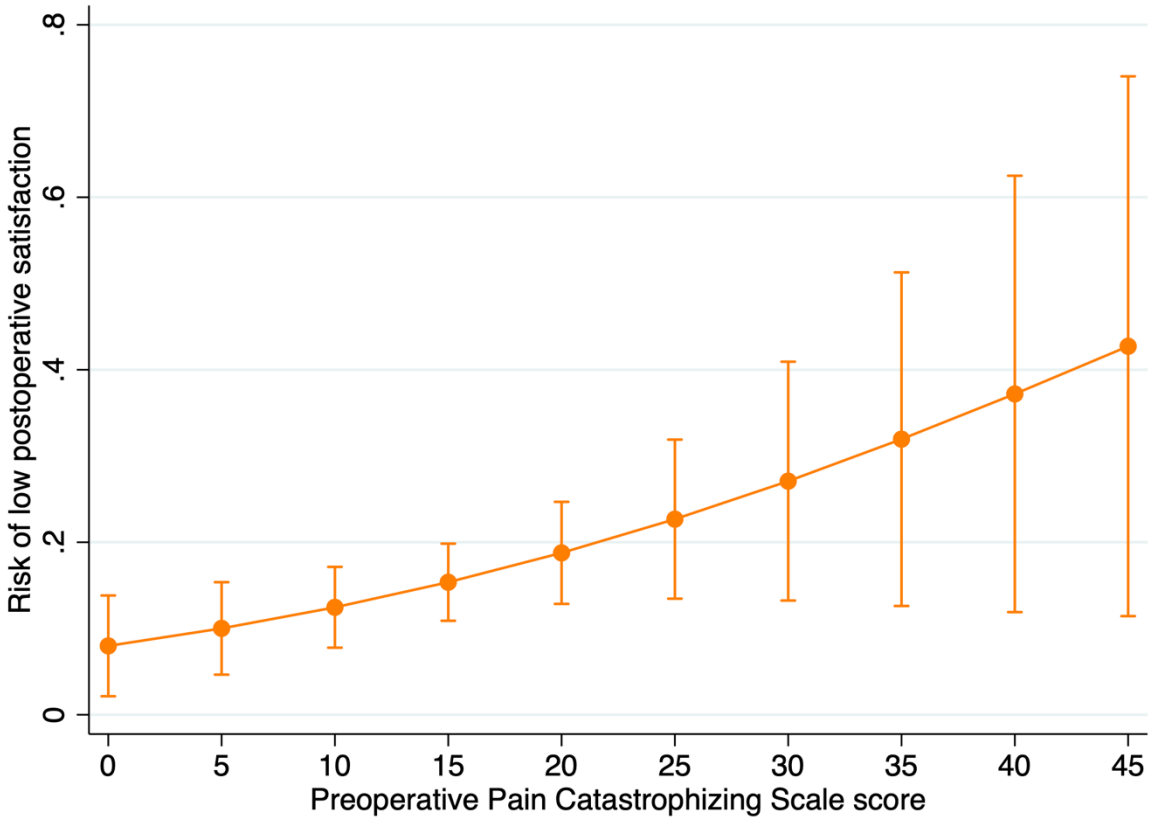
Figure 13: Preoperative and postoperative scores after carpal tunnel release



There was a statistically significant correlation between preoperative PCS score and preoperative DASH and EQ-5D scores of Spearman's rho = 0.61 and rho = -0.50 respectively ($p < 0.001$).

In the fully adjusted logistic regression models, only preoperative PCS score was a significant predictor of postoperative patient satisfaction, where a 1-unit increase in PCS lead to an OR of 1.05 [95% CI: 1.01 – 1.10] ($p = 0.022$) for increased risk of low postoperative patient reported satisfaction. Preoperative EQ-5D, DASH, distal motor latency, and civil status had no statistically significant predictive effect on postoperative patient-reported satisfaction in the fully adjusted logistic regression models ($p > 0.066$).

Figure 14: Predicted probability of low postoperative satisfaction after carpal tunnel release depending on preoperative Pain Catastrophizing Scale score



The patients were further dichotomized into two groups depending on their preoperative PCS score as either high (PCS > 30) or low (PCS ≤ 30) as suggested in the PCS user manual[143]. Patients in the high PCS group had increased risk of low postoperative satisfaction in both an unadjusted logistic regression model (OR = 2.24 [95% CI: 1.27-3.96]) and a logistic regression model adjusted for age, gender, civil status, and surgical technique (OR = 2.56 [95% CI: 1.38-4.74]). However, when the model was further adjusted for preoperative EQ-5D, DASH and distal motor latency, it was no longer significant (OR = 1.85 [95% CI: 0.78-4.39]).

6.4 Study III

In the final study cohort, 119 patients were included. 31 of the patients (58% females) with a mean age of 57 years were included at Regional Hospital Holstebro as the reliability group and 88 patients (53% females) with a mean age of 60 years were included at Sonderborg University Hospital as the validity and responsiveness group.

There were good measurement properties of both the FSS and SSS subscales from the BCTQ with ES values of 1.0 for the FSS and 1.8 for the SSS and SRM values of 0.9 for the FSS and 1.5 for the SSS.

Both the FSS and SSS also showed good measurement properties assessed by the ICC, SEM, MDC and Cronbach's alpha. The values from both subscales can be seen in Table 5, as well as the values from validations in other languages.

Table 5: Measurement properties of the Danish BCTQ and the highest values identified in existing validations

	Danish validation		*Best validation*	
	FSS	*SSS*	*FSS*	*SSS*
Effect Size	0.99	1.76	0.56 [A]	1.12 [A]
Standardized Response Mean	0.86	1.50	0.62 [A]	1.03 [A]
Intraclass Correlation Coefficient	0.94	0.90	0.89 [B]	0.88 [B]
Standard Error of Measurement	0.22	0.25	0.27 [A]	0.31 [A]
Minimal Detectable Change	0.61	0.69	0.75 [C]	0.86 [C]
Cronbach's Alpha	0.93	0.92	0.92 [D]	0.91 [D]
QuickDASH Correlation	0.84	0.79	0.70 [C]	0.64 [C]

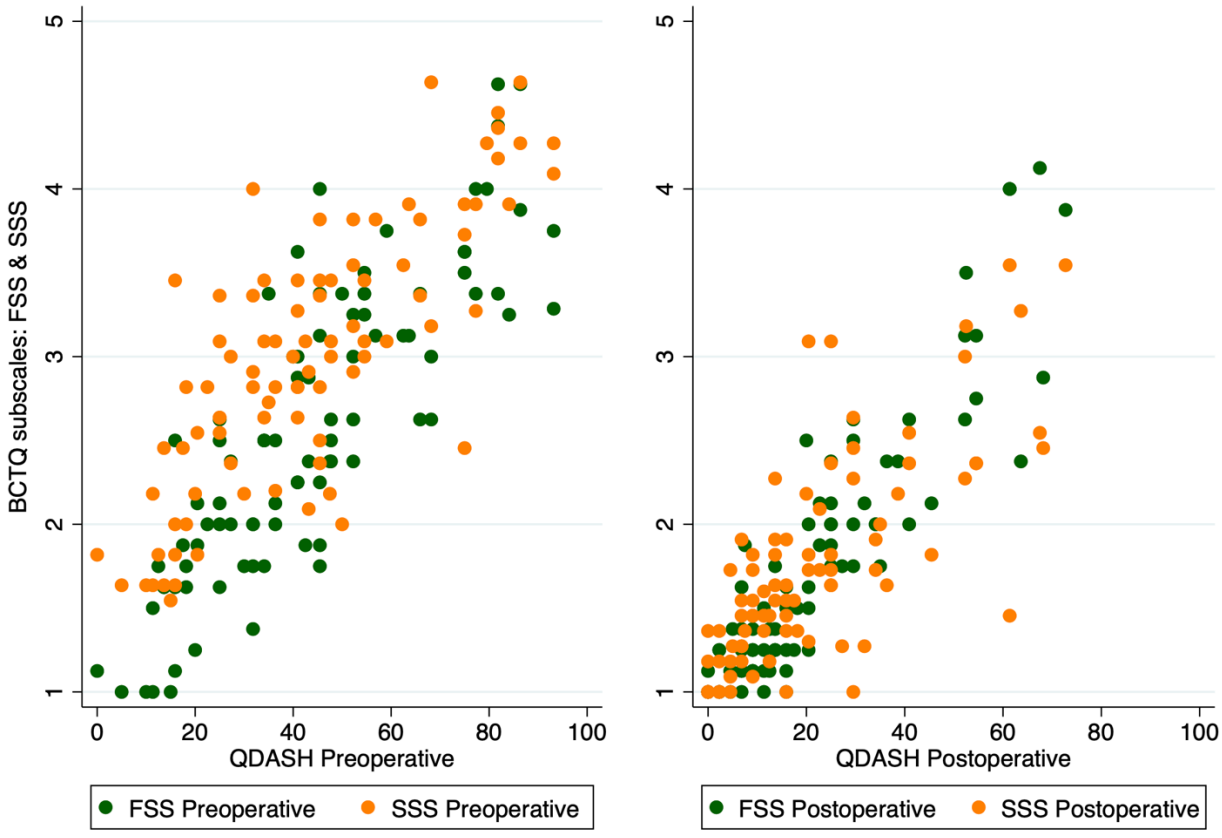
A, Chinese validation [92]; B, Arabic validation [144]; C, Persian validation [145]; D, Polish validation [94]

Table 6: The influence of effect size (Cohen's D) on required sample size		
Effect Size	*Cohen's D*	*Sample size given power = 80% and alpha = 0.10.*
Small	0.2	452
Medium	0.5	72
Large	0.8	28

Table 6 shows the effect of ES on sample size calculation. For both ES and SRM, a value below 0.5 is considered small, a value between 0.5 and 0.8 is considered moderate, and a value above 0.8 is considered large [142].

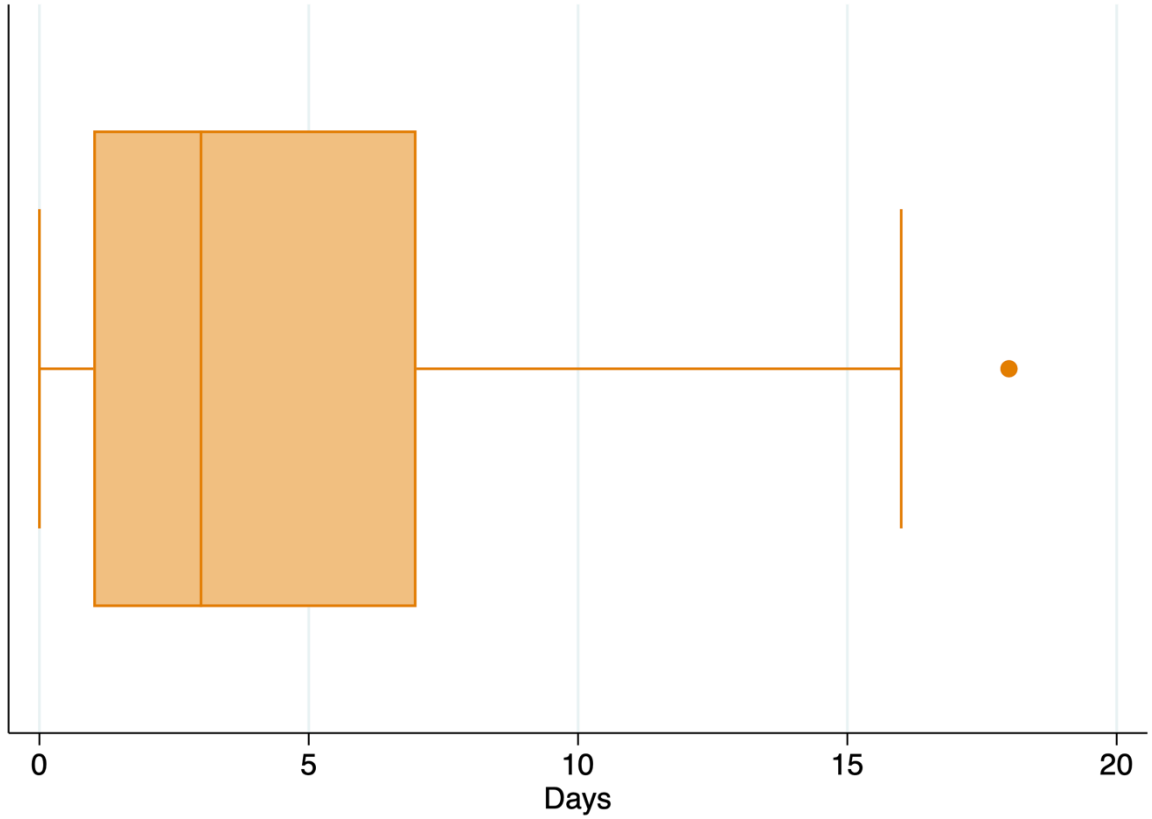
Further, the FSS and SSS were both strongly correlated to the QDASH, with preoperative correlations of 0.85 and 0.77, respectively, and postoperative correlations of 0.89 and 0.75, respectively (Figure 15).

Figure 15: Scatterplots of the preoperative and postoperative scores on QDASH and both the FSS and SSS subscale



The time between first and second completion of the BCTQ in the reliability group is illustrated using a boxplot in figure 16.

Figure 16: Boxplot of the days between first and second completion of the BCTQ



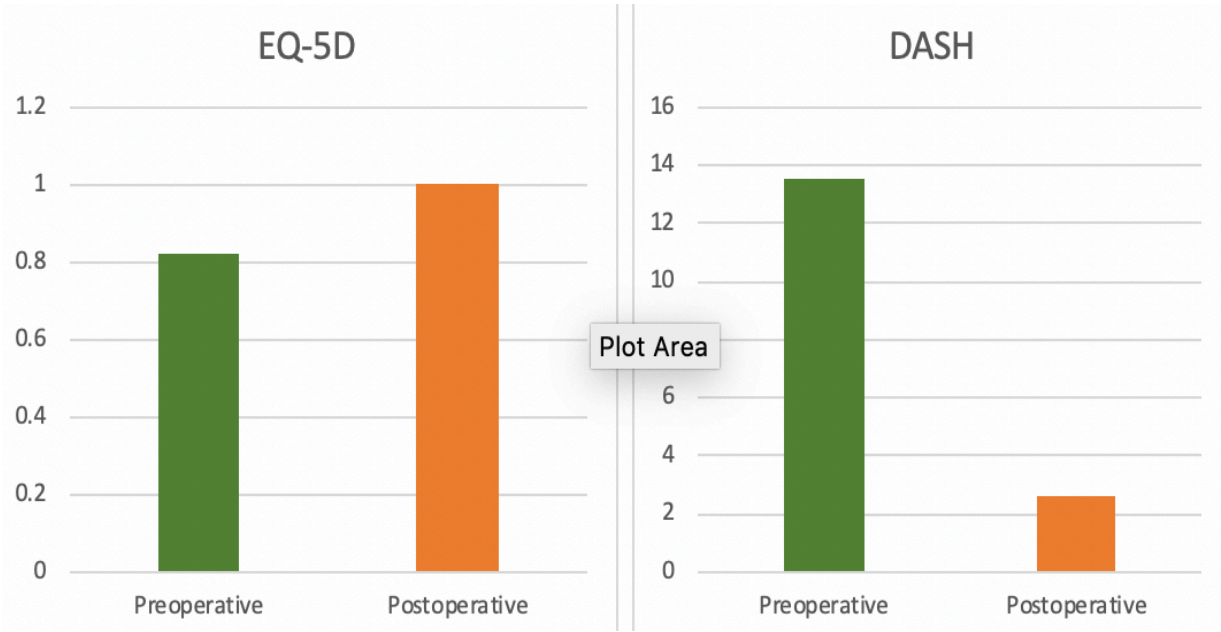
6.5 Study IV

413 patients (105 with Dupuytren's disease, 223 with trigger finger, 85 with wrist ganglia) were included in the final study cohort and consisted of 53% females, with a mean age of 59 years.

The median DASH score improvement was 10.9 ($p < 0.001$), representing an improvement close to the MCID of 12 for the Danish validated DASH score[125]. The median EQ-5D score improvement was 0.18 ($p < 0.001$), representing an improvement above the MCID of 0.10 [135] (Figure 17).

The main outcome was satisfaction, and 90.3% of the patients were either satisfied or very satisfied 12 months after surgery.

Figure 17: Preoperative and postoperative scores after surgical treatment of Dupuytren's disease, trigger finger, and wrist ganglia



The predictive effect of preoperative PCS on postoperative patient satisfaction was examined in four ways:

1. PCS as a continuous predictor
2. PCS dichotomized at 27.5
3. PCS dichotomized at 12
4. PCS dichotomized at 2.9

Cut-points of 27.5 and 2.9 were chosen because they were identified as the most important cut-points from a classification tree. A cut-point of 12 was chosen as it represents the 75th percentile, which is recommended in the PCS manual [143] and used in previous studies [146].

Table 7: Logistic regression models on the odds ratio for low postoperative satisfaction predicted by preoperative score on the Pain Catastrophizing Scale (Adapted from Study IV)

Preoperative	*Odds ratio*	*95% CI*	*p value*
PCS			
Unadjusted	1.04	1.00 – 1.07	**0.038**
+ Demographics [A]	1.04	1.01 – 1.08	**0.024**
+ Disability [B]	1.02	0.98 – 1.06	0.417
PCS > 27.5			
Unadjusted	5.81	1.62 – 20.80	**0.007**
+ Demographics [A]	6.44	1.65 – 25.14	**0.007**
+ Disability [B]	3.71	0.88 – 15.68	0.074
PCS > 12			
Unadjusted	1.51	0.75 – 3.06	0.247
+ Demographics [A]	1.65	0.79 – 3.43	0.179
+ Disability [B]	0.91	0.38 – 2.17	0.835
PCS > 2.9			
Unadjusted	3.21	1.32 – 7.85	**0.010**
+ Demographics [A]	3.82	1.51 – 9.61	**0.005**
+ Disability [B]	2.81	1.05 – 7.48	**0.038**

A: Adjusted for age, gender, living alone, and dominant hand. B: Adjusted for age, gender, living alone, dominant hand, DASH, and EQ-5D

There was no statistically significant predictive effect of PCS dichotomized at the 75th percentile. After adjusting for demographics (age, gender, civil status, and dominant hand) both the continuous PCS, PCS > 27.5, and PCS > 2.9 were statistically significant. When further adjusted for disability (preoperative DASH and EQ-5D score), only PCS > 2.9 remained a statistically significant predictor, Table 7.

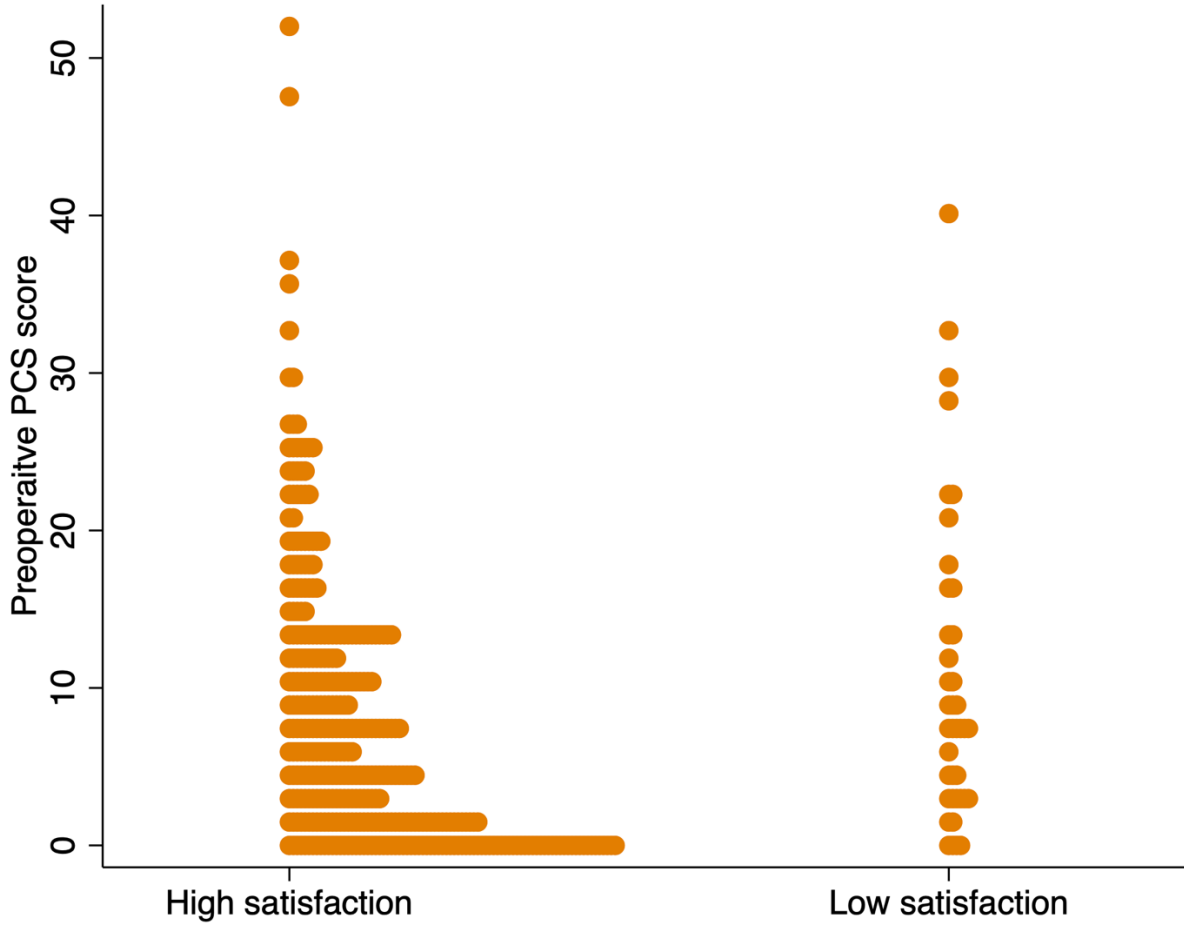
The proportion of satisfied and unsatisfied patients in the high and low PCS group at each cut-point are presented in Table 8.

Table 8: The distribution of satisfied and unsatisfied at each PCS score cut-point

	PCS ≤2.9	*PCS > 2.9*	*PCS ≤12*	*PCS > 12*	*PCS ≤27.5*	*PCS > 27.5*
Satisfied	135 95.7 %	238 87.5 %	283 91.3 %	90 87.4 %	366 91.0 %	7 63.6 %
Unsatisfied	6 4.3 %	34 12.5 %	27 8.7%	13 12.6 %	36 9.0 %	4 36.4 %

We illustrated the preoperative PCS score distribution between patients reporting high postoperative satisfaction, and patients reporting low postoperative satisfaction (Figure 18). This shows that the group reporting high postoperative satisfaction is mainly scoring low on the PCS preoperatively with a small tail toward the higher scores. The group reporting low postoperative satisfaction is somewhat evenly distributed with no peaks regarding the preoperative PCS score.

Figure 18: Preoperative PCS score distribution in patients with low self-reported satisfaction and high self-reported satisfaction 12 months after surgery



7. Discussion

7.1 Key findings

In Study I, we found overall statistically significant and clinically relevant improvement in grip strength (from 21.6 kg to 27.6 kg), DASH score (from 42.0. to 15.9), VAS measured pain at activity (from 7.9 to 2.5), and VAS measured pain at rest (from 3.5 to 0.6) 12 months after total trapeziometacarpal arthroplasty. Likewise, other studies have shown joint arthroplasty to be an effective treatment. However, none of the included variables had a statistically significant effect on postoperative outcome when DASH score or grip strength improvement was used as outcome. There was no single predictor with a significant association to all outcomes.

In Study II, we found overall statistically significant improvement in DASH score (from 24.88 to 12.60) and EQ-5D score (from 0.74 to 0.89) 12 months after CTR. Similar results were found in Study IV in patients surgically treated for TF, Dupuytren's disease, and wrist ganglia, with statistically significant improvements in DASH score (from 13.5 to 2.6) and EQ-5D score (from 0.82 to 1.0) 12 months after surgery. Twelve-month postoperative patient-reported satisfaction was high in both Study II (84.2% satisfied) and Study IV (90.3% satisfied). There were moderate to strong correlations between preoperative PCS, DASH, and EQ-5D scores in Study II and Study IV, with correlations from 0.53 to 0.61 between PCS and DASH scores, and correlations from −0.43 to −0.50 between PCS and EQ-5D scores. The PCS score worked as a statistically significant predictor of postoperative satisfaction in Study II and Study IV, with an increased OR of low satisfaction ranging from 1.02 to 1.09 for a 1-unit increase in preoperative PCS, depending on patient group and variable adjustment.

In Study III, we found good measurement properties of the Danish BCTQ regarding responsiveness, validity, and reliability of both the FSS and the SSS subscales.

7.2 The Pain Catastrophizing Scale

The preoperative PCS scores of the patients included in Study II and Study IV were 13.0 (95% CI: 11.9–14.1) in the CTS group, 5.1 (95% CI: 3.6–6.7) in the Dupuytren's group, 9.8 (95% CI: 8.6–10.9) in the TF group, and 6.6 (95% CI. 5.0–8.2) in the wrist ganglia group. Although baseline PCS scores were different in Study II and Study IV, the PCS score was still a statistically significant predictor of postoperative satisfaction in both studies. Several other studies have also examined the predictive effect of the preoperative PCS score.

7.2.1 The Pain Catastrophizing Scale in medical research

As shown in Table 1, the PCS has been used in several studies. Regarding postoperative pain, preoperative PCS score has been found to be a predictor in lumbar surgery [74] and abdominal surgery [76]. In these studies, the outcome measure, pain, was assessed 1 and 2 days after surgery, which does not necessarily reflect the predictive abilities of pain measured later. The PCS score has also been examined in relation to patients undergoing total knee arthroplasty and total hip arthroplasty [78, 79]. In a recent prospective cohort study in patients undergoing total knee arthroplasty, patients with a high PCS score reported higher levels of pain and worse general health both before and after surgery [79]. On the other hand, a study in patients undergoing total hip arthroplasty did not find that the PCS predicted pain 3 months after surgery [78].

7.2.1.1 The Pain Catastrophizing Scale in medical research on upper-extremity disorders

The previously described correlation between PCS score and disability and pain was also shown in a recent study in 255 patients scheduled for non-invasive treatment of osteoarthritis in the first carpometacarpal joint [147]. They found a preoperative PCS score to be correlated to pre-treatment pain, which was also shown in a study in 229 patients scheduled for surgical treatment of de Quervain's tenosynovitis. The same study concluded that the PCS score was correlated to preoperative function measured

using the Patient-Rated Wrist/Hand Evaluation questionnaire [148]. In patients treated for distal radius fracture, the PCS score was also correlated to function (grip strength and range of motion) 4 weeks after surgery [66]. Additionally, the PCS score has been found to correlate to pain intensity in trigger finger patients [149]. A study in patients with CTS, trigger finger, and benign tumors of the hand found no correlation between postoperative PCS and DASH scores [82]. However, there was a correlation between PCS score and pain at the time of suture removal (10–14 days after surgery) [82]. Common for these studies is that there seems to be a time compliance between the PCS and pain when scored at the same time. This could be related to the fear avoidance model (Figure 9) because experienced pain can cause catastrophic thinking about pain [73].

7.2.1.2 Mental health in hand surgery prediction studies

A study in 241 patients with a mean age of 44.6 years (66% females) undergoing CTR examined preoperative predictors of postoperative satisfaction and functional outcome [53]. The authors found worse preoperative mental health to be predictive of worse 18-month postoperative satisfaction and function. Additionally, a systematic review of 13 studies on patients surgically treated for CTS found worse preoperative mental health to increase the duration of postoperative sick-leave [150]. An British prospective study in 97 patients with a mean age of 53.4 years (75 females / 22 males) scheduled for CTR evaluated the influence of mental health on symptoms and disability using the Patient Evaluation Measure [67], which consists of 10 questions addressing symptoms in the hand and hand function [151]. They found a significant correlation between psychological disturbance and symptoms and disability of the hand. However, their study did not show a significant association between preoperative psychological disturbance measured using the Hospital Anxiety and Depression Scale (HADS) and postoperative surgical outcome. The HADS is used to measure anxiety and depression at a hospital setting through 14 questions [152]. There has been found moderate correlations between PCS score and the depression and anxiety subscales of the HADS, with Pearson's correlations of 0.51 for the depression

subscale and 0.64 for the anxiety subscale [153]. Given the correlation between the two scales, the results using the HADS can be used to get a better understanding of the influence of mental health.

The use of the PCS score in prediction studies is seldom dealt with in the existing literature. A retrospective study in 82 American patients with a mean age of 61 years (53 females/29 males), examined the predictive value of PCS score with regard to n postoperative satisfaction and perceived disability in patients surgically treated with OCTR [65]. In contrast to the results in Study II and Study IV, the authors of the American study did not find PCS to predict postoperative satisfaction. The age and gender distributions are fairly comparable to those in Study II and Study IV except for the lower proportion of females in Study IV (53%). However, they did not find either age or gender to be predictive of postoperative satisfaction. Based on the abovementioned studies and Study II and Study IV, it is expected that the PCS score could provide a useful tool to predict postoperative outcomes and satisfaction. For easier and faster clinical use, it is desirable to define a preoperative cut-point for the PCS score to be able to identify patients at increased risk of low postoperative satisfaction.

7.2.1.3 Preoperative cut-point on the PCS

Using the definitions in the PCS user manual, a PCS score > 20 is defined as moderate and a PCS score > 30 is defined as high because 30 represented the 75th percentile in a study population of 851 injured workers with back pain [143]. This study population is very different from the patients with degenerative and functional hand problems in Study II and Study IV. In Study II, the mean preoperative PCS score was 13.0 (95% CI: 11.9–14.1), the 75th percentile was 18.0, and 8% had a preoperative PCS score > 30. In Study IV, the mean preoperative PCS score was 7.9 (95% CI: 7.1–8.7), the 75th percentile was 12.0, and 2% had a preoperative PCS score > 30. Using 30 as a cut-point would then represent only a small proportion of the patients, as both CTS, TF, Dupuytren's, and wrist ganglia patients report lower pain levels and lower PCS scores. In Study II,

we dichotomized the patients into a high PCS group > 30 and a low PCS group ≤ 30, and found the high PCS group to have an OR of 2.24 (95% CI: 1.27–3.96) for low postoperative patient-reported satisfaction compared to the low PCS group. The results remained almost the same after adjusting for age, gender, living alone, and operation technique. However, when further adjusting for preoperative DASH score, EQ-5D score, and distal motor latency, the OR was 1.85 (95% CI: 0.78–4.39) and no longer statistically significant. The same cut-point was used in a study in American patients suffering from atraumatic hand disorders (arthritis, cyst, Dupuytren's disease, nerve compression, tendinitis, and wrist pain). In this study the authors found higher scores in the MHOQ for patients in the high group but similar improvement in both PCS groups at 1 and 3 months after surgery [84]. A Korean study in hand fracture patients used the 75th percentile as cut-point in their study cohort [146]. In this study, the 75th percentile represented a PCS score of 35. The authors found that patients in the high PCS group experienced less improvement in grip strength, range of motion, and QDASH score 3 months after surgery but had outcomes similar to those of patients with preoperative PCS scores below the cut-point of 35 at 6 months after surgery, and thus the PCS score predicted longer rehabilitation in patients with hand fractures.

In study IV, there was an increased focus on defining a useful cut-point for the PCS score. Using the 75th percentile of 12, there was no predictive effect on 12-month postoperative satisfaction using either the unadjusted regression models or the adjusted regression models in patients surgically treated for Dupuytren's disease, TF, or wrist ganglia. Using a classification tree, cut-points of 27.5 and 2.9 were defined. These cut-points were statistically significant predictors of postoperative satisfaction both unadjusted and adjusted for demographics, but only the 2.9 cut-point remained statistically significant after further adjusting for preoperative EQ-5D and DASH score. The fully adjusted regression model using 27.5 as cut-point showed an OR of 3.71 (95% CI: 0.88–15.68) and might have been statistically significant if the study population had been larger.

The ORs of low postoperative satisfaction are highest in the models using 27.5 as cut-point compared to the models using 2.9 as cut-point, Table 7.

Using 27.5 as a cut-point leaves 2.7% of the patients in the high PCS group, greatly decreasing the statistical power, as the remaining 97.3% of the patients are in the low PCS group. As shown in Table 8, the group at highest risk of low postoperative satisfaction is the group with a PCS score > 27.5, where 36.4% report low satisfaction. But using such a high cut-point would leave 36 of the 40 patients with low satisfaction to be wrongly classified as low risk. However, using 2.9 as cut-point would wrongly classify 238 (57.6%) in the high-risk group. The Dupuytren's disease, TF, and wrist ganglia patients reporting low satisfaction had a mean PCS score of 10.6 (range from 0–40) (Figure 18), further denoting the missing pattern in patients reporting low satisfaction with regard to preoperative PCS score.

For this reason, it is not possible to identify one clinically important and useful cut-point on the PCS score. Nonetheless, the results from Study IV show that the use of 30 as a cut-point and the 75th percentile are not necessarily the most relevant cut-point in prediction studies in patients with lower preoperative PCS scores than the ones in the PCS manual [143]. The existing literature on PCS and PCS cut-points in hand surgery is limited, and more research is needed to examine the predictive effect of PCS.

7.2.2 Use of covariates in models including the Pain Catastrophizing Scale

In both Study II and Study IV, the statistical modeling was done in three steps:

1. Unadjusted
2. Adjusted for age, gender, living alone, and dominant hand
3. Adjusted for age, gender, living alone, dominant hand, DASH score, and EQ-5D score.

The previously described Korean study on the association between preoperative PCS score and postoperative range of motion, grip strength, and QDASH score in patients with hand fractures also adjusted for several covariates in their regression analysis [146]. They used a forward stepwise variable selection method and ended up including both PCS score, the Pain Anxiety Symptoms Scale score, the Hand Injury Severity Scoring System, and age in some of their models.

As it has been shown that the PCS score is correlated to both the DASH and EQ-5D scores (Study II and Study IV), adjusting for these should be done with caution and be highly dependent on the purpose of the given study. In Table 7, it is seen that after adjusting for EQ-5D and DASH scores, the OR of low satisfaction related to the PCS score decreased in all four logistic regression models. In Study II and Study IV, this was done to isolate the effect of the PCS score independently of preoperative disability and quality of life. If the purpose of the study is to create the best possible prediction model of a given outcome, other statistical modeling techniques could be more useful. Preferably clear guidelines should be followed, like the "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnoses" statement, which provides recommendations for studies developing a prediction model [118, 119].

7.3 Measurement properties of the Danish BCTQ

The Boston Carpal Tunnel Questionnaire has been validated in several languages including Swedish [88], Portuguese [90], Spanish [154], Chinese [92], Greek [93], Turkish [91], Polish [94], Persian [145], Arabic [144], and Dutch [155]. The measurement properties of all validations are considered good, but there is some variation between the studies. The measurement properties of the Danish BCTQ were assessed in Study II, and the different measures are presented in Table 5. All of the measures in Table 5 are of great importance as they represent responsiveness, reliability, and validity.

7.3.1 BCTQ responsiveness

ES and SRM are two ways to assess the responsiveness of a questionnaire, where responsiveness refers to the ability to identify true change in status over time [156]. However, it has been suggested that the quality of a questionnaire should not be evaluated using responsiveness measures like ES and SRM in the COSMIN checklist. This is argued because the responsiveness reflects the impact of an intervention rather than the quality of the measurement tool [120, 121]. However, the responsiveness of a measurement tool or questionnaire can be used when the sample size is calculated for future studies using the Danish translation of the BCTQ [157]. The influence of these values on research is illustrated in Table 6, showing the necessary sample size given different effect sizes estimated using Cohen's D.

7.3.2 BCTQ reliability

The reliability measures used include ICC, SEM, MDC, and Cronbach's alpha for internal consistency, all of which are recommended in the COMSIN checklist [120, 121]. All of these measures showed better values than the ones found in the existing validations, Table 5. The ICC shows the reliability in a test and re-test setting on a scale ranging from 0 to 1, where a higher score reflects a better reliability. A higher ICC value indicates that the patient's answers are more consistent when they are asked to complete the same questionnaire two times; a high consistency ultimately reduces potential bias. Related to this is the SEM, which indicates the distribution around the unknown "true score." This makes it highly desirable to have a SEM as low as possible since the value shows the amount of error related to the final score on the scale.

To calculate the SEM, it is necessary to first calculate the ICC as it appears in the formula of the SEM. When the SEM is estimated, it is then possible to calculate the MDC, which is often used to tell whether a change in the score is beyond the statistically bound variation of the scale. In Study III, the MDC was estimated to be 0.61 for the FSS and 0.69 for the SSS subscales. These MDCs are lower than the lowest

in the existing validations, showing that the Danish BCTQ is highly useful for detecting changes in a baseline and post intervention setting.

7.3.3 BCTQ Cronbach's alpha

Cronbach's alpha was used to test the internal consistency of both subscales of the Danish BCTQ as recommended [158] and not as a direct measure of reliability. The values reported in Study II are very close to the values obtained in the Polish [94], Spanish [154], Turkish [91], Persian [145], and Arabic [144] versions of the BCTQ.

The internal consistency refers to the relation between each question or statement in a questionnaire; a higher value reflects a higher relation between the questions, thus high internal consistency. A very high value could make it possible to remove one or more of the questions if they are very closely related. It has been suggested that Cronbach's alpha should not exceed 0.9 [159]. With this in mind, it might be possible to shorten both the FSS and SSS because the Cronbach's alphas of these in Study III were estimated to 0.93 and 0.92, respectively, which might be an indication of redundancy [160]. Thus, a high Cronbach's alpha value is not always an indication of a good questionnaire.

7.3.4 BCTQ validity

The validated Danish QDASH questionnaire was used to assess convergent validity of the BCTQ subscales using Pearson's correlation. The QDASH questionnaire highly correlates to the DASH questionnaire ($r = 0.98$) and provides equal responsiveness and validity [126-128]. Both the QDASH questionnaire and the DASH questionnaire have been used as a measure of disability in several studies on CTS [58, 65, 82, 111]. In Study II, there were correlations of 0.84 for the FSS and 0.79 for the SSS. Only the Persian validation study [145] examined the validity of the QDASH questionnaire and found lower correlations of 0.70 and 0.64 for FSS and SSS, respectively. However, the primary reason for assessing the measurement properties of the Danish BCTQ questionnaire was to establish a better tool to evaluate symptoms and function in CTS patients as

compared to the DASH and QDASH questionnaires. The higher correlation does not indicate that the Danish BCTQ questionnaire is better than the BCTQ questionnaires in other languages. Instead it shows, that the Danish BCTQ questionnaire might be more correlated to the QDASH questionnaire than it is in other languages.

7.3.5 Overall high values in the Danish BCTQ questionnaire validation

The high values regarding the reliability measures (ICC, SEM, MDC) were all remarkably high in Study II. A reason for this could be that some patients filled out the questionnaire shortly after the surgery. The mean time between the two completions of the questionnaire was 5 days (range 1–18 days) (Figure 16). In the Swedish and Polish validations, the mean time between completion was 14 days [88, 94]. However, in the Spanish validation, the time between the two was 7 days [154], the Turkish was within 7 days [91], the Chinese ranged from 2–7 days [92], and the Persian ranged from 2–6 days [145]. The Persian and Chinese validations showed the best MDC and SEM values and also had the shortest times between repeat questionnaires. These findings indicate that the time between completions may influence the reliability assessment.

7.4 Limitations

7.4.1 Study I

In study I, only patients treated with total joint arthroplasty were included, and patients treated with trapeziectomy were not included. Total joint arthroplasty was the preferred treatment in active patients, reserving trapeziectomy for patients with more severe degenerative changes, including the joint between the trapezium and the scaphoid, and for the elderly more sedentary patients. This inclusion bias may, however, be justified in that the changes in self-reported functional outcome and objective measures may be easier to measure in high activity patients than in sedentary elderly patients with low functional demands.

We used a large number of different implant types during the inclusion period because of the evaluation of various new implant designs and implants during the study period. This may have flawed the results, as high failure rates of some of the implant types [161-164] may have led to biased functional outcome due to different implants. However, the well-known problems with aseptic loosening of the trapezium component do normally not lead to early implant failure within 12 months and would expectedly not bias the outcome in this study. Furthermore, the implant type was adjusted for in the regression models.

The inclusion rate was 100%, but not all patients answered all questions in the DASH questionnaire preoperatively and at follow-up, leading to exclusion in the analysis due to missing items in the DASH score. Preoperative missing data can affect the external validity of the results, and postoperative missing data could cause selection bias. Sadly, we did not test whether there was a difference between patients with missing data and patients without missing data.

In Study I, we did not use the PCS score as we did in Studies II+IV. This was due to the timeline in our data and hand database establishment. The database including total joint arthroplasty patients was established in 2008, and we did not start to collect data on psychological factors and the influence on outcome after hand surgery until 2013 with the establishment of the database with other hand conditions.

7.4.2 Study II

For decompression of the carpal tunnel, we used both ECTR and OCTR. Our standard technique is ECTR, reserving OCTR for elderly, retired patients, patients with inflammatory diseases and CTR after wrist fractures. As the difference in outcome between OCTR and ECTR is primarily related to a reduction in sick leave in the patients returning to work, and because the difference fades after a few months [165], the influence on the measured outcomes in our study at 12 months may, however, have only been of minor importance. Additionally, as the regression models were adjusted for surgical technique, this was not considered a confounder. However, there could potentially be an interaction between surgical technique and the other included variables that we did not examine in Study II.

All patients had to fill out the preoperative questionnaire, but not surprisingly, some patients did not answer all questions. Also, the relatively high number of missing data at the 12-month follow-up is a well-known problem in questionnaire-based research. As a result, we had to exclude a relatively large number of patients, but the exclusion of patients did not lead to statistically significant changes in preoperative baseline characteristics in the remaining patients. This should, however, be assessed by looking for differences between excluded patients and included patients instead of a change in preoperative baseline characteristics before and after surgery as we did. If the excluded patients have different preoperative characteristics compared to the included patients, this could negatively affect the external validity and selection bias.

7.4.3 Study III

The inclusion of patients at two different hand clinics may have led to potential bias regarding differences in indication, operation technique, and postoperative treatment plus rehabilitation. We did, however, try to use the same indication at both clinics, and all operations were performed in local anesthesia, but the rate of patients undergoing ECTR versus OCTR may be different. The postoperative treatment plus rehabilitation was, however, the same. To reduce the potential bias this could cause, the patients

undergoing surgery at Regional Hospital Holstebro were used as a reliability group, and the patients included at Sonderborg University Hospital were used as a validity and responsiveness group. In the reliability group, there were both complete inclusion and complete follow-up. However, in the validity and responsiveness group, 44% of the patients were excluded due to missing data. The differences between included and excluded patients were assessed, and there were no differences in FSS score, SSS score, QDASH score, diabetes, age, and dominant hand. There was a difference in the gender distribution, with 71% females in the excluded group and 53% females in the final analysis cohort, which could cause selection bias.

7.4.4 Study IV

We included only three large groups of patients with Dupuytren's disease, trigger finger, or wrist ganglia. We excluded other common types of hand conditions such as de Quervain's tenosynovitis, osteoarthritis, fractures, and Kienböck's disease due to small group numbers. It may have led to different results if all hand conditions had been included, but from a statistical point of view it was important to focus on conditions with a relatively large number of patients in the database. Also, traumatic injuries such as distal radius fractures and finger fractures may have been interesting to investigate, but as the focus in the database was on elective surgery, we were not able to investigate traumatic injuries. All patients had to fill out the preoperative questionnaire, but as in Study II some patients did not answer all questions in the DASH, EQ-5D and PCS questionnaires. Also, the relatively high number of missing data 12 months after surgery are a well-known problem in questionnaire-based research. In Study IV, we tried to address this issue by using imputation of missing data. This will, however, always be secondary to having a dataset with a higher completion rate. In three of four regression models, we dichotomized the preoperative PCS score. If a variable is cut roughly, it can become imprecise and cause residual confounding.

7.4.5 Other potential confounding predictors

Study I, Study II, and Study IV all aimed to identify risk factors for negative outcome measured as either lack of improvement (in quality of life, grip strength, function, disability, or pain) or low postoperative patient-reported satisfaction. However, several other confounders could be present in the three studies. The existing literature on identified risk factors in hand surgery includes diabetes [62, 166], smoking [53, 58, 62], alcohol [53, 62], physical activity [146], socioeconomy [57], income [49], and education [167]. These are all potential confounders that can be found in the existing literature, and as in any other study, there might be other confounders that we are not aware of at the moment. Common for both known and unknown confounders is that both are unmeasured, which could cause bias. Also, we did not test the internal validity in the three prediction studies (Study I, Study II, and Study IV), which could be done using bootstrapping commands. Furthermore, these models were conducted using our data, and the external validity remains unknown. This could be tested using the same cut-point in patients from other hospitals with the same diseases to examine whether the predictive value of the preoperative PCS score is similar.

8. Conclusion

It is difficult to identify preoperative risk factors for limited or no improvement after surgery of common hand surgeries that are useful in the preoperative assessment in the daily treatment of hand related conditions in our clinic. The Pain Catastrophizing Scale seems to be a reliable predictor of postoperative patient satisfaction, and postoperative patient satisfaction may also be reflected in patient-reported outcome assessed using standardized outcomes such as the Boston Carpal Tunnel Questionnaire; Disabilities of the Arm, Shoulder, and Hand Questionnaire; and the EuroQol-5D questionnaire. The Danish translated Boston Carpal Tunnel Questionnaire shows good measurement properties regarding reliability and responsiveness, and can be used as measurement of symptoms and severity in Danish studies of carpal tunnel syndrome.

9. Perspectives and future research

In future studies, it would be of great interest to examine the potential influence of the preoperative Pain Catastrophizing Scale score on postoperative patient satisfaction after treatment of trapeziometacarpal osteoarthritis after different treatment options.

Also, the studies that make up this thesis did not include patients treated for traumatic hand conditions. Future studies should examine the preoperative effect of the Pain Catastrophizing Scale score on the postoperative result and patient satisfaction after treatment of traumatic hand conditions.

Furthermore, the results in the studies in this thesis do not provide preoperative cut-points on the Pain Catastrophizing Scale score that would be useful in daily clinical practice. Prospective cohort studies of specific diseases should aim to build prediction models that could be useful as risk prediction tools in daily clinical practice. Doing so, data on known potential preoperative predictors assessed using the optimal questionnaires, including the Pain Catastrophizing Scale score, should be collected. When the aim is to build a prediction model for CTS patients it is recommended to use the disease-specific BCTQ to asses function and symptoms. Preferably, the guidelines for developing prediction models like the "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis" [118, 119] should be followed.

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Appendices

Appendices list

Appendix I

Risk factors for limited improvement after total trapeziometacarpal joint arthroplasty.

Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen.

Health and Quality of Life Outcomes, 2020 Mar 30;18(1):90

Appendix II

Higher preoperative pain catastrophizing increases the risk of low patient-reported satisfaction after carpal tunnel release: a prospective study.

Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen.

BMC Musculuskeletal Disorders 2020, 21(1):42

Appendix III

Measurement properties of the Danish version of the Boston Carpal Tunnel Questionnaire.

Sebastian Breddam Mosegaard, Maiken Stilling, Marianne Breddam,

Torben B. Hansen.

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Appendix IV

Pain Catastrophizing Scale as a predictor of low postoperative satisfaction after hand surgery.

Sebastian Breddam Mosegaard, Maiken Stilling, Torben B. Hansen

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Study I

Health and Quality of Life Outcomes

RESEARCH Open Access

Risk factors for limited improvement after total trapeziometacarpal joint arthroplasty

Sebastian Breddam Mosegaard[1,2*], Maiken Stilling[1,2] and Torben Bæk Hansen[1,2]

Abstract

Background: Trapeziometacarpal (TMC) osteoarthritis can be painful and cause disability for patients. Total joint replacement of the TMC joint provides a pseudo arthrosis with good restoration of the thumb motion and pain relief in most patients. But there is also a risk of no improvement following the operation. The purpose of this study was to identify patients at risk of no clinically important improvement following operative treatment of osteoarthritis of the TMC joint.

Methods: We included 287 consecutive patients (225 women, 62 men) treated with total joint replacement of the TMC joint due to osteoarthritis with a mean age of 58.9 years (range 41–80) in a prospective cohort study. We collected information preoperatively and 12 months postoperatively on disabilities of the arm, shoulder and hand score (DASH), grip strength and pain at rest and activity on a visual analogue scale (VAS).Results: We found a statistically significant improvement in DASH from 42.0 to 15.9 ($p < 0.001$), VAS at rest from 3.5 to 0.6 ($p < 0.001$), VAS at activity from 7.9 to 2.5 ($p < 0.001$) and grip strength from 21.6 kg to 27.6 kg ($p < 0.001$) 12 months after the operation, when analysed as a group. There was an increased risk of no clinically important improvement in hand function for patients with preoperative high preoperative grip strength. Also, we found an increased risk of no clinically important improvement in female patients when using VAS as outcome.

Conclusion: However, we were unable to detect one isolated preoperative predictor as indicator of successful result after operative treatment of TMC osteoarthritis, and as so it was not possible to establish a clinical valid tool for patient selection before surgery.
Informed consent was obtained from all patients for being included in the study. The study needed no approval from The Regional Committee of Biomedical Research Ethics as the data was collected, as part of our normal pre- and postoperative clinical pathway, but the study is part of an outcome study of the results after total joint arthroplasty (TJA) of the TMC joint registered in Clinicaltrials.gov (NCT01554748).

Trial registration: Clinicaltrials.gov (NCT01554748). Registered 15 March 2012.

Keywords: Osteoarthritis, Trapeziometacarpal joint, Total joint replacement, Risk factors, Functionality, Postoperative improvement

* Correspondence: sebmos@rm.dk
[1]University Clinic for Hand, Hip and Knee Surgery, Department of Orthopaedics, Lægårdvej 12, 7500 Holstebro, Denmark
[2]Department of Clinical Medicine, Aarhus University, Palle Juul-Jensens Boulevard 99, Aarhus N 8200, Denmark

Introduction

Osteoarthritis of the trapeziometacarpal (TMC) joint is a very common condition with a prevalence of more than 40% in men and women older than 50 years [1] leading to impaired hand function with pain and reduced grip and pinch strength. The standard operative treatment after failed conservative treatment is trapeziectomy with or without interposition arthroplasty [2]. Trapeziectomy provides a pseudoarthrosis with good restoration of thumb motion and pain relief in most patients where up to 86% would undergo the same surgery again [3].

Total joint replacement of the TMC joint has also been used for years as treatment of TMC joint osteoarthritis. The implant design is a ball and socket articulation resembling a total hip arthroplasty, with a metacarpal stem and modular neck-head segment which articulates with a trapezium cup. The first TMC implants were cemented [4], but during the last 10–15 years cementless TMC implants have been widely introduced, and improvements in cup and stem designs have increased implant survival [5–7].

Total joint replacement of the TMC joint may give a more rapid rehabilitation and better restoration of grip and pinch strength compared to Trapeziectomy [8, 9]. However, careful patient selection and information is important due to a relatively high risk of complications leading to the need for revision surgery with a possible salvage procedure and removal of the implants [10].

In recent years, a general treatment effect-measure of surgical hand intervention, which include the value for the patient, has been debated [11], but not yet defined [12, 13].

The purpose of this study was to see if it is possible preoperatively to identify patients at risk of no clinically important improvement in hand function or symptoms after operative treatment of osteoarthritis with total joint replacement of the TMC joint based on a statistical prediction model using preoperative assessments, and to establish a combination of patient reported outcome measures to be used in evaluation of the result after operative treatment of osteoarthritis of the TMC joint.

Methods

The study is based on a consecutive cohort of 375 hands in 287 patients (79% female hands, $n = 298$) with a mean age of 58.7 years (range 41–80) treated for osteoarthritis in the TMC joint using TMC TJA in the period 2008–2015 at the Department of Orthopaedics at Holstebro Regional Hospital. Patients were treated with six different prosthesis models (Table 1). The treatment was carried out by a small team of 4 surgeons using the same indications and treatment protocol throughout the study period.

Nine patients were excluded due to missing 12 months follow-up. All the nine patients (2.5%) had a reoperation with trapeziectomy during the first 12 months postoperative. In two patients the reason was an undiscovered intra-operative trapezium fracture, in 4 patients the reason was postoperative trapezium fracture after thumb trauma, in 1 patient multiple joint dislocations, and in 2 patients the reason was a cementing failure leading to lack of cup fixation. In the study period we used TJA as standard treatment in patients with symptomatic Eaton grade 2–3 osteoarthritis of the TMC joint. Trapeziectomy was only used in patients with Eaton grade 4, patients with severe comorbidity and patients not willing to have the risk of TJA implant failure.

We collected data on disabilities of the arm, shoulder and hand (DASH), pain at rest (VAS at rest), pain at activity (VAS at activity) and grip strength prospectively. DASH and VAS was collected using a self-reported questionnaire. The DASH questionnaire is a 30-item questionnaire used to measure patient reported disability through 30 statements on a 5-point Likert scale, where a higher score reflects more disability. The total score was then transformed to a score out of 100 by subtracting one and multiplying by 25. Grip strength was measured by an independent observer (outpatient clinic nurse) using a dynamometer (Jamar hand dynamometer, North Coast Medical, Morgan Hill, CA).

We did not have any specific inclusion criteria and included all patients having a total joint replacement of the TMC joint due to osteoarthritis.

Table 1 Showing the number and percentage of patients treated with different prosthesis in this study. Furthermore, the table shows the different baseline characteristics within each prosthesis group with mean and 95% confidence intervals

Prosthesis	1, $N = 62$	2, $N = 142$	3, $N = 10$	4, $N = 41$	5, $N = 20$	6, $N = 12$
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
DASH	37.5 (32.9–42.1)	47.8 (44.2–51.3)	36.7 (29.7–43.7)	36.6 (30.4–42.8)	34.3 (24.4–44.1)	45.7 (29.6–62.8)
VAS activity	7.7 (7.2–8.2)	8.2 (7.9–8.5)	7.1 (5.2–9.0)	7.9 (7.3–8.5)	7.5 (6.5–8.6)	8.6 (7.2–9.8)
VAS rest	3.5 (2.9–4.1)	3.8 (3.4–4.3)	3.0 (1.4–4.6)	3.1 (2.3–3.9)	2.9 (1.7–4.1)	4.5 (3.5–5.5)
Grip strength	24.1 (20.5–27.7)	20.8 (18.8–22.7)	25.9 (15.6.- 36.1)	22.8 (17.6–28.0)	22.7 (15.2–30.2)	16.3 (5.9–26.8)
Age	58.8 (56.3–59.8)	58.5 (57.2–59.8)	57.9 (51.2–64.6)	60.5 (58.6–62.5)	60.0 (56.7–63.3)	60.4 (54.6–66.2)

Prosthesis 1 = Elektra Bimetal cementless cup, prosthesis 2 = Moovis press-fit dual-mobility cementless cup, prosthesis 3 = Elektra cemented polyethylene cup, prosthesis 4 = Motec cemented polyethylene cup, prosthesis 5 = Motec cementless titanium cup, prosthesis 6 = Elektra cementless cup. All patients were treated with ball and socket design prosthesis with different cup designs combined with cementless titanium metacarpal stems. DASH = The disabilities of the arm, shoulder and hand. Grip strength is measured in kg

To avoid statistical dependence only the first operated hand was included in bilateral operated patients, leaving 287 hands/patients with a mean age of 58.9 years (range 41–78) and consisted of 78% females ($n = 225$). The patients were followed prospectively with self-reported pain score at rest and activity (VAS from 0 to 10) with a higher score indicating higher pain, grip strength (kg) and DASH with a higher score indicating higher disability [14] preoperatively and after 12 months. We used a Danish translated and validated version of the DASH questionnaire [15, 16].

The procedures followed in this study were in accordance with the Helsinki Declaration of 1975, as revised in 2000. The study was generally approved by the local research ethics committee, and no further specific approval was demanded because the study is an outcome study, which according to the Danish law "Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and authorization": Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material. The study was registered in The Danish data Protection Agency and ClinicalTrials.gov Identifier: (NCT01554748).

Statistical analysis

Logistic regression and linear regression models were used to test predictors of patient reported outcome in VAS, DASH and grip strength. Dichotomous dependent variables were required for logistic regression, and these were defined by the change in VAS, DASH and grip strength from preoperative measurements to measurements made 12 months postoperatively. A previous study found the minimal clinical important difference (MCID) for DASH to be ten points (range 5–15) [17]. The MCID for the Danish version of DASH has been found to be 12 points [18]. We defined a positive change in DASH to be a postoperative DASH reduction > 15 points lower than the preoperative, which should secure that a positive outcome is really clinically important. Also, a change in DASH of 15 points is recommended by the DASH organization on their website as limit for registration of changes. For a positive change in pain at activity and rest, the postoperative measurement was set to be > 2 VAS points lower than preoperative as the MCID [19]. Based on a previous study that found the clinically important difference in grip strength to be 19%, we defined a positive change to be a postoperative measurement > 19% higher than the preoperative [20]. Additionally, two new combined variables VAS rest + DASH and VAS activity + DASH were defined. A positive outcome was defined by a positive outcome in both VAS at rest and DASH or VAS at activity and DASH respectively. According to Peduzzi et al., [21] the sample size using a multiple logistic regression model can be estimated using the formula "N = (10 * covariates)/ smallest proportion of success failure". This estimates a sample size of 250 for our most demanding regression model. Using GPower software we conducted a sensitivity analysis for the required effect size with a = 0.05, power = 0.8 and sample size = 287 showing a required effect size of odds ratio = 1.52.

Collinearity in the regression model was inspected using variance inflation factor (VIF) showing VIFs ranging from 1.06 to 2.17, revealing no critical collinearity problems. In both Tables 2 and 3 the same potential predictive covariates were used, including: Preoperative VAS at rest and activity, preoperative DASH score, preoperative grip strength, prosthesis type, age and gender. Since we were unable to identify prediction studies on total joint replacement in the TMC joint, the decision on variables included was made from existing literature on other hand related prediction studies. The tested predictive variables with a p value > 0.09 are not presented in the tables as these are far from being statistically significant.

Patients with missing data on all variables were excluded as it was not possible to calculate a difference/improvement score. Patients with partially missing data were only used to calculate overall mean postoperative improvement.

Further, to avoid ceiling effect patients with preoperative DASH< 15 and VAS < 3 were not used in the

Table 2 Adjusted odds ratios for independent variables included in the multiple logistic regression model for prediction of positive outcome

Outcome	Adjusted Odds ratio	95% CI	p value
VAS at activity			
Preoperative DASH	0.96	0.94–0.99	0.002*
Preoperative Grip strength	0.96	0.91–1.00	0.048*
Male vs female ref	3.53	0.96–12.97	0.057
VAS at rest			
Preoperative grip strength	0.96	0.92–1.01	0.088
Male vs female ref	4.12	1.19–14.22	0.025*
DASH			
Preoperative grip strength	0.96	0.92–1.01	0.086
Grip strength			
Male vs female ref	0.50	0.23–1.09	0.081
DASH + VAS at rest			
Preoperative grip strength	0.95	0.91–0.99	0.044*
Male vs female ref	2.77	0.86–8.93	0.088
DASH + VAS at activity			
Preoperative grip strength	0.95	0.92–0.99	0.044*

The table is divided into the six different outcome measures: "VAS at activity", "VAS at rest", "DASH", "Grip strength", "DASH + VAS at rest" and "DASH + VAS at activity". DASH = The disabilities of the arm, shoulder and hand. Grip strength is measured in kg. All models are adjusted for baseline measurements, prosthesis, age and gender. Predictors with a p value > 0.09 are not presented in the table

*Indicates a significant p-value below 0.05

Table 3 Coefficients for independent variables included in the multiple linear regression model for prediction of improvement in VAS at rest and activity, grip strength and DASH score

Outcome	Coefficient	S.E.	95% CI	*P* value
VAS at activity, $R^2 = 0.08$				
Preoperative DASH score	−0.05	0.01	−0.08 - -0.02	0.001*
Male vs female ref	1.73	0.75	0.25–3.20	0.022*
VAS at rest, $R^2 = 0.13$				
VAS at activity	0.28	0.10	0.09–0.47	0.004*
Preoperative DASH score	0.02	0.01	0.00–0.04	0.020*
Preoperative grip strength	−0.05	0.02	− 0.09 - -0.01	0.009*
Male vs female ref	1.14	0.56	0.05–2.24	0.043*
DASH score, $R^2 = 0.07$				
Preoperative grip strength	−0.42	0.16	−0.73 - -0.11	0.009*
Grip strength, $R^2 = 0.01$				
Preoperative VAS at rest	0.53	0.30	−0.08 – 1.10	0.088

The table is divided into four different outcome measures: "VAS at activity", "VAS at rest", "DASH" and "Grip strength". DASH = The disabilities of the arm, shoulder and hand. Grip strength is measured in kg All models are adjusted for baseline measurements, prosthesis, age and gender. Predictors with a *p* value > 0.09 are not presented in the table
*Indicates a significant *p*-value below 0.05

logistic regression analysis of preoperative predictors of outcome. With regards to the external validity of the results from the logistic regression models these should only be related to patients with preoperative scores above or equal to the MCIDs for DASH (15) and VAS (3). When using DASH as outcome 13 patients were excluded due to too low preoperative DASH. When using VAS at rest and VAS at activity as outcome 82 and 2 patients respectively were excluded due to too low preoperative VAS. No patients had preoperative DASH< 15 and VAS at activity< 3. These excluded patients were only used when calculating pre- and postoperative mean scores. The tests of differences between pre- and postoperative mean scores was made using Wilcoxon signed rank test. A significance level of 0.05 was used in all models. All statistical analyses were made using STATA, version 15 IC (Stata Corp, College Station, TX, USA).

Results

Overall, we found a statistically significant improvement in DASH, VAS and grip strength 12 months after the operation, when the patients were analysed as a group. The mean grip strength was 21.6 kg (SD 12.2) preoperatively and 27.6 kg (SD 12.0) postoperatively, with a mean improvement in grip strength of 6.0 kg (SD 9.0) ($p < 0.001$). The mean DASH score was 42.0 (SD 18.6) preoperatively and 15.9 (SD 17.5) postoperatively, with a mean improvement in DASH score of 26.1 (SD 18.50) ($p < 0.001$). The mean VAS at rest was 3.5 (SD 2.4) preoperatively and 0.6 (SD 1.4) postoperatively, with a mean improvement in VAS at rest of 2.9 (SD 2.5) ($p < 0.001$). The mean VAS at activity was 7.9 (SD 1.8) preoperatively and 2.5 (SD 2.8) postoperatively, with a mean improvement in VAS at activity of 5.4 (SD 3.1) ($p < 0.001$), (Fig. 1).

The percentage of successful joint arthroplasties based on the MCIDs are shown in (Fig. 2).

The predictive variables were not the same among the different outcome variables.

VAS as outcome variable

Using VAS at activity as outcome, higher preoperative DASH ($p = 0.001$) and higher preoperative grip strength ($p = 0.048$) decreased the probability of a clinically important improvement, (Table 2). McFadden's pseudo R^2 for this model was 0.10. We found that approximately 50% of patients with preoperative VAS at activity from 3 to 6 ($n = 41$) did not reach a clinically important improvement using VAS at activity as outcome measure.

Using VAS at rest as outcome, male gender ($p = 0.025$) increased the probability of a clinically important improvement, (Table 2). McFadden's pseudo R^2 for this model was 0.06.

Grip strength as outcome variable

Using grip strength as outcome, none of the explanatory variables had a significant effect, (Table 2). McFadden's pseudo R^2 for this model was 0.04.

DASH as outcome variable

Using DASH as outcome, none of the explanatory variables had a significant effect, (Table 2). We found that approximately 50% of patients with a preoperative DASH score between 15 and 24 did not reach a clinically important improvement. McFadden's pseudo R^2 for this model was 0.05 indicating that the model explains little of the variation in outcome. We carried out this analysis with an improvement in DASH score > 11 defining positive outcome as found to be the Danish validated MCID [18] and found no difference.

VAS and DASH as combined outcome variables

Using the VAS rest + DASH variable as outcome, higher preoperative grip strength ($p = 0.022$) decreased the probability of a clinically important improvement, (Table 2). McFadden's pseudo R^2 for this model was 0.03.

Using the VAS activity + DASH variable as outcome, higher preoperative grip strength ($p = 004$) decreased the probability of a clinically important improvement, (Table 2). McFadden's pseudo R^2 for this model was 0.06 indicating that the model explains little of the variation in outcome. Furthermore, we found a correlation of (r = 0.3365) between preoperative measures of pain at activity and rest indicating that the patients did not interpret both questions alike.

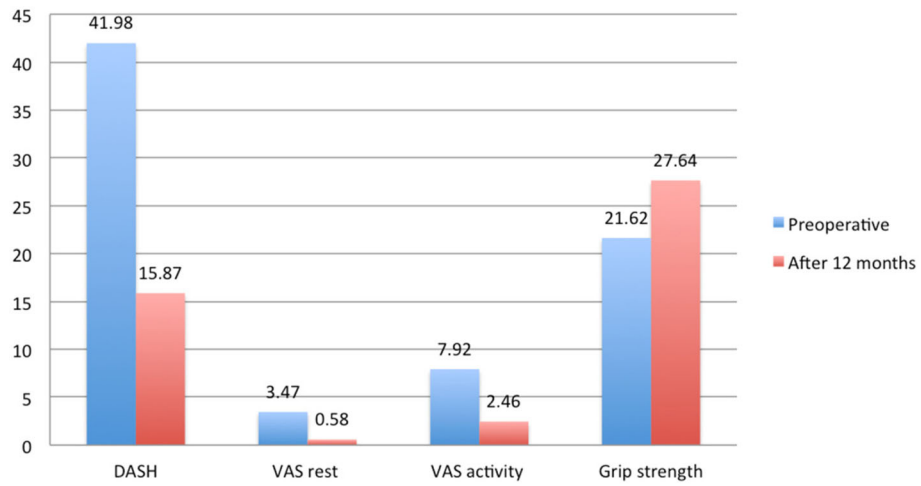

Fig. 1 Preoperative and 12 months postoperative measurements. Legend: Showing mean scores for DASH, VAS at rest, VAS at activity and grip strength before - and 12 months after total joint replacement of the trapeziometacarpal joint. There were significant improvements in all four measures ($p < 0.001$)

Using multiple linear regression models, we examined the same covariates using absolute change values as dependent variables (Table 3). With these models we were still unable to identify find predictors for improvement in grip strength. Using VAS at activity DASH remained a predictor, whereas grip strength became insignificant and male gender were related to higher improvement ($p = 0.022$). Using VAS at rest men remained likely to improve more than women. Furthermore, both patients with higher preoperative DASH ($p = 0.020$) and higher VAS at activity ($p = 0.004$) were related to higher postoperative improvement. A higher preoperative grip strength was related to less postoperative improvement ($p = 0.009$). Higher preoperative grip strength was also related to less postoperative improvement using DASH score as outcome ($p = 0.009$).

Discussion

We found a general improvement in both VAS at rest, VAS at activity, DASH and grip strength after operation for osteoarthritis in the TMC joint with a total joint replacement. When using the defined MCIDs in improvement as outcome we found that 25–46% of patients did not improve (Fig. 2) and that the predictive effect of baseline measurements varied. It was not possible to identify one specific preoperative measure that had a significant effect on all outcome measures.

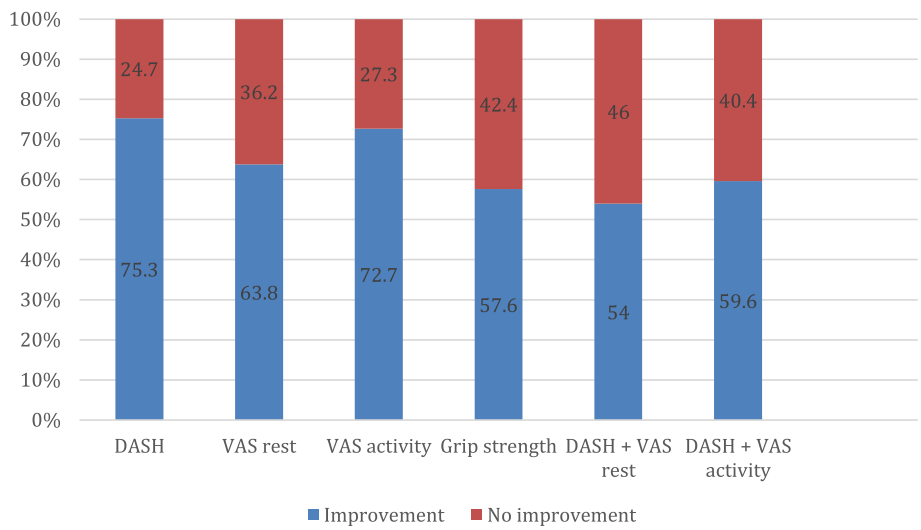

Fig. 2 Percentage of patients improving 12 months postoperatively. Legend: Percentage of improvement and no improvement defined by different outcome variables (DASH, VAS at rest, VAS at activity, grip strength, DASH + VAS at activity and DASH + VAS at rest)

In this study, we only used patients treated with TJA, because this type of treatment is the standard in our clinic in this type of patients. This choice of treatment is controversial due to high failure rates, but the failure rate during the first 12 months is very low (2.5%) and may not have biased the outcome evaluation. Furthermore, the rapid restoration of movement and grip strength after total joint TJA leads to overall improvements that make a good base for analysis in this outcome study. We did not test for difference in outcome between the different prosthesis since we believe that the short-term effect within 12 months does not vary between different implants but first occurs later due to different designs of the implants resulting in different failure rates over time. We did however adjust for prosthesis type in the logistic- and linear regression models to be sure that prosthesis type did not introduce bias.

Unfortunately, similar studies of the effect of operation due to carpometacarpal osteoarthritis have to our knowledge not been made. However, the effect of surgery on other hand conditions have been studied, especially the effect of Carpal Tunnel Release (CTR) and surgical treatment of Distal Radius fractures (DRF). Female gender has a tendency to increase the risk of no clinically important improvement in CTR [22] and surgical treatment of Distal Radius fractures [23]. Also, females are more likely to develop Chronic Pain Syndrome (CRPS) following surgical treatment of DRF [24, 25], with an estimated odds ratio of 3 to 4 [26]. However, other studies did not find predictive effect of gender after CTR [27] or on recurrence after Open Ganglion Excision [28]. Slutsky et al. proposed that these differences in the effect of gender on outcome might be due to differences in expectations, functional demands and pain tolerance between genders [29]. In our study we found an increased risk of nonclinical important improvement in pain at rest measured by VAS (Table 2). As our gender ratio is close to 1:4 this might affect the findings from this analysis.

We also found that older age at the time of operation negatively influenced postoperative VAS at rest and grip strength using multiple logistic regressions. In CTR the effect of age seems unclear as the results differ in different studies [22, 25, 27, 30, 31]. No effect of age has been found in studies on surgical treatment for DRF [23], surgical treatment for Dupuytren's Contracture [32], and open dorsal wrist ganglion excision [28] which makes it hard to determine whether or not age at the time of operation has an effect on hand surgical outcome.

Considerations and limitations

We used DASH, VAS at rest, VAS at activity and grip strength as outcome measures of successful TJA, but it may lead to some considerations and limitations.

DASH score

The DASH outcome measure questionnaire includes questions about both arm, hand and shoulder disabilities. In this study, we examined the effect of TMC total joint replacement but other injuries and disabilities in the patient's arm and shoulder can potentially influence the DASH improvement and lead to loss of validity. Additionally, some patients avoid answering certain personal questions from the DASH questionnaire, especially regarding sexual activities leading to missing responses with lack of basis for a total score and subsequently exclusion of 93 patients in the logistic regression analysis. We did not investigate the dominant hand involvements effect on the outcome.

Some questions evaluate tasks that are done with the dominant hand and not necessarily the injured hand making them difficult to answer and can potentially lead to bias. In our data 46% of patients had surgery on the left hand, which probably indicate that both dominant and non-dominant hands were treated. This might affect the validity of the DASH scores. However, the DASH questionnaire is not specifically targeting the operated hand, so the influence of hand domination may not be important.

Other measures of daily function might be more suitable than DASH. The Australian Canadian Osteoarthritis Hand Index (AUSCAN) is a hand specific osteoarthritis function score that do not relate to neither elbow nor shoulder [33] potentially eliminating bias due to comorbidities in elbow or shoulder. Additionally, the AUSCAN has a high reliability, is easily accessible and recommended for research use [33].

VAS pain

To determine if patients improved in pain at rest and activity after the operation we used a VAS scale. When asking about pain at rest and activity we did not define a certain context. Thus, some patients might think of pain at rest as pain after finishing hand-demanding tasks while others might think of it as pain such as disturbing night sleep. The same potential problem of individual interpretation might affect pain at activity since the specific context is not explained. Due to the low correlation between pain at activity and pain at rest, we believe that patients were able to differentiate between pain at rest and pain at activity.

Grip strength

There are several factors related to grip strength including both age and gender which we also found in the multiple logistic regression analysis. When considering age as predictor of outcome other factors than osteoarthritis in the TMC joint that can affect grip strength in older people. Patients could have other comorbidities we do not know about that could affect and minimize

improvement in grip strength leading to lower validity. Furthermore, patients were measured using grip strength that examines the grip strength of the entire hand. As this study focuses on TMC arthritis pinch strength might have been more sensitive to changes in grip strength before- and after surgery.

Combined DASH and VAS pain

We combined different outcome measures (DASH, VAS activity and VAS rest) to examine potential predictive preoperative factors in relation to treatment with TMC TJA but did not find a combination with higher predictive value than the single outcome models.

We found a high mean preoperative VAS at activity of 7.9 and a low mean preoperative VAS at rest of 3.5. Using a VAS MCID of 3 points we excluded multiple patients due to "too good" VAS at rest scores making it a difficult outcome measure. Due to the high pain score at activity we believe that VAS at activity should be used as outcome measure. Another important measure is hand function, which we measured using DASH. As previously described there are several limitations using DASH in relation to a hand specific surgery. It would probably have been better to use both pain at activity and a hand specific function score such as AUSCAN to evaluate the outcome following total joint replacement of the TMC joint.

Using our cut-off points for the combined DASH + VAS activity outcome we found that 40% did not reach a clinically important improvement. This could be explained by the surgery not being sufficiently effective, our cut-off points, or because some patients just had "too good scores" before surgery. Further, patients are often reporting either only high DASH score or high VAS score making improvement above the MCIDs for both DASH and VAS hard to reach.

In patients with a preoperative VAS at activity ranging from 3 to 6 ($n = 41$) we found that approximately 50% did not achieve a clinically important improvement using VAS at activity as outcome. Though only 41 patients had such low preoperative VAS at activity scores, it could indicate that some of the patients had "too good" VAS prior to surgery to achieve a clinically important improvement in VAS at activity.

Using different measures of outcome, we found low McFadden's pseudo R^2s indicating that other variables outside our models might increase the explanatory effect.

Other potential predictors

Inclusion of other covariates as: work related factors, bone mineral quality, education and income would be of great interest. Other studies have found predictive effect of other preoperative measures such as education, income, smoking and alcohol use. In CTS patients low income [22], high alcohol consumption [31, 34] and smoking [34, 35] has been found to have a negative effect on surgical outcome. In DRF patients both low income [23, 24] and short education [24, 36] has been found to have a negative effect on surgical outcome. If we had asked about these prior to surgery we might have been able to explain more of the variability in outcome. Also, we did not ask about patient satisfaction, which would be an interesting outcome measure in order to examine the relationship between patient satisfactions, change in VAS, DASH and grip strength and preoperative measurements. We do not have data on patient's analgesics use or patient expectation. It would be of great interest to include these as covariates in a future study.

The same study may have been performed in patients treated with trapeziectomy, but as this is not our preferred method, the number of trapeziectomies during the study period was very low, and the patients were not included in the study to avoid bias and confounding by indication.

Conclusion

We were unable to detect one isolated preoperative predictor as indicator of successful result after operative treatment of TMC osteoarthritis, and as so it was not possible to establish a clinical valid tool for patient selection before surgery. Given that higher preoperative grip strength tends towards being a predictive factor in both the logistic- and linear regression models, patients with high preoperative grip strength might tend to improve less in both self-reported DASH and pain at rest and activity although not statistically significant in all models. When isolating a single outcome of interest this study shows that higher preoperative DASH and higher preoperative grip strength could be risk factors for nonclinical important improvement in pain at activity and combined DASH and pain respectively.

The surgeon should however be aware that patients with a preoperative high grip strength and females have an increased risk of having no clinical effect of the operation. Additional studies based on outcome of operative treatment of TMC joint osteoarthritis and patient satisfaction may provide greater explanatory power on potential preoperative predictors of outcome and help define a combined outcome of this surgical treatment.

Abbreviations

AUSCAN: The Australian Canadian Osteoarthritis Hand Index; CTR: Carpal tunnel release; CRPS: Chronic pain syndrome; DASH: Disabilities of arm, shoulder and hand; DRF: Distal radius fracture; MCID: Minimal clinical important difference; TJA: Total joint arthroplasty; TMC: Trapeziometacarpal; VAS: Visual analogue scale

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Authors' contributions

TBH designed the study; SBM performed the analysis and interpretation of data; SBM, TBH and MS wrote the paper; SBM, TBH and MS read and approved the final manuscript;

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
The procedures followed in this study were in accordance with the Helsinki Declaration of 1975, as revised in 2000. The study was generally approved by the local research ethics committee, and no further specific approval was demanded because the study is an outcome study, which according to the Danish law "Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and authorization": Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material. The study was registered in The Danish data Protection Agency and ClinicalTrials.gov Identifier: (NCT01554748).

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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Study II

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Higher preoperative pain catastrophizing increases the risk of low patient reported satisfaction after carpal tunnel release: a prospective study

Sebastian Breddam Mosegaard[1,2*], Maiken Stilling[1,2] and Torben Bæk Hansen[1,2]

Abstract

Background: Carpal tunnel syndrome is a common upper-limb nerve compression disease. Carpal tunnel syndrome can lead to several symptoms such as tingling or numbness, pain in the hand or wrist, and reduced grip strength. Based on demographic characteristics, patient reported outcome measures, and with special attention to pain catastrophizing, the purpose of this study was to identify risk factors for low patient-reported satisfaction following surgical treatment of idiopathic carpal tunnel syndrome.

Methods: A total of 417 hands from 417 patients (64. 5% females) with a mean age of 58. 0 years were included in this 1-year prospective follow-up study. We collected preoperative data on disability using the Disability of the Arm, Shoulder and Hand questionnaire (DASH), quality of life using the EuroQol-5D (EQ-5D), pain catastrophizing using the Pain Catastrophizing Scale (PCS) and distal motor latency. Data on DASH score, EQ-5D, and patient satisfaction was collected 12 months postoperatively. Wilcoxon matched-pairs signed-rank test was used to test for difference in preoperative and postoperative DASH and EQ-5D score. Risk factors for low postoperative patient reported satisfaction was examined using stepwise multiple logistic regression analysis.

Results: We found a general improvement in patients' DASH scores (12.29 [95% CI: 10.65–13.90], $p < 0.001$) and EQ-5D (0.14 [95% CI: 0.13–0.16], $p < 0.001$) from preoperative to 12 months postoperative. In the fully adjusted multiple regression analysis we found a statistically significant effect of preoperative PCS on patient reported satisfaction with OR = 1.05 ($p = 0.022$), for a one unit increase in preoperative PCS. There was no statistically significant predictive effect of preoperative EQ-5D ($p = 0.869$), DASH ($p = 0.076$), distal motor latency ($p = 0.067$), age ($p = 0.505$) or gender ($p = 0.222$).

Conclusions: Patients improved in both DASH and EQ-5D from preoperative to 12 months postoperative. Higher preoperative PCS seems to have a negative effect on postoperative patient reported satisfaction after carpal tunnel release.

Keywords: Carpal tunnel syndrome, Pain catastrophizing scale, Patient satisfaction, Risk factors

* Correspondence: sebmos@rm.dk
[1]Department of Orthopaedics, University Clinic for Hand, Hip and Knee Surgery, Lægårdvej 12, 7500 Holstebro, Denmark
[2]Department of Clinical Medicine, Aarhus University, 8000 Aarhus, Denmark

Background

Idiopathic carpal tunnel syndrome (CTS) is a common upper limb nerve compression disease [1]. CTS can lead to several symptoms such as tingling or numbness, pain, and reduced grip strength [2]. It appears mainly in middle-aged women [1, 3, 4], with an approximated gender ratio of 3:1 [5]. The European prevalence is estimated to be 1–7% [5, 6], with an incidence of 1.8 per 1000 years [5], leading to roughly 300,000 operations per year in Germany [7]. Emphasizing the incidence of CTS, it is estimated that close to 1 million people annually need medical treatment of CTS in America [3]. Surgical decompression with either endoscopic carpal tunnel release (ECTR) or open carpal tunnel release (OCTR) is used to improve function and relieve symptoms [8] when conservative treatment (steroid injections and orthoses) of the hand is inadequate [9]. Although the outcome following carpal tunnel release (CTR) is mainly positive, symptoms remain or reoccur in 3–20% of cases [10, 11]. Several factors have been suggested to be predictive of negative surgical outcomes; smoking, bilateral CTS, low preoperative symptom severity, diabetes, older age, poor physical health, and poor mental health [12–14].

The use of patient reported outcome measures (PROMs) to evaluate the surgical outcome has increased. Furthermore, the overall patient satisfaction has been shown to predict the sick leave duration following CTR [15]. In a systematic review from 2017, 3 of 5 studies showed a significant correlation between patient satisfaction and psychological measures of depression and mental health in CTS patients [16]. Studies further show that self-reported depression is correlated to poorer self-evaluated hand function in patients suffering from trapeziometacarpal arthritis [17]. In CTS patients, preoperative hospital anxiety is associated with worse preoperative symptom severity [18]. Additionally, a worse score on the 5-item Mental Health interview has been associated to lower postoperative patient satisfaction [13]. These studies indicate the effect of psychological factors on different outcome measures including satisfaction. However, little attention has been drawn to the effect of pain catastrophizing (measured using the Pain Catastrophizing Scale (PCS)) on patient satisfaction following CTR. A study from 2010 on 120 patients with different hand diseases (carpal tunnel syndrome, trigger finger, and benign tumors) did not find a correlation between preoperative PCS and postoperative DASH scores [19]. Conversely, a newer study from 2014 on 256 patients with atraumatic hand disorders found an association between PCS and the Michigan Hand Outcome Questionnaire (MHOQ). The study showed worse scores on the MHOQ for patients with high PCS (PCS > 30) compared to patients with low PCS (PCS ≤ 30) at baseline, and at 1- and 2-month follow-ups [20].

To our knowledge, only one study has briefly examined the effect of PCS on patient satisfaction in CTS patients [21]. This retrospective study on 82 patients did not find an association between PCS and patient satisfaction in a univariate analysis and did not examine it further. Given the results from other studies indicating an effect of mental health and PCS on the outcome after treatment of hand disorders, this study aimed to further investigate the effect of PCS.

Based on demographic characteristics, PROMs, and with special attention to PCS, the purpose of this study was to identify risk factors for low patient-reported satisfaction following surgical treatment of idiopathic CTS with CTR. The main hypothesis of this study was that higher preoperative PCS scores increase the risk of low postoperative patient reported satisfaction.

Methods

Patients with nerve conduction verified Carpal Tunnel Syndrome (CTS) were recruited between February 11th 2011 and January 5th 2015 at the Department of Orthopaedics, Regional Hospital Holstebro. This prospective cohort consists of 732 hands from 714 patients treated surgically for CTS with either open carpal tunnel release (OCTR - 38%) or endoscopic carpal tunnel release (ECTR - 62%). Patients were asked to fill out a set of questionnaires preoperatively and 12 months postoperatively. The preoperative questionnaires included; a health-related quality of life assessment using EQ-5D, hand function using a translated and validated version of the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) [22, 23], and catastrophic thinking of pain using the Pain Catastrophizing Scale (PCS). The DASH questionnaire is a 30-item questionnaire used to measure patient reported disability through 30 statements on a 5-point Likert scale, where a higher score reflects more disability [24]. PCS is used to measure coping skills and negative feelings of pain through 13 statements with 4 possible options from 1 “not at all” to 4 “all the time” with a higher score reflecting higher catastrophic thinking [25]. The score can further be categorized as either high (PCS > 30) or low (PCS ≤ 30) [26]. Distal motor latency was registered following preoperative nerve conduction tests.

The 12-month postoperative questionnaire included the EQ-5D, DASH, and a question on patient satisfaction with 4 options ranging from 1 “I am dissatisfied” to 4 “I am very satisfied”. We then pooled options 1 and 2 as low satisfaction and options 3 and 4 as high satisfaction.

Patient demographics

All patients with nerve conduction verified CTS were assessed for eligibility (714). The second operated hand was excluded from 18 bilateral patients to avoid

statistical dependence, and 92 hands were excluded due to missing preoperative data on DASH, EQ-5D, and PCS. A further 205 hands were excluded due to missing 12-month postoperative data on DASH and EQ-5D, leaving 417 patients (64. 5% women) with a mean age of 58 years (range, 18–92 yrs.) for analysis. The exclusion of patients did not lead to statistically significant changes in preoperative baseline characteristics. Further patient characteristics before and after exclusion can be seen in Table 1.

The study was reviewed by the local research ethics committee, and no further specific approval was demanded because the study is an outcome study, which according to the Danish law,"Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and Authorization: Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material." The study was registered in The Danish Data Protection Agency: jr. nr.: 2007-58-0010.

Statistics

Wilcoxon matched-pairs signed-rank test was used to test for difference in preoperative and postoperative DASH and EQ-5D scores due to non-normality. Logistic regression analysis and multiple logistic regression analysis were used to test predictors of low patient reported satisfaction following surgical treatment of CTS in Tables 2 and 3. This was done in four steps. Step 1 was crude logistic regressions of the associations between the variables of interest one by one and the dichotomous outcome high/low satisfaction. Step 2 was to adjust for preoperative baseline characteristics; age, gender, and operation technique. Step 3 was to adjust for age, gender, operation technique, and further adjust for the other predictors of interest; PCS, EQ-5D, DASH, and distal motor latency. The 4th and final step was to examine multicollinearity in the models. We examined multicollinearity in the multivariate logistic regression models using variance inflation factors (VIF), finding no VIF > 2.02. All statistical analyses were made using STATA, Version 15 IC (Stata Corp, College Station, TX, USA).

Results

When analyzing the patients as one group, we found a statistically significant improvement in both DASH and EQ-5D at the 12-month follow-up. The mean improvement in EQ-5D was 0.14 [95% CI: 0.13–0.16] ($p < 0.001$), which was a change from 0.74 [95% CI: 0.72–0.76] preoperatively to 0.89 [95% CI: 0.87–0.91] 12 months postoperatively, which is more than the estimated minimal clinical important difference (MCID) of 0.10 [27]. DASH scores improved by 12.29 [95% CI:10.65–13.90] ($p < 0.001$), which was a change from 24.88 [95% CI:22.87–26.89] preoperatively to 12.60 [95% CI,10.73–14.47] 12 months postoperatively, which is more than the MCID of 12 points for the Danish validated DASH [28].

The patients reporting low satisfaction at 12 months had a higher preoperative PCS score, lower EQ-5D, and higher DASH score. Further, the patients reporting low satisfaction had a tendency toward lower preoperative distal motor latency but with overlapping confidence intervals for the mean. There was no statistical difference in age and gender between patients reporting low satisfaction and patients reporting high satisfaction. Means and confidence intervals can be seen in Table 2.

Table 3 shows the logistic regression models of the association between the possible predictive preoperative variables. After including both demographics (age, gender, operation technique, and living alone) and preoperative disability (PCS, EQ-5D, DASH, and distal motor latency) in the model, we found a statistically significant effect of preoperative PCS on patient reported satisfaction with OR = 1.05 ($p = 0.022$) for a 1-unit increase in preoperative PCS.

We did not find a statistically significant effect of EQ-5D ($p = 0.869$), DASH ($p = 0.076$), distal motor latency ($p = 0.067$), age ($p = 0.505$), or gender ($p = 0.222$).

Table 1 Preoperative baseline characteristics with 95% confidence intervals before and after exclusion

	Baseline before exclusion ($N = 732$)		Baseline after exclusion ($N = 417$)	
	Mean	95% CI	Mean	95% CI
Female %	63. 9%	.	64. 5%	.
Age, years	58. 0	56. 9–59. 1	58. 0	56. 5–59. 4
Female age, years	57. 2	55. 8–58. 6	56. 7	54. 9–58. 5
Male age, years	59. 5	57. 5–61. 4	60. 4	58. 0–62. 8
DASH	26. 1	24. 2–27. 9	25. 4	23. 5–27. 4
EQ-5d	0. 74	0. 72–0. 76	0. 74	0. 72–0. 76
PCS	13. 3	12. 3–14. 3	13. 0	11. 9–14. 1
Distal motor latency, m/s	5. 7	5. 6–5. 9	5. 7	5. 5–5. 9

Preoperative data on patients before and after exclusion both preoperative and 12-months postoperative

Table 2 Preoperative baseline characteristics for highly satisfied and lowly satisfied patients

	High satisfaction		Low satisfaction	
	Mean	95% CI	Mean	95% CI
Female, %	66. 0%	.	60. 1%	.
Age, years	55. 8	53. 8–57. 7	56. 2	51. 6–60. 9
DASH	22. 7	20. 4–24. 9	38. 0	31. 6–44. 4
Eq-5d	0. 76	0. 74–0. 78	0. 66	0. 59–0. 74
PCS	11. 2	10. 0–12. 4	19. 6	16. 0–23. 3
Distal motor latency, m/s	5. 70	5. 46–5. 93	5. 13	4. 72–5. 56

Preoperative baseline characteristics with mean and 95% confidence intervals for patients reporting high satisfaction and patients reporting low satisfaction 12 months postoperative

Although the *p*-value related to the preoperative DASH score exceeded the 0.05 significance level, the 95% confidence interval for the odds ratio ranging from [1.00–1.05] indicates that there could be a tendency toward an increased risk of low patient reported satisfaction with an increased preoperative DASH score.

Table 4 shows an analysis of the risk of low satisfaction for patients with preoperative PCS > 30 compared to patients with PCS ≤ 30. Unadjusted and adjusted for demographics, we found an OR of 2.24 and 2.56 respectively for low satisfaction for patients with preoperative PCS > 30 ($p = 0.005$ & $p = 0.003$ respectively). However, when further adjusting for preoperative DASH, EQ-5D, and distal motor latency, the OR dropped to 1.85 [95% CI: 0.78–4.39], and was no longer significant.

Finally, Fig. 1 shows a scatter plot of the preoperative PCS and the preoperative DASH and EQ-5D scores. Correlation analysis using Spearman's rho shows a correlation of rho = 0.6135 ($p < 0.001$) and rho = – 0.4950 ($p < 0.001$) for PCS and DASH, and PCS and EQ-5D respectively. This indicate that the patients with high preoperative PCS tend to score worse on both preoperative DASH and EQ-5D.

Since DASH and EQ-5D were collected both at baseline and 12 months postoperatively, we analyzed the effect of improvement in DASH and EQ-5D on the patient reported satisfaction after CTR. In the fully adjusted models, we found an OR for low patient reported satisfaction of 0.93 for a 1-unit increased improvement in DASH ($p < 0.001$) and an OR of 0.54 for a 0.1-unit increased improvement in EQ-5D ($p < 0.001$). For both

Table 3 The association between baseline characteristics and patient reported satisfaction

Preoperative	Odds ratio for low patient reported satisfaction following CTR		
	Odds ratio	95% CI	*p*
PCS			
Unadjusted[a]	1. 08	1. 05–1. 11	< 0. 001*
+ Demographics[b]	1. 09	1. 06–1. 12	< 0. 001*
+ Disability[c]	1. 05	1. 01–1. 10	0. 022*
EQ-5D			
Unadjusted[a]	0. 13	0. 03–0. 51	0. 004*
+ Demographics[b]	0. 10	0. 02–0. 46	0. 003*
+ Disability[c]	0. 82	0. 09–7. 82	0. 869
DASH			
Unadjusted[a]	1. 04	1. 02–1. 05	< 0. 001*
+ Demographics[b]	1. 04	1. 02–1. 06	< 0. 001*
+ Disability[c]	1. 02	1. 00–1. 05	0. 056
Distal motor latency			
Unadjusted[a]	0. 83	0. 68–1. 01	0. 063
+ Demographics[b]	0. 78	0. 63–0. 98	0. 030*
+ Disability[c]	0. 75	0. 55–1. 02	0. 067
Living alone			
Unadjusted [a]	0. 70	0. 35–1. 41	0. 320
+ Demographics [b]	0. 69	0. 33–1. 44	0. 321
+ Disability [c]	0. 36	0. 11–1. 81	0. 092

Multiple logistic regression analysis on the association between baseline characteristics and patient reported satisfaction 12 months postoperative
*Denotes statistical significance
[a]Unadjusted crude association on odds ratio for low patient reported satisfaction
[b]Adjusted for age, gender, living alone and operation technique
[c]Adjusted for age, gender, operation technique, living alone and preoperative scores (PCS, EQ-5D, DASH and distal motor latency)

Table 4 The risk of low patient reported satisfaction for patients with preoperative PCS > 30

Preoperative	Odds ratio for low patient reported satisfaction following CTR		
	Odds ratio	95% CI	*p*
PCS > 30			
Unadjusted [a]	2. 24	1. 27–3. 96	0. 005*
+ Demographics[b]	2. 56	1. 38–4. 74	0. 003*
+ Disability [c]	1. 85	0. 78–4. 39	0. 165

Multiple logistic regression analysis on the risk of low patient reported satisfaction 12 months postoperative for patients with preoperative PCS > 30 compared to patients with PCS ≤ 30
*Denotes statistical significance
[a]Unadjusted crude association on odds ratio for low patient reported satisfaction
[b]Adjusted for age, gender, living alone and operation technique
[c]Adjusted for age, gender, operation technique, living alone and preoperative variables (DASH, EQ-5D and Distal motor latency)

DASH and EQ-5D, it shows that the risk of low patient reported satisfaction is reduced with increased improvement.

Discussion

We found a significant improvement above the MCIDs in patient disability measured by DASH, and in quality of life measured by EQ-5D, from baseline to the 12-month follow-up after CTR. A total of 84.2% of the patients felt either satisfied or very satisfied 12 months after the operation. Higher preoperative PCS had a statistically significant negative influence on patient reported satisfaction. Furthermore, we found a trend towards a negative predictive effect of low preoperative distal motor latency and a high preoperative DASH score. There was no predictive effect of age, gender, or preoperative EQ-5D, on postoperative patient satisfaction.

In secondary analyses, we found that lower improvements in both postoperative DASH and EQ-5D increased the risk of low patient reported satisfaction, Table 5.

Age and gender

Although we did not find age and gender to be a predictor of patient satisfaction, previous studies have shown diverse findings. In 1998, Atroshi et al. found higher age to be a risk factor for low patient reported satisfaction 6 months after OCTR in a study on 128 Swedish patients (mean age 51 years, range 21–94) [29]. On the contrary, a Taiwanese study including 58 patients (mean age 50.6 years, SD = 10.54) did not find a predictive effect of age on postoperative patient

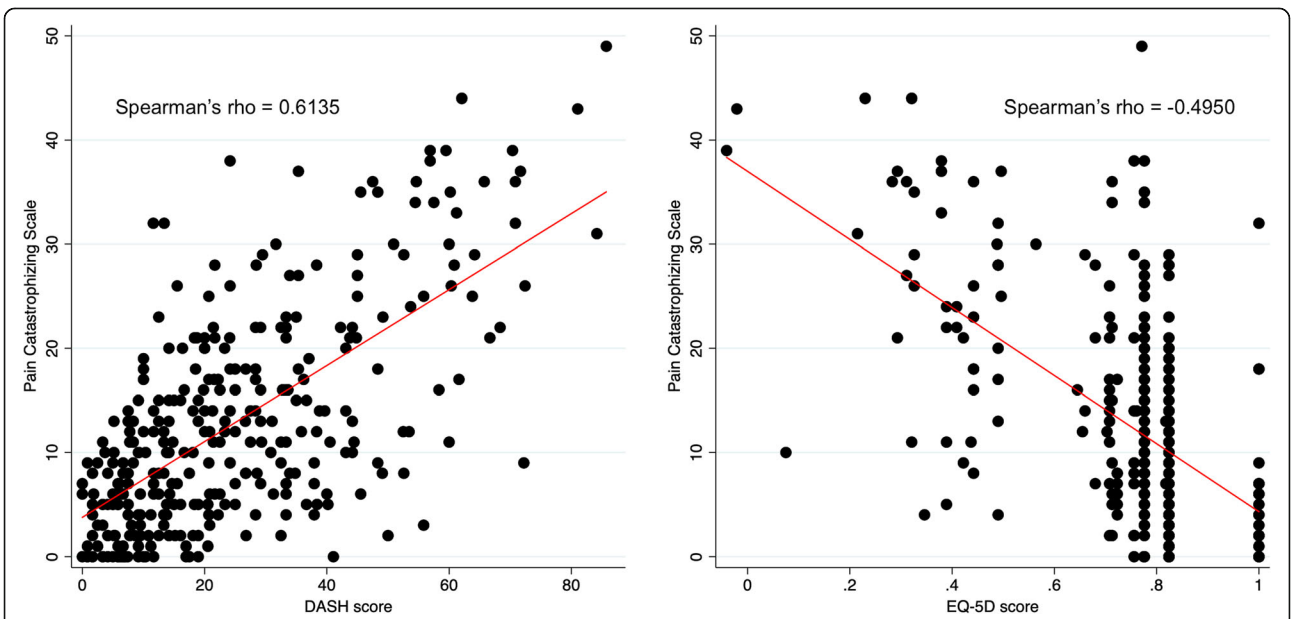

Fig. 1 Preoperative PCS against DASH and EQ-5D. Left side: Scatterplot of preoperative PSC and DASH score showing a positive correlation between PCS and DASH score with Spearman's rho = 0. 6135. The red line illustrates a linear line of best fit. Right side: Scatterplot of preoperative PSC and EQ-5D score showing a negative correlation between PCS and EQ-5D score with Spearman's rho = − 0. 4950. The red line illustrates a linear line of best fit

Table 5 The association of change in DASH and EQ-5D and low patient reported satisfaction

Change	Odds ratio for low patient reported satisfaction following CTR		
	Odds ratio	95% CI	*p*
DASH [d]			
Unadjusted	0. 93	0. 90–0. 96	< 0. 001*
+ Demographics [a]	0. 93	0. 91–0. 96	< 0. 001*
+ Disability [b]	0. 92	0. 89–0. 95	< 0. 001*
EQ 5D [e]			
Unadjusted	0. 54	0. 43–0. 67	< 0. 001*
+ Demographics [a]	0. 54	0. 43–0. 68	< 0. 001*
+ Disability [c]	0. 53	0. 40–0. 69	< 0. 001*

Multiple logistic regression analysis on the association of change in DASH and EQ-5D and low patient reported satisfaction 12 months postoperative
*Denotes statistical significance
[a]Unadjusted crude association on odds ratio for low patient reported satisfaction
[b]Adjusted for age, gender, living alone and operation technique
[c]Adjusted for age, gender, operation technique, living alone and preoperative variables (PCS, EQ-5D and distal motor latency)
[d]The effect of a 1- unit increase in DASH improvement
[e]The effect of a 0. 1- unit increase in Eq-5d improvement

satisfaction [30]. The effect of age has also been examined with other outcomes such as return to work, disability, and symptom relief, with mixed findings showing no effect of age on return to work [31], QuickDASH improvement [12], or disability [32]. But higher age has been found to have a negative effect on symptom relief 6 months after CTR [33].

As with age, we did not find a similar effect of gender on patient satisfaction as Atroshi et al. [29]. However, a Danish prospective cohort study on 101 patients did find males to be less satisfied than females 2 months after ECTR [34]. Additionally, gender had no effect in studies of return to work [31], QuickDASH improvement [12], disability [32], or symptom relief [33]. With the mixed results from this study and previous studies in mind, the effects of both age and gender still seem unclear.

Distal motor latency

We found that lower preoperative distal motor latency might increase the risk of low patient reported satisfaction 12 months after CTR. The same has been shown in a study measuring patient satisfaction 6 months after CTR [29], indicating that preoperative distal motor latency could be a valuable tool in predicting postoperative patient satisfaction. This may also reflect that patients with low distal motor latency have less to gain after an operation compared to patients with more severe nerve compression. Conversely, a Danish study on 75 patients found that higher distal motor latency, indicating more severe median nerve compression, led to longer sick leave from work following CTR [35].

PCS

In this study, preoperative PCS was found to have a predictive effect on the 12-month postoperative patient satisfaction, with a higher (worse) PCS increasing the risk of low postoperative patient satisfaction. Dissimilar to our results, a retrospective study from 2008 with comparable age and gender distribution on 82 (53 women / 29 men) American patients (mean age 61 years, range 34–92), did not find a correlation between PCS and patient satisfaction after a minimum of 2 years [21]. Additionally, another American study on 120 patients (69 women / 51 men) with a mean age of 61 years (range 18–86), showed no correlation between postoperative PCS and DASH, but a correlation between PCS and pain at the time of suture removal (10–14 days after surgery) in a cohort of patients treated for CTS ($n = 39$), trigger finger ($n = 65$) and benign tumors ($n = 16$) [19]. This difference in results may reflect the different study designs and number of patients.

The effects of other psychological measures have been examined in previous studies with various results. “The Hospital Anxiety and Depression Score” (HADS), is a reliable instrument used to detect and evaluate severity of depression and anxiety [36]. An English study from 2005 showed no difference in patient satisfaction and Boston Carpal Tunnel Questionnaire (BCTQ) between patients with high and low HADS 6 months after CTR surgery [18]. Mental health status measured by subscales from the SF-36 has shown that worse mental health status predicts lower postoperative patient satisfaction 18 months after CTR [13]. Similarly, a 13-study systematic review found that a worse mental health status leads to longer sick leave after CTR [37]. Additionally, a weak correlation between depression and patient satisfaction was shown in an 8-study systematic review [16], where 3 in 5 studies on patients treated with CTR established a significant negative association between patient

satisfaction and psychological factors measured using the Centers of the Epidemiological Study of Depression Instrument (CES-D), 5-item Mental Health Interview, and HADS.

The results from the present study indicate a predictive negative effect of higher preoperative PCS on patient reported satisfaction 12 months after CTR. If possible, clinicians should examine both the patient's physical- and mental health status and discuss these parameters with the patient before performing CTR. PCS might be a useful tool for doing so even though this study did not find a statistically significant increased risk when dividing patients in PCS groups using a score ≥ 30 as the cut-off value [26]. We believe that these results call for further studies on the predictive effects of PCS.

Considerations

We used the DASH score as a measure of patient disability. Since DASH targets both the arm, shoulder and hand, other injuries not related to CTS might affect the validity of DASH as an instrument to measure disability related to CTS. The use of a CTS related disability questionnaire e.g. the Boston Carpal Tunnel Questionnaire, might have increased the accuracy of the measurements.

Another consideration is the exclusion of 315 (43%) patients due to missing data. 43% is a large number of excluded patients, which potentially could lead to bias. We did however not see a change in baseline characteristics after exclusion of patients without a full dataset.

Several other factors, which were not investigated in this study, such as lower income [31], active smoking status [12, 38], and higher alcohol consumption [13, 38], have been shown to negatively affect the patients' outcome after CTR. Therefore, it would be of great interest to include these in statistical models on the predictive effect of PCS on patient satisfaction.

We used a 4-item Likert scale to examine patient satisfaction using one statement. An English study with 810 patients examined "The Friends and Family Test" (FFT), which is a variation of the "Net Promoter Score" (NPS) used to measure overall patient satisfaction. They found the FFT to be correlated to patient satisfaction, hospital experience, and functional outcome [39]. It would be interesting to examine the possible predictive effect of PCS on FFT. Given FFT's correlation to both satisfaction and function, a possible association between PCS and FFT would enable practitioners and surgeons to counsel the patient's potential outcome after CTR, not only based on satisfaction, but also as a surrogate marker of functional outcome.

Conclusion

CTR is an effective treatment for carpal tunnel syndrome with high patient satisfaction and improvement after 12 months in both DASH score and EQ-5D. Higher preoperative PCS seems to have a negative effect on postoperative patient reported satisfaction after CTR. Further studies on patient satisfaction should include additional information on patient smoking habits, alcohol consumption, BMI, diabetes, and income, to strengthen the explanatory power.

Abbreviations

BCTQ: Boston Carpal Tunnel Questionnaire; CES-D: Centers of the Epidemiological Study of Depression Instrument; CTR: Carpal tunnel release; CTS: Carpal tunnel syndrome; DASH: Disabilities of the Arm Shoulder and Hand questionnaire; ECTR: Endoscopic carpal tunnel release; FFT: The Friends and Family Test; HADS: Hospital anxiety and depression scale; MCID: Minimal clinical important difference; MHOQ: Michigan Hand Outcome Questionnaire; NPS: Net Promotor Score; OCTR: Open carpal tunnel release; VIF: Variance inflation factor

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None.

Authors' contributions

SBM: Data analysis, interpreting results, statistical analysis, drafting and editing manuscript. MS: Study design, data collection, interpreting results and editing manuscript. TBH: Study design, data collection, interpreting results and editing manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The patients were informed about the research study and data collection as they completed the questionnaires in relation to their booking for surgical treatment for carpal tunnel syndrome. At this time, they gave their verbal consent to the examiner. Prior to study initiation, the protocol was reviewed by the local research ethics committee, and no specific approval was demanded because the study is a quality assurance study, which according to the Danish law "Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and Authorization: Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material."

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Study III

Abstract

Introduction: Patient reported outcome measures are often used in medical research to evaluate symptoms and functional status in patients. The Boston Carpal Tunnel Questionnaire is specifically designed to evaluate functional status and symptom severity in patients with Carpal Tunnel Syndrome. The purpose of this study was to validate and examine the psychometric properties of the Functional Status Scale and Symptom Severity Scale from the Danish translated Boston Carpal Tunnel Questionnaire.

Methods: We analyzed 88 prospectively enrolled patients in the validity and responsiveness group and 31 prospectively enrolled patients in the reliability group. Patients in the validity and responsiveness group answered the Quick Disabilities of the Arm, Shoulder and Hand Questionnaire and the Danish translated Boston Carpal Tunnel Questionnaire preoperatively and after surgery. Patients in the responsiveness group answered the same questionnaire two times prior to surgery.

Results: Responsiveness of the two subscales were high (Effect Size 0.99/1.76; Standardized Response Mean 0.86/1.50). Correlation to the Danish validated QuickDASH was high (rho 0.75/0.89). Test-retest reliability was high (ICC 0.94/0.90) and the internal consistency was high (Cronbach's alpha 0.93/0.92).

Conclusion: Our study shows satisfactory results of both subscales of the Danish translated Boston Carpal Tunnel Questionnaire. This makes it highly useful when conducting research on patients with Carpal Tunnel Syndrome.

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Trial registration: The Danish Data Protection Agency: jr. nr. 2007-58-0010

Keywords: Validation, Boston Carpal Tunnel Questionnaire, Danish, Carpal Tunnel Syndrome

1. Introduction

Carpal tunnel syndrome (CTS) is a common neuropathy of the hand and wrist, with symptoms such as pain, numbness and tingling in the hand and/or wrist[1]. It is estimated that the European prevalence of CTS is 1% - 7%[2] and surgical decompression of the carpal tunnel is one of the most common hand surgical procedures. Due to the high incidence, several studies have examined predictors of the surgical outcome in CTS patients. To do so, it is crucial to use well-established measures to evaluate the function and symptom severity in CTS patients. The Boston Carpal Tunnel Questionnaire (BCTQ) is a CTS specific questionnaire used to asses function and symptoms[3]. The BCTQ is divided into two parts: The Symptom Severity Scale (SSS) and the Functional Status Scale (FSS), which examine the symptom severity and the level of disability, respectively. The BCTQ has been validated and evaluated in several languages, including Swedish[4], Portuguese[5], Spanish[6], Chinese[7], Greek[8], Turkish[9], and Polish[10]. A Danish validation of the BCTQ is not available. The purpose of this study was to examine the psychometric properties of the Danish version of the BCTQ including the SSS and FSS subscales. This was done through validity, responsiveness and reliability.

2. Materials and methods

The study was registered in The Danish Data Protection Agency: jr. nr. 2007-58-0010. No further registration or permissions were needed according to Danish Law.

The Danish translated BCTQ we used was translated at our institution more than 20 years ago[12]. For the validation of the psychometric properties of the Danish translated BCTQ, we used the checklist in the Consensus-Based Standards for the Selection of Health Status Measurement Instrument (COSMIN)[13, 14] as guideline and inspiration. The COSMIN checklist includes 4 items;

validity, responsiveness, reliability and interpretability[13, 14]. As the purpose of this study was to examine the measurement properties of the Danish translated BCTQ, we did not assess the interpretability but focused on validity, responsiveness and reliability.

Data was collected in two Danish hospitals. At one hospital data was collected to evaluate validity and responsiveness, and at the other hospital data was collected to evaluate reliability of the Danish translated BCTQ (DBCTQ). In both groups patients with nerve conduction studies verified idiopathic CTS were included. The patients from both hospitals were asked to complete an identical set of questionnaires including both the Quick Disabilities of the Arm, Shoulder and Hand Questionnaire (QDASH) and the Danish translated BCTQ.

2.1 Validity and responsiveness group

The patients in the validity and responsiveness group were recruited in the Department of Orthopaedics at Hospital of Southern Jutland, Sønderborg, Denmark, from March 2018 to December 2018. Patients in this group were asked to complete the questionnaire preoperatively and again 8 weeks postoperatively. The patients completed the questionnaire preoperative at the time when the decision to operate was made at the hospital, and 8 weeks postoperative where the questionnaire was sent home to the patients. We recruited 157 patients (61% females) with a mean age of 58 years (range: 22 – 89). After patient drop out due to insufficient questionnaire completion (missing preoperative SSS n=3, preoperative QDASH n=7, postoperative FSS n=52, postoperative SSS n=53, postoperative QDASH n=57) the analyzed cohort consisted of 88 patients (53% females) with a mean age of 60 years (range: 22 – 88). The patients were excluded if they had more than one missing item in the QDASH, or more than two missing items in either FSS or SSS.

The mean time from surgery to follow-up was 68 ± 16 days. Further patient characteristics are given in table 1.

Table 1: *Patient characteristics in the validity/responsiveness group and the reliability group*

Characteristics	Validity and responsiveness group (N=88)	Reliability group (N=31)
Age, mean ± SD (range)	60 ± 16 [57 – 63]	57 ± 16 [51 – 63]
Gender (Male / Female)	41 / 47	13 / 18
Dominant hand, %	55 %	68 %
Diabetes, %	10 %	10 %
DBCTQ: FSS, mean ± SD	2.6 ± 0.9	2.7 ± 0.9
DBCTQ: SSS, mean ± SD	3.0 ± 0.8	2.9 ± 0.8
QDASH, mean ± SD	43.1 ± 23.0	44.0 ± 22.3

Table 1: SSS = Symptom Severity Scale. FSS = Functional Status Scale. QDASH = Quick Disability of the Arm, Shoulder and Hand questionnaire.

2.2 Reliability group

The patients in the reliability group were recruited in the Department of Orthopaedics at Holstebro Regional Hospital, Holstebro, Denmark, from April 2019 to October 2019. Patients in this group were asked to complete the questionnaire two times prior to surgery. We recruited 31 patients (58% females) with a mean age of 57 years (range: 21 – 85). The patients were asked to complete the questionnaire at the first visit at the hospital, and they were asked to return a second BCTQ again after five days. The mean time between the two assessments was 5 ± 4 days. There was complete follow-up in this group. Further patient characteristics are given in table 1.

2.3 Questionnaires

The BCTQ is a questionnaire used to evaluate symptom severity and functional status in CTS patients, and is both responsive, reliable and valid[3]. It consists of two subscales: an 8-item subscale for functional status (FSS) and an 11-item subscale for symptom severity (SSS). The FSS examines hand function through 8 statements on daily activities. The SSS examine symptom severity through 11

statements on e.g. weakness, numbness and pain. On both subscales, the items are answered on a 5-point scale from 1 (no difficulty / no symptoms) to 5 (cannot perform the activity at all / the worst symptoms) for the FSS and SSS respectively. A single score is then calculated for each subscale as the mean of the scores on the 8-item FSS and 11-item SSS.

To enable a comparison of the DBCTQ to a validated tool, the patients were also asked to fill out the QDASH. The QDASH is an 11-item shortened version of the original 30-item Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH) used to evaluate patient disability and function in the arm, shoulder and hand[15]. The QDASH has been showed to be comparable to the full DASH ($r=0.98$) with both similar construct validity and responsiveness compared to the full DASH[16-18]. We used a translated and validated Danish translated version of the QDASH[19].

3. Statistical analyses

Normally distributed data is presented using means, standard deviations (SD), and 95% confidence intervals (95% CI) and non-normally distributed data is presented using medians with interquartile range. Normality of data was assessed using Quantile-Quantile plots (Q-Q plots).

In the validity and responsiveness group we analyzed acceptability, responsiveness and construct validity.

3,1 Acceptability

To assess the acceptability we used floor and ceiling effects with an acceptance level of 15% [20] and skewness considered acceptable in the range from -1 – 1 as suggested by existing literature[21].

3.2 Responsiveness

In the COSMIN checklist they do not suggest the use of responsiveness measures like Effect Size (ES) and Standardized Response Mean (SRM) as they are considered measures of change magnitude after intervention rather than a measure of quality. However, we used the SRM and the ES to analyze the responsiveness of the SSS- and FSS subscales of the DBCTQ as they can affect sample size calculations in future studies. The SRM was calculated as the mean of the change scores divided by the standard deviation of the change scores. ES was calculated using Cohen's D where the mean of the change scores is divided by the pooled standard deviation of the first and second measurement. For both SRM and ES we considered a value between 0.2 and 0.5 as small, a value between 0.5 and 0.8 as moderate, and a value above 0.8 as large[22].

3.3 Construct validity

As suggested in the COSMIN checklist the validity can be assessed using construct validity and hypothesis testing. The construct validity was examined through the convergent validity of both the FSS and SSS of the DBCQT using the Pearson's correlation between these and the Danish QDASH. We hypothesized that both the FSS and SSS subscale of the DBCTQ would have moderate to strong positive correlations with the Danish QDASH.

3.4 Relative and absolute reliability

In the reliability group we analyzed the relative and absolute reliability and internal consistency. This was done using Intraclass Correlation Coefficient (ICC), Standard Error of Measurement (SEM) and Minimal Detectable Change (MCC) which are all a part of the COSMIN checklist[13, 14].

We used the ICC to assess the relative reliability where a value equal to or above 0.75 is considered excellent. To assess the absolute reliability, we used the SEM and MDC. We calculated the SEM as

the standard deviation of both test scores multiplied with the square root of 1-ICC. The MDC was calculated as ($SEM * 1.96 * \sqrt{2}$)[7]. Finally, Cronbach's alpha was used to evaluate the internal consistency as suggested in the COSMIN checklist[13, 14].

All statistical analyses were made using STATA, version 15 IC (Stata Corp, College Station, TX, USA).

4. Results

Patient demographic and baseline values of FSS, SSS and QDASH in the validity and responsiveness group and reliability group are presented in table 1. Beside of a tendency towards a higher percentage of patients with CTS in the dominant hand in the reliability group, there was no difference in patient characteristics between the two groups.

4.1 Acceptability

We did not find skewness outside the range of -1 – 1 in the baseline measurements of either FSS, SSS, or QDASH. In both FSS, SSS, and QDASH there was no ceiling effect at baseline and the floor effects was 4.6% for FSS, 0% for SSS and 1.1% for QDASH at baseline.

8 weeks postoperatively there was also no ceiling effect for either FSS, SSS, or QDASH. The floor effect was increased to 14.8% for FSS, 12.5% for SSS and 8.0% for QDASH 8 weeks postoperatively, but all remained within the limit of 15.0%. However, the skewness criterion of -1 – 1 was not met 8 weeks postoperatively for neither FSS (1.4), SSS (1.1) nor QDASH (1.1).

4.2 Responsiveness

We found large ES's and SRM's for both FSS, SSS of the DBCTQ and QDASH. The largest values for both ES and SRM was found in the SSS. The lowest values for both ES and SRM was found in the FSS, table 2.

Table 2: *Responsiveness of the Danish FSS, SSS of the DBCTQ and QDASH with mean scores, mean differences, ES and SRM*

Scale	Pre-operative Mean ± SD	Follow-up Mean ± SD	Difference Mean ± SD	ES	SRM
DBCTQ: FSS	2.6 ± 0.9	1.7 ± 0.8	0.8 ± 1.0	1.0	0.9
DBCTQ: SSS	3.0 ± 0.8	1.7 ± 0.6	1.3 ± 0.8	1.8	1.5
QDASH	43.1 ± 23.0	21.1 ± 18.5	22.0 ± 22.7	1.1	1.0

Table 2: FSS = Functional Status Scale, SSS = Symptom Severity Score, QDASH = Quick Disability of the Arm, Shoulder and Hand Questionnaire. ES = Cohen's D Effect Size, SRM = Standardized Response Mean.

4.3 Construct validity

Both the SSS and the FSS were highly correlated with QDASH (rho=0.77 and 0.85 respectively) at the preoperative assessment. At the 8-week follow-up the correlation appeared almost the same for both SSS and FSS of the DBCTQ (rho=0.75 and 0.89), respectively.

4.4 Test-retest reliability

The FSS and SSS of the DBCTQ showed high relative reliability (ICC), high absolute reliability (SEM and MDC) and high internal consistency (Cronbach's Alpha). See table 3 for the scores of FSS, SSS of the DBCTQ and QDASH.

Table 3: *Intraclass Correlation Coefficient, Standard Error of Measurement, Minimal Detectable Change and Cronbach's alpha for the Danish FSS, SSS of the DBCTQ and QDASH with mean scores, mean differences, ES and SRM*

Scale	ICC	SEM	MDC	Alpha
DBCTQ: FSS	0.94	0.22	0.61	0.93
DBCTQ: SSS	0.90	0.25	0.69	0.92
QDASH	0.91	3.16	8.76	0.95

Table 3: FSS = Functional Status Scale, SSS = Symptom Severity Score, QDASH = Quick Disability of the Arm, Shoulder and Hand Questionnaire. ICC = Intraclass Correlation Coefficient, SEM = Standard Error of the Measurements, MDC = Minimal Detectable Change, Alpha = Cronbach's alpha.

Using Pearson's correlation, we found high correlation between first and second measurement of both the SSS and FSS of 0.91 and 0.95 respectively. The two Bland-Altman plots in figure 1 shows that the average difference between first and second measurement of SSS and FSS of the DBCTQ was not affected by the patients' score on the two subscales. This shows the reliability is the same for patients with severe symptoms as for patients with mild symptoms.

Figure 1*:* Bland-Altman and scatterplot of the first and second measurement of the SSS and FSS of the BCTQ.

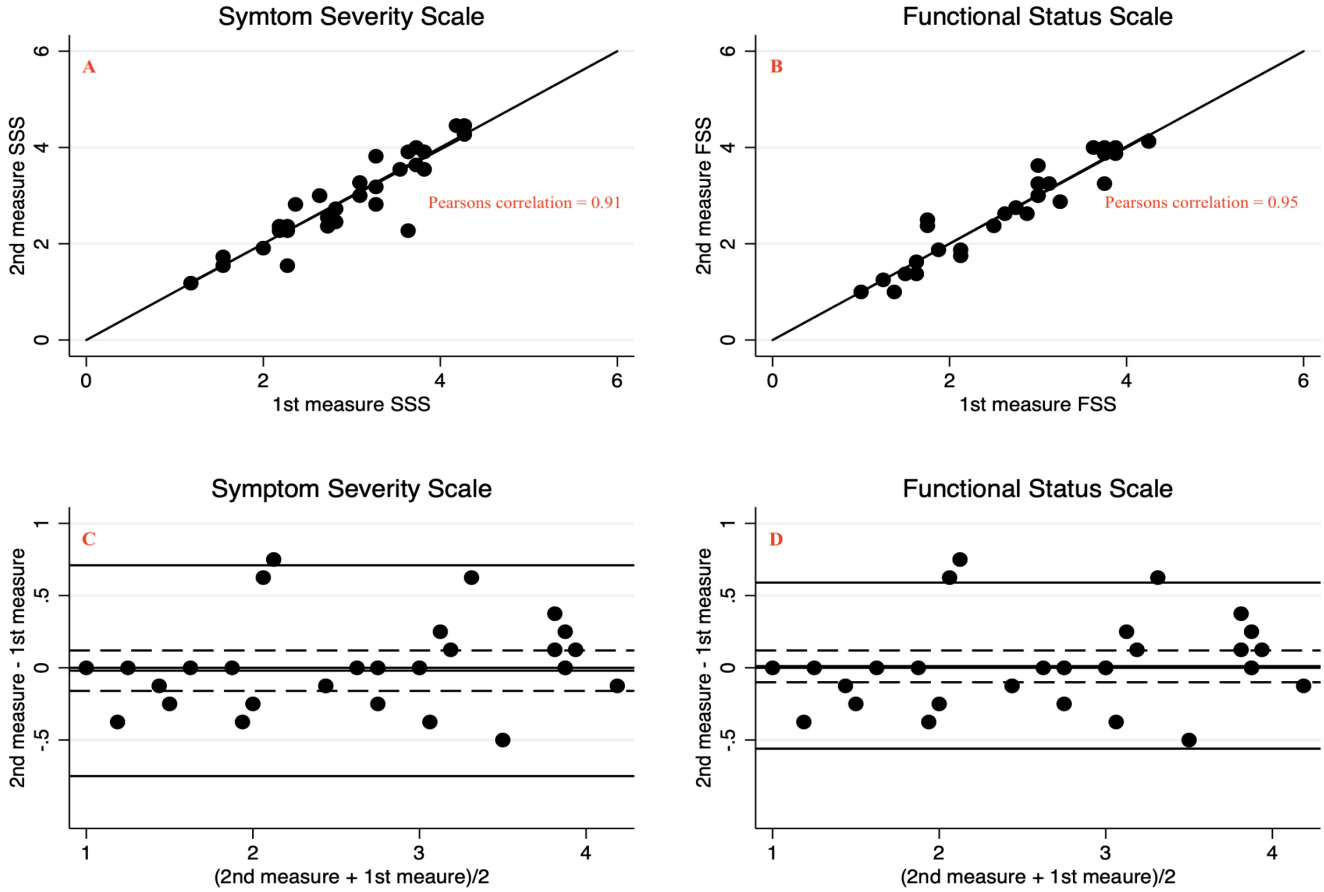

Figure 1: A: Scatterplot and Pearson's correlation of the first and second assessment of the Symptom Severity Scale. B: Scatterplot and Pearson's correlation of the first and second assessment of the Functional Status Scale. C: Bland-Altman plot with 95% confidence interval for mean difference and 95% prediction interval for the difference between first and second assessment of the Symptom Severity Scale. D: Bland-Altman plot with 95% confidence interval for mean difference and 95% prediction interval for the difference between first and second assessment of the Functional Status Scale.

5. Discussion

The aim of this study was to examine the measurement properties of the FSS and SSS subscales from the Danish BCTQ evaluating responsiveness, validity and reliability. Overall, the results from this study shows good responsiveness, validity and reliability of both the FSS and the SSS subscales.

This study showed ES's of 0.99 and 1.76, and SRMs of 0.86 and 1.50, for the FSS and SSS, respectively, which indicate a higher responsiveness of the SSS. For both measures, we considered a value < 0.5 as small, a value between 0.5 and 0.8 as moderate, and a value > 0.8 as large[22]. The values from this study are considered high, making it useful for research on changes in symptoms and functionality in patients with carpal tunnel syndrome. The highest responsiveness we have been able to find in the existing literature was found in a Chinese validation of the BCTQ where they found ES's of 0.56 and 1.12, and SRMs of 0.62 and 1.03, for the FSS and SSS respectively[7].

The construct validity of the FSS and SSS was examined using a correlation analysis to the Danish validated QDASH[19] and revealed high correlations both preoperatively and postoperatively on both BCQT subscales. Only the Persian validation study of the BCTQ also used the QDASH to evaluate construct validity and found Pearson's correlations of 0.70 and 0.64, for FSS and SSS, respectively. In this Danish validation of the BCQT we found correlations of 0.84 and 0.79 preoperatively, and 0.91 and 0.75 postoperatively, for the FSS and SSS, indicating high validity. The high construct validity is important and useful for research purposes as it shows that both subscales measures what they are intended to when compared to the QDASH. However, given as the purpose of this study was to validate the psychometric properties of a questionnaire assumed to be more accurate than the QDASH and DASH for CTS patients, the construct validity is not directly stating a high validity of the Danish BCTQ.

Also, we examined the reliability of the Danish BCTQ using ICC, SEM, MDC and Cronbach's alpha. The ICC has also been examined in the Persian, Polish, Arabic and Chinese validations of the BCTQ

[7, 10, 23, 24] with ICC's ranging from 0.77 in the Persian to 0.89 in the Arabic FSS, and from 0.54 in the Persian to 0.88 in the Arabic SSS. The ICC's of 0.94 and 0.90 in this study shows high test-retest reliability of both subscales. When doing research, it is highly important that the reliability is as good as possible as it shows that the patients do not score differently if they were to fill out the questionnaire twice reducing the bias in research results.

Since the true score is always unknown, it is desirable to have a measure where repeated measures distribute as little as possible around the true score. A lower SEM then represents a lower uncertainty and a measured score closer to the true score. We examined the SEM, which was also done in the Polish and Chinese validations. These studies found slightly higher SEMs of the SSS of 0.32 and 0.31 compared to our finding of 0.25, and slightly higher SEMs of the FSS of 0.34 and 0.27 compared to our finding 0.22.

The SEMs from this study lead to MDCs of 0.61 and 0.69 for the FSS and SSS respectively. These values are slightly lower than those found in the Polish validation of 0.93 and 0.90 and those from the Persian study of 0.75 and 0.86. As the MDC represents the amount of change that is needed to be beyond measurement variation, our study shows that the Danish BCTQ is useful to detect changes in functional status and symptom severity in CTS patients.

Lastly, we examined the internal consistency of both subscales. This was also done in the Turkish, Spanish, Persian and Polish BCQT validation with reporting of Cronbach's alpha values of 0.88, 0.91, 0.88 and 0.92 for the FSS, and 0.82, 0.90, 0.86 and 0.91 for the SSS, respectively [6, 9, 10, 23]. These all represent values comparable to our findings, showing that the FSS and SSS has high internal consistency with closely related questions in the Danish validation as well as the aforementioned validations. It has been suggested, that Cronbach's alpha values should not exceed 0.9[25]. As the values for both the FSS and SSS are above 0.9 the questionnaire could potentially be shortened by one or more questions.

This study shows good properties with regards to responsiveness, validity and reliability of this Danish validation of the BCTQ. As the DBCTQ is designed to asses function and symptoms specifically in CTS patients it does not include questions related to the shoulder and hand as in the DASH and QDASH. By aiming directly at the desired function and symptom of the hand in CTS patients, other possible disabilities in the arm and shoulder will not affect the measured score.

Study limitations should be mentioned in any study, and specifically for this study some selection bias may arise from the 69 (44%) excluded patients due to missing answers. However, the excluded patients did not differ from the included patients with regards to age, FSS, SSS, QDASH, diabetes or dominant hand. On the contrary, the excluded patients did differ in gender, where 71% of the excluded patients were females compared to the 53% females in the final study sample.

The inclusion of patients at two different clinics could cause bias due to differences in indications, surgical technique and postoperative treatment. At both clinics the same indication was used where all operations were performed in local anesthesia and the postoperative procedure was the same. However, the distribution of OCTS versus ECTS may be different. To reduce biased results, the patients included at one clinic was used as a validity and responsiveness group and the patients included at the other clinic were used as a reliability group.

6. Conclusion

This study shows satisfactory results of validity, responsiveness and reliability on both subscales of the Danish translated BCTQ. The Danish validated BCTQ is a useful tool to asses and evaluate function and symptoms in CTS patients. Using the Danish validated BCTQ in Danish research enables researchers to compare their study results to study results from other countries using the

BCTQ. We suggest that the Danish version of the BCTS can and should be used when research is conducted on functional status and symptom severity in Danish speaking CTS patients.

Disclosure statement

The authors declare that they have no competing interests.

Authorship contributions

SBM: Conceptualization, Formal analysis, methodology, project administration, manuscript draft

MS: Conceptualization, methodology, supervision, manuscript editing

MB: Data curation, manuscript editing

TBH: Data curation, conceptualization, methodology, supervision, manuscript editing

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Study IV

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Pain Catastrophizing Scale as a predictor of low postoperative satisfaction after hand surgery

Sebastian Breddam Mosegaard[a,b,*], Maiken Stilling[a,b], Torben Bæk Hansen[a,b]

[a] University Clinic for Hand, Hip and Knee Surgery, Department of Orthopaedics, Lægårdvej 12, 7500, Holstebro, Denmark
[b] Department of Clinical Medicine, Aarhus University, Palle Juul-Jensens Boulevard 99, 8200, Aarhus N, Denmark

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ABSTRACT

Background: Psychological measures are used increasingly in outcome studies. The Pain Catastrophizing Scale is a 13-item questionnaire used to measure coping skills and negative feelings of pain. In the existing literature it is suggested that the Pain Catastrophizing Scale could be associated with the outcome following surgery. The aim of this study was to examine the effect of catastrophic thinking on postoperative satisfaction after treatment for hand conditions where pain is not the predominant symptom (Dupuytren's disease, trigger finger and wrist ganglia), and further to estimate cut-points on the Pain Catastrophizing Scale.

Methods: A total of 413 patients (53% females) with a mean age of 59 years were included in this one-year prospective follow-up study. The patients were diagnosed with either Dupuytren's disease (N = 133), trigger finger (N = 365), or wrist ganglia (N = 147). Preoperative data included disability (Disability of the Arm, Shoulder and Hand questionnaire (DASH)), quality of life (EuroQol-5D (EQ-5D)), and pain catastrophizing (Pain Catastrophizing Scale (PCS)). One year postoperative, data on DASH score, EQ-5D, and patient satisfaction were collected. We used a classification tree to define the most important cut-points, which could classify patients as low-risk or high-risk of low postoperative satisfaction. These cut-points and the 75th percentile cut-point was then used in logistic regression models with postoperative satisfaction as outcome variable.

Results: The median DASH score improved from 13.5 to 2.6 ($p < 0.01$), and the median EQ-5D score improved from 0.82 to 1.00, and 90.3% of patients were satisfied or very satisfied with the surgery.Using the 75th percentile (≤12) we did not find a predictive effect of PCS. However, when using the two cut-points from the classification tree (≤27.5 & ≤2.9) all tested models were statistically significant with odds ratios for risk of low satisfaction ranging from 2.81 to 6.44. Only the model using PCS ≤27.5 adjusted for both demographics and disability was insignificant.

Conclusion: This study suggests that PCS can be a valuable tool in predicting postoperative satisfaction in hand conditions where pain is not the predominant symptom, and that ≤27.5 and ≤ 2.9 are the optimal cut-point on the preoperative PCS.

1. Background

Musculoskeletal disorders (MSDs) is one of the main reasons for patients to be referred for assessment by a hand surgeon. Functional improvement after hand surgery is well studied, and beside using function, disability and pain as outcome measures, there has been an increasing interest in patient satisfaction data to assess the quality of surgical care.[1] Several studies suggest that psychological factors are determinant of health and that postoperative pain following surgical treatment of soft tissue disorders of the hand can be influenced by psychological factors.[2]

The relationship between psychological factors and various outcome measures has been examined in Carpal Tunnel Syndrome (CTS) and distal radius fractures (DRF).[3–6] Three out of five studies in a systematic review showed a statistically significant correlation between psychological measures of depression and heath and patient satisfaction in patients with CTS.[3] Catastrophic thinking measured using the Pain Catastrophizing Scale (PCS) was found predictive of greater finger stiffness after surgery of DRF.[7] In a study on several atraumatic hand disorders they found that patients scoring above 30 on the PCS had poorer score on the Michigan Hand Outcomes Questionnaire (MHQ), compared to patients scoring 30 or below .[8] The effect of PCS on postoperative satisfaction following surgery of soft tissue disorders, where pain is not the predominant symptom, is not equally well

* Corresponding author. Lægårdvej 12, 7500, Holstebro, Denmark.
E-mail addresses: sebmos@rm.dk (S.B. Mosegaard), maiken.stilling@clin.au.dk (M. Stilling), torbehns@rm.dk (T.B. Hansen).

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examined, although it is suggested that psychological factors might affect patient satisfaction in Dupuytren's patients.[9] Further, a recent study on patients with trigger finger suggested that catastrophic thinking of pain might affect the postoperative outcome.[10]

It is of interest to detect preoperative factors associated with postoperative patient satisfaction, as it enables physicians to identify patients that may not benefit from surgical intervention. Dupuytren's disease, trigger finger and wrist ganglia are common hand and wrist disorders causing mainly functional limitations and disability, and little is known about the predictive value of PCS on postoperative outcome in these patients.[9,11,12] Therefore, the aim of this study was to investigate the effect of PCS on postoperative satisfaction in patients with Dupuytren's disease, trigger finger and wrist ganglia. For predictive purpose and better clinical use, we further aimed to evaluate the optimal preoperative cut-point on the PCS to identify patients with increased risk of low postoperative satisfaction.

2. Methods

Prior to study initiation, the protocol was reviewed by the local research ethics committee, and no specific approval was demanded as the study is a quality assurance study, which according to the Danish law "Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects", Part 3 "Notification and authorization": Questionnaire-based projects and register research projects shall only be notified to a regional committee if the project also involves human biological material. The project was registered with The Danish Data Protection Agency (jr. nr.: 2007-58-0010) and informed patient consent was obtained. The Helsinki II declaration was followed, and all data was handled according to the General Data Protection Regulation (GDPR).

2.1. Study sample

645 patients were enrolled in a prospectively updated database between February 11th, 2011 and January 5th, 2015. Patients were diagnosed with and surgically treated for Dupuytren's disease (N = 133), trigger finger (N = 365), or wrist ganglia (N = 147). Due to missing data on the outcome score, patient satisfaction score, or multiple surgeries a total of 232 patients were excluded leaving 413 patients for analysis. The excluded patients were younger and more likely to be living alone. Patient demographics for the included and excluded patients can be seen in Table 1. A comparison of the baseline scores between diagnosis groups is shown in Table 2.

2.2. Measures

The study was designed as a prospective study with follow-up measures one year after surgery to ensure full recovery after the surgery. The patients were asked to complete a questionnaire prior to surgery on Pain Catastrophizing Scale (PCS), Disability of Arm, Shoulder and Hand (DASH), and EuroQol-5D (EQ-5D). One year postoperatively the patients were asked to complete a questionnaire on DASH, EQ-5D, and satisfaction with the surgery.

Table 1
Preoperative baseline characteristics for included and excluded patients.

	Included patients (N = 413)		Excluded patients (N = 232)	
	Mean	95% CI	Mean	95% CI
Females	52.8%	.	58.2%	.
Dominant hand	58.0%	.	59.8%	.
Living alone	22.3%	.	29.2%	.
Age (years)	58.8	57.4–60.3	49.2	45.9–52.5
DASH	14.8	13.2–16.4	17.7	14.5–20.8
EQ-5D	0.8	0.8–0.9	0.8	0.8–0.8
PCS	7.6	6.5–8.5	8.8	7.4–10.3

Table 2
Comparison of baseline scores between diagnosis groups.

Diagnosis N	Dupuytren's	Trigger finger	Wrist ganglia
	105	223	85
Age, mean	64.1	62.3	50.7
95% CI	62.1–66.2	60.9–63.7	47.0–54.3
PCS, mean	5.1	9.8	6.6
95% CI	3.6–6.7	8.6–10.9	5.0–8.2
DASH, mean	9.3	21.1	11.7
95% CI	7.6–11.0	19.1–23.0	8.9–14.5
EQ-5D, mean	0.88	0.78	0.85
95% CI	0.86–0.90	0.77–0.80	0.81–0.88

The primary preoperative measure of interest in this study was PCS. PCS is a 13-item questionnaire used to measure coping skills and negative feelings of pain on a scale from 0 to 52. Each of the 13 statements have 5 answering options ranging from 0 "not at all" to 4 "all the time" where a higher score reflects higher catastrophic thinking. The 30-item DASH questionnaire was used to measure patient disability through 30 statements, which each are scored on a 5-point Likert scale, where a higher score reflects more disability on a scale from 0 to 100 In this study, a Danish translated and validated version of DASH was used.[13] Finally, the patients completed the health-related quality of life questionnaire EQ-5D, where a higher score indicates a better health-related quality of life. In the 1-year postoperative questionnaire, the patients where further asked to evaluate their satisfaction with the treatment on a score ranging from 1 "I am very satisfied" to 4 "I am dissatisfied". We then pooled scores of 1 or 2 as satisfied and scores of 3 or 4 as dissatisfied.

In the final study cohort of 413 patients, we had missing data on preoperative PCS (14.04%), preoperative DASH (9.44%), preoperative EQ-5D (6.05%), postoperative DASH (7.27%), postoperative EQ-5D (3.39%), dominant hand (2.66%), and civil status (1.94%). This data was addressed using the "missForest" function in the software R, as it handles missing data of both continuous (PCS, DASH and EQ-5D) and/or categorical types (dominant hand and civil status).

3. Statistics

Data normal distribution was assessed using quantile-quantile plots. Due to non-normality, Wilcoxon matched-pairs signed-rank test was used to test for change in preoperative and postoperative DASH and EQ-5D score. We used Pearson's correlation to assess the correlation between preoperative measures of PCS, DASH and EQ-5d. We used the package "tree" in R (R Core Team (2013), R Foundation for Statistical Computing, Vienna, Austria) to generate a classification tree to decide the optimal cut-point on the continuous preoperative PCS (https://cran.r-project.org/web/packages/tree/tree.pdf).

The classification tree splits the independent variable in order to find optimal cut-points related to a given outcome variable, in this case the one-year postoperative patient satisfaction. The two most important cut-points were then used for further analysis. Beside these two cut-points, we used the 75th percentile on the PCS (PCS ≤ 12) as a cut-point as it is used in the PCS manual[14] and finally PCS as a continuous variable without dividing it into two groups. The three cut-points and the continuous PCS were then each used in three logistic regression models with different adjustments.

First, we performed unadjusted logistic regression models on the effect of preoperative PCS (the 3 cut-points and continuous) on

postoperative satisfaction. Next, we tested the same models but this time adjusted for demographics (age, gender, dominant hand, civil status). Finally, we further adjusted the models for disability (EQ-5D score and DASH).

Descriptive statistics and logistic regression models were made using STATA, version 15 IC (Stata Corp, College Station, TX, USA). Imputation, data cleaning and regression trees were made in R (R Core Team (2013), R Foundation for Statistical Computing, Vienna, Austria).

4. Results

Patients improved statically significant in both DASH- and EQ-5D score from the preoperative assessment to the postoperative. The median DASH score improved from 13.5 to 2.6 ($p < 0.001$) and the median EQ-5D score improved from 0.82 to 1.00 ($p < 0.001$). DASH score improvement was close to the minimal clinical important difference (MCID) of 12[15] and EQ-5D score improved more than the MCID of 0.10.[16] Furthermore, 90.3% of the patients were either satisfied or very satisfied with the surgery one year postoperatively.

4.1. Preoperative cut-points on the PCS

The first estimated cut-point on the preoperative PCS from the classification tree was ≤27.5. Using this cut-point, we found a higher percentage of dissatisfied patients in the group scoring PCS above the estimated cut-point, with 36.4% in the high PCS group reporting low satisfaction compared to 9.0% of patients in the low PCS group reporting low satisfaction ($p < 0.01$).

The second estimated cut-point on the preoperative PCS was ≤2.9. We also found more dissatisfied patients in the high PCS group using this cut-point. In the high PCS group, 12.50% reported low satisfaction, and in the low PCS group, 4.26% reported low satisfaction ($p < 0.01$). Using the 75th percentile (PCS≤12), 12.62% reported low satisfaction in the high PCS group and 8.71% reported low satisfaction in the low PCS group ($p = 0.25$).

4.2. Logistic regressions using different cut-points

Preoperative continuous PCS: Without using a cut-point on the PCS there was a significant negative effect of increased preoperative PCS on postoperative patient reported satisfaction (OR = 1.04 [95% CI: 1.00–1.07]) in the simple logistic regression model and the logistic regression model adjusted for demographics ($p < 0.04$). When we further adjusted this model for preoperative disability, the model was no longer statistically significant for prediction of a low postoperative satisfaction ($p > 0.41$).

Preoperative PCS cut 75th percentile: When we divided the patients into high and low PCS using the 75th percentile as cut-point (PCS≤12) there was no significant effect of PCS on postoperative patient satisfaction in any of the three models ($p > 0.17$).

Preoperative PCS cut ≤27.5: Using the first estimated cut-point (PCS≤27.5) we found a statistically significantly increased risk of low postoperative satisfaction in the high PCS group both when unadjusted (OR = 5.81 [95% CI: 1.62–20.80]) and when adjusted for demographics (OR = 6.44 [95% CI: 1.65–25.14]) ($p < 0.01$).

Preoperative PCS cut ≤2.9: In the last model, we used the secondary cut-point (PCS≤2.9) and found a statistically significant effect in all three models. The highest OR was in the model adjusted for demographics (OR = 3.82 [95% CI: 1.51–9.61]) ($p < 0.01$) and the lowest OR was in the model adjusted for demographics and disability (OR = 2.81 [95% CI: 1.05–7.48]) ($p < 0.04$). All results from the logistic regression models can be seen in Table 3.

4.3. Correlation between PCS, EQ-5D and DASH score

We found significant correlations between all three preoperative scores ($p < 0.01$). The highest correlation was found between preoperative DASH and preoperative EQ-5D ($r = -0.72$). The second strongest correlation was between preoperative PCS and preoperative DASH ($r = 0.53$). Weakest was the correlation between preoperative PCS and preoperative EQ-5D ($r = -0.43$).

Table 3
Logistic regression models on the odds ratio for postoperative dissatisfaction predicted by preoperative score on the Pain Catastrophizing Scale.

Preoperative	Odds ratio for low patient reported satisfaction after minor hand surgery		
	Odds ratio	95% CI	p value
PCS			
Unadjusted[a]	1.04	1.00–1.07	0.038*
+ Demographics[b]	1.04	1.01–1.08	0.024*
+ Disability[c]	1.02	0.98–1.06	0.417
PCS > 27.5			
Unadjusted[a]	5.81	1.62–20.80	0.007*
+ Demographics[b]	6.44	1.65–25.14	0.007*
+ Disability[c]	3.71	0.88–15.68	0.074
PCS > 12			
Unadjusted[a]	1.51	0.75–3.06	0.247
+ Demographics[b]	1.65	0.79–3.43	0.179
+ Disability[c]	0.91	0.38–2.17	0.835
PCS > 2.9			
Unadjusted[a]	3.21	1.32–7.85	0.010*
+ Demographics[b]	3.82	1.51–9.61	0.005*
+ Disability[c]	2.81	1.05–7.48	0.038*

Table 3: Logistic regression analysis on the association between preoperative score on the Pain Catastrophizing Scale and patient reported satisfaction 1 year after minor hand surgery. *: Denotes statistical significance. a: Unadjusted association logistic regression model. b: Adjusted for age, gender, living alone and dominant hand. c: Adjusted for age, gender, living alone, dominant hand, preoperative EQ-5D and preoperative DASH score.

5. Discussion

Patients treated surgically for Dupuytren's disease, trigger finger and wrist ganglia generally improved in both EQ-5D and DASH score from preoperative to one year postoperative. More than 90% of patients felt either satisfied or very satisfied one year after surgery, and there was no difference between diagnosis groups. However, this implies means that almost 10% were dissatisfied, and we showed that preoperative PCS margin scores ≤27.5 and ≤ 2.9 significantly increased the risk of low postoperative satisfaction, and can be a useful preoperative tool to identify patients at risk of feeling low satisfaction after surgery for Dupuytren's disease, trigger finger or wrist ganglia.

5.1. Pain Catastrophizing Scale

The existing literature shows mixed findings regarding the association between PCS and various outcomes. A study on patients with Carpal Tunnel Syndrome found a higher PCS to be associated to a higher DASH score but no association between PCS and patients satisfaction.[5] However, a higher PCS has also been found to be associated to lower postoperative patient satisfaction in CTS patients.[17] Additionally, a study from South Korea in patients with distal radius fractures found an association between PCS and range of motion and grip strength at 4 weeks but not at 12 weeks.[6] It is suggested that patients with high PCS might be more cautious about using their arm and hand after surgery, which could lead to reduced range of motion and grip strength. This study did not define cut-points on the preoperative PCS, which is necessary to identify patients at risk.

Our study showed that the predictive effect of PCS on postoperative satisfaction depended on the cut-point. The PCS manual defines a PCS score of 30 as a clinically relevant pain catastrophizing, representing the 75th percentile in chronic pain patients.[14] Using this cut-point, an

American study on patients suffering from atraumatic hand disorders found that patients with a PCS score > 30 had a higher score on the Michigan Hand Outcomes Questionnaire (MHQ) at baseline. However, the improvement in MHQ over time was the same for patients with PCS score > 30 and patients with PCS score ≤ 30.[8] A Korean study on patients surgically treated for hand fractures examined the effect of preoperative PCS on grip strength, range of motion and disability 3 and 6 months after surgery.[18] In this study, they also used the 75th percentile as cut-point which in this study represented a PCS score of 27. Using this cut-point, they found an association between PCS and grip strength, range of motion and disability 3 months postoperatively, but not 6 months postoperatively.

5.2. The optimal cut-point

In our study on patients with Dupuytren's disease, trigger finger and wrist ganglia we used three different cut-points and examined if this would lead to different results. Using a classification tree, we found the two most important cut-points to be 27.5 and 2.9. Additionally, we used the 75th percentile as cut-point, which in our study was a PCS score of 12. This is lower than we have seen in other studies as the patients in our study generally scored lower on the PCS. Using 12 as cut-point was the only time, we did not find an association in either the unadjusted regression, the demographics adjusted regression, or the demographics and disability adjusted regression, which indicate that the 75th percentile is not a useful cut-point in our data. Using the two cut-points from the classification tree we found statistically significant predictive effects of PCS in all the models besides the demographics and disability adjusted regression with PCS ≤ 27.5. Given our results, we are unable to state whether 2.9 or 27.5 is the most important cut-points as there is a large difference in false positives and false negatives between these cut-points. However, this study indicates that using the 75th percentile as cut-point might be unsuitable given that this was the only cut-point without statistically significant predictive effect.

5.3. Considerations

We excluded almost 36% of the included patients due to missing data. The excluded patients were younger, more likely to be living alone and slightly more of these were females, which might have led to bias. Additionally, the suggested cut-points in this study is not necessarily the optimal cut-points in other samples, since our cut-points has not been externally validated, but we encourage this to be done. Also, the use of DASH as a measure of disability might affect the validity negatively. DASH targets both the arm, shoulder and hand, which could cause musculoskeletal problems in anatomical sites other than the hand to affect the validity of the disability score. Further studies on patient satisfaction should include additional information such as patient smoking habits, alcohol consumption, BMI, education and income to strengthen the explanatory power.

6. Conclusion

Patients generally improved in EQ-5D and DASH score and more than 90% of the patients was either satisfied or very satisfied one year postoperatively. We tested three different cut-points on the preoperative PCS to predict postoperative patient satisfaction. Using the 75th percentile (≤12) we did not find a predictive effect of PCS. However, when using the two cut-points from a classification tree (≤27.5 & ≤2.9) all tested models were statistically significant with odds ratios for risk of low satisfaction ranging from 2.81 to 6.44. Only the model using PCS ≤27.5 adjusted for both demographics and disability was insignificant. This study suggests that PCS can be a valuable tool in predicting postoperative satisfaction in hand surgery. Further, the results from this study indicates that using the 75th percentile as cut-point on the PCS might not be the optimal solution in prediction studies. Finally, we suggest that the cut-points should be validated on external data in order to investigate the external validity of our suggested cut-points.

Declaration of competing interest

None.

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Co-authorship declarations

AARHUS UNIVERSITY

Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Sebastian Breddam Mosegaard

This declaration concerns the following article/manuscript:

Title:	Risk factors for limited improvement after total trapeziometacarpal joint arthroplasty
Authors:	Sebastian Breddam Mosegaard, Maiken Stilling, Torben Bæk Hansen

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If accepted or submitted, state journal: Health and quality of life outcomes

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

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Please rate (A-F) your contribution to the elements of this article/manuscript, **and** elaborate on your rating in the free text section below.

A. Has essentially done all the work (>90%)
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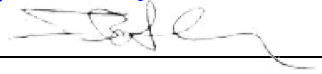
D. Has contributed (10-33 %)
E. No or little contribution (<10%)
F. N/A

Category of contribution	Extent (A-F)
The conception or design of the work:	B
Free text description of PhD student's contribution ***(mandatory)*** The database was created before the beginning of the PhD project. The conception and design of the study was done by the student and the supervisors.	
The acquisition, analysis, or interpretation of data:	B
Free text description of PhD student's contribution ***(mandatory)*** After the acquisition the analysis and interpretation of the data was done by the student.	
Drafting the manuscript:	A
Free text description of PhD student's contribution ***(mandatory)*** The student drafted the manuscript with minor guidance from the supervisors.	
Submission process including revisions:	A

Free text description of PhD student's contribution ***(mandatory)***
The student did the submission process and revisions with minor guidance from the supervisors

Signatures of first- and last author, and main supervisor

Date	Name	Signature
28.04.2020	Sebastian Breddam Mosegaard	
29.04.2020	Maiken Stilling	
29.04.2020	Torben Bæk Hansen	

Date: **30.04.2020**

Signature of the PhD student

AARHUS UNIVERSITY

Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Sebastian Breddam Mosegaard

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Authors:	Sebastian Breddam Mosegaard, Maiken Stilling, Torben Bæk Hansen

The article/manuscript is: Published ☒ Accepted ☐ Submitted ☐ In preperation ☐

If published, state full reference: Mosegaard SB, Stilling M, Hansen TB: Higher preoperative pain catastrophizing increases the risk of low patient reported satisfaction after carpal tunnel release: a prospective study. BMC musculoskeletal disorders 2020, 21(1):42.

If accepted or submitted, state journal: BMC Musculoskeletal disorders

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

No ☒ Yes ☐ If yes, give details:

Your contribution

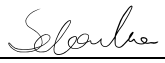
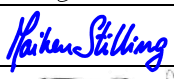
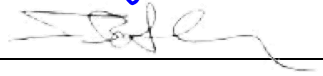
Please rate (A-F) your contribution to the elements of this article/manuscript, **and** elaborate on your rating in the free text section below.

A. Has essentially done all the work (>90%)
B. Has done most of the work (67-90 %)
C. Has contributed considerably (34-66 %)
D. Has contributed (10-33 %)
E. No or little contribution (<10%)
F. N/A

Category of contribution	Extent (A-F)
The conception or design of the work:	B
Free text description of PhD student's contribution ***(mandatory)*** The database was created before the beginning of the PhD project. The conception and design of the study was done by the student and the supervisors.	
The acquisition, analysis, or interpretation of data:	B
Free text description of PhD student's contribution ***(mandatory)*** After the acquisition the analysis and interpretation of the data was done by the student.	
Drafting the manuscript:	A
Free text description of PhD student's contribution ***(mandatory)*** The student drafted the manuscript with minor guidance from the supervisors.	
Submission process including revisions:	A

Free text description of PhD student's contribution ***(mandatory)***
The student did the submission process and revisions with minor guidance from the supervisors

Signatures of first- and last author, and main supervisor

Date	Name	Signature
28.04.2020	Sebastian Breddam Mosegaard	
29.04.2020	Maiken Stilling	
29.04.2020	Torben Bæk Hansen	

Date: **30.04.2020**

Signature of the PhD student

AARHUS UNIVERSITY

Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Sebastian Breddam Mosegaard

This declaration concerns the following article/manuscript:

Title:	Psychometric properties of the Danish version of the Boston Carpal Tunnel. Questionnaire
Authors:	Sebastian Breddam Mosegaard, Maiken Stilling, Marianne Breddam, Torben Bæk Hansen

The article/manuscript is: Published ☐ Accepted ☐ Submitted ☒ In preperation ☐

If published, state full reference:

If accepted or submitted, state journal: Journal of Orthopaedics

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

No ☒ Yes ☐ If yes, give details:

Your contribution

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F. N/A

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Free text description of PhD student's contribution ***(mandatory)*** The conception and design was done in collaboration between the student and the supervisors.	
The acquisition, analysis, or interpretation of data:	B
Free text description of PhD student's contribution ***(mandatory)*** The analysis and interpretation of the data was done by the student. The acquisition was done in collaboration with the supervisors and Marianne Breddam.	
Drafting the manuscript:	A
Free text description of PhD student's contribution ***(mandatory)*** The student drafted the manuscript with minor guidane for the supervisors.	
Submission process including revisions:	F

Free text description of PhD student's contribution ***(mandatory)***
There has not been a review process yet.

Signatures of first- and last author, and main supervisor

Date	Name	Signature
28.04.2020	Sebastian Breddam Mosegaard	
29.04.2020	Maiken Stilling	
29.04.2020	Torben Bæk Hansen	

Date: **30.04.2020**

Signature of the PhD student

AARHUS UNIVERSITY

Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Sebastian Breddam Mosegaard

This declaration concerns the following article/manuscript:

Title:	Pain Catastrophizing Scale as a predictor of low postoperative satisfaction after hand surgery
Authors:	Sebastian Breddam Mosegaard, Maiken Stilling, Torben Bæk Hansen

The article/manuscript is: Published ☒ Accepted ☐ Submitted ☐ In preperation ☐

If published, state full reference: Mosegaard SB, Stilling M, Hansen TB: Pain Catastrophizing Scale as a predictor of low postoperative satisfaction after hand surgery. Journal of orthopaedics 2020, 21:245-248.

If accepted or submitted, state journal: Journal of Orthopaedics

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

No ☒ Yes ☐ If yes, give details:

Your contribution

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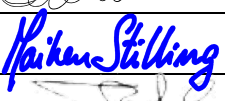
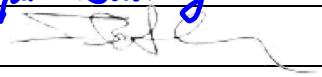
29.04.2020	Maiken Stilling	
29.04.2020	Torben Bæk Hansen	

Date: **30.04.2020**

Signature of the PhD student