



Thumb Carpometacarpal Osteoarthritis

NEW INSIGHTS &
TREATMENT OPPORTUNITIES

Janna S.E. Ottenhoff



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Work performed at University Medical Center Utrecht, Utrecht University | St. Antonius Hospital, Nieuwegein | Jeroen Bosch Hospital, Den Bosch | Dell Medical School, The University of Texas at Austin.

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Thumb Carpometacarpal Osteoarthritis

New insights & Treatment opportunities

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Nieuwe inzichten & Behandel mogelijkheden
(met een samenvatting in het Nederlands)

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Introduction



If we live long enough, everyone eventually develops osteoarthritis of their first carpometacarpal (CMC1) joint.¹⁻³ Symptoms vary greatly among people. Most people, up to 96%⁴, adapt and do not seek medical care.⁵ Pain at the base of the thumb is a common reason for people to consult their physician. Basal thumb pain can cause reduced pinch strength and impaired hand capability such as difficulty opening jars or turning a key. Since most people do not require additional care after their first visit with a doctor⁶, the aim of care seems to be adaptation, in addition to splinting and analgesics. Notwithstanding, numerous surgical options are available but there is no consensus about which surgical treatment is most effective. In this thesis we will explore patients' and surgeons' perspectives on CMC1 osteoarthritis and discuss existing and novel treatment options.

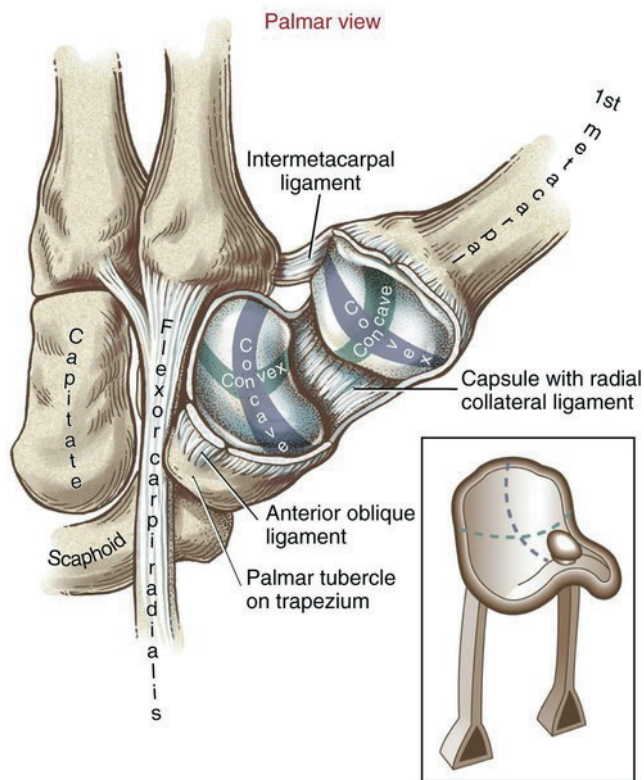


Figure 1. The carpometacarpal of the right thumb is opened to expose the saddle shape of the joint. Reprinted from *Essentials of Kinesiology for the Physical Therapist Assistant*, Third Edition, P.J. Mansfield and D.A. Neumann, Chapter 7: Structure and Function of the Hand, 2019, with permission from Elsevier.

Anatomy

The thumb sits in a different plane than the other fingers (opposition). The thumb plays a unique role in many hand capabilities such as fine motor skills, pinch, power grip and dexterity. The CMC1 joint is formed by the articulation of the first metacarpal bone and the trapezium. This joint is also known as the trapeziometacarpal joint or basal thumb joint (Figure 1). It is unique because of its saddle shapes that allows thumb motion in three ways: flexion-extension, abduction-adduction and pronation-supination. For stability, the CMC1 joint depends on multiple ligaments, the joint capsule and associated tendons.⁷⁻⁹

In addition to its wide range of motion and relative stability, the thumb is able to sustain heavy forces during pinch and grip strength. A strong grasp can induce compression forces up to 120 kilograms.¹⁰ These large forces combined with the complex biomechanics of the CMC1 joint and the large range of motion make the joint susceptible to injury and osteoarthritis. These issues have complicated the search for a reliable joint replacement for osteoarthritis. Therefore, surgery usually involves partial or complete trapeziectomy, with or without additional procedures.¹¹

Incidence and etiology

There is compelling evidence that everyone will get osteoarthritis at the thumb base if we live long enough.^{1,2,12} It is not something some of us get and some of us do not. Sodha *et al.* showed that the prevalence of CMC1 osteoarthritis in the United States steadily increased from the age of 41 years.² Becker *et al.* reports a prevalence of radiographic CMC1 osteoarthritis of more than 60% for people aged 60 years and older.¹ This increases to 90% for adults aged 80 years or older and up to 100% for those over 90 years of age.¹ Lawrence *et al.* showed comparable results among nearly 3000 people in England.¹² In other words: thumb base osteoarthritis is part of normal human aging. However, many people perceive symptomatic CMC1 osteoarthritis as an acute problem or injury, which is a misconception.¹⁵ The etiology of CMC1 osteoarthritis remains unclear. Some studies suggest that it arises from laxity of the volar beak ligament resulting in synovitis formation, subluxation, greater contact stresses and articular degeneration.^{7,14} Others indicate that laxity of the dorsoradial ligament causes the subluxation seen in CMC1 osteoarthritis.^{8,9} Thoughts about the etiology of osteoarthritis moved away from it solely being a degenerative wear-and-tear condition. Instead, an ongoing imbalance between the repair and destruction of joint tissues seems to be at play.^{15,16} This affects all components of the joint and can result in cartilage erosions, subchondral bone marrow lesions, synovitis, increased vascularity and osteophyte formation.¹⁶ How the imbalance between repair and destruction arises as we age is still debated. Studies indicate that prior fracture, obesity,

and female sex are associated with development of CMC1 osteoarthritis at an earlier age.^{17,18} Counter-intuitively, heavy physical labor and hand dominance do not seem to be associated with early development of CMC1 osteoarthritis.^{18,19} Early osteoarthritic changes of the CMC1 joint can also be part of auto-immune mediated osteoarthritis, like rheumatoid arthritis, but this is outside the scope of this thesis.

Presentation and diagnosis

CMC1 osteoarthritis is primarily a clinical diagnosis, based on presentation and physical examination. On physical examination, the basal thumb joint can be painful during palpation.²⁰ The thumb metacarpal base can appear prominent because of osteophytes or subluxation. This is sometimes referred to as the "shoulder-sign".²¹ The metacarpal may be adducted and the metacarpophalangeal joint hyperextended to maintain adequate abduction and pinch strength.²² This collapse of the first ray is referred to as a zigzag deformity.¹¹ Several provocative maneuvers are commonly used to confirm the diagnosis of CMC1 osteoarthritis.^{21,23,24} The "grind test" is positive when there is pain or crepitation during axial compression and rotation of the thumb metacarpal.²¹ This test has a specificity of 97% but a sensitivity between 30%-64%.^{23,24} The "pressure-shear" test is reported to have a sensitivity of 99% and specificity of 95%.²³ For this test, the examiner applies pressure on the volar side of the CMC1 joint with her thumb (over the anterior oblique ligament) while pushing the first metacarpal dorsal. Counter pressure can be provided from dorsal with the index finger of the examiner's hand. Subsequently, the first metacarpal can be rocked back and forth from volar to dorsal by alternating pressure between the thumb and index finger. In this test, pain at the thumb base indicates the presence of CMC1 osteoarthritis.

Imaging

Hand radiographs are often used to visualize osteoarthritic changes of the basal thumb joint. Even though imaging is not necessary to reliably diagnose CMC1 osteoarthritis, radiographic imaging can be performed to provide information for surgical planning and serve as medico-legal proof of CMC1 osteoarthritis. It is important to keep in mind that severity of radiographic changes does not correlate with symptoms, which diminishes the value of routine use of radiographs for CMC1 osteoarthritis.^{4,25} Specialized joint views, such as the lateral Bett's view, depicts all four trapezial articulations without overlap from surrounding bones.²⁶ The radiographic classification system by Eaton is most widely used to determine the severity of CMC1 osteoarthritis (Table 1).^{22,27} It ranges from stage I (no change) to stage IV (osteoarthritis of the CMC1 and scapho-trapezio-trapezoidal [STT] joint). A more simplified rating system was developed by Sodha *et al.* and has comparable observer reliability.² The Sodha classification has three categories for radiographic severity: grade I includes

no more than mild arthrosis; grade II shows obvious arthrosis; grade III indicates severe arthrosis with a totally destroyed joint.² Some research focusses on the use of computed tomography (CT)²⁸ or magnetic resonance imaging (MRI)^{29,30}, but the added value compared to stand radiographs currently seems limited.

Table 1. Classification system by Eaton for staging of radiographic CMC1 osteoarthritis.^{22,27}

Stage I	The articular contours are normal. There may be a slight widening of the joint space due to effusion or laxity of the ligamentous support of the CMC1 joint.
Stage II	The CMC1 joint is slightly narrowed with minimal subchondral sclerosis. There may be joint debris < 2 mm in diameter in the form of osteophytes or loose bodies. The STT joint should appear normal.
Stage III	The CMC1 joint space is markedly narrowed or obliterated with cystic changes, sclerotic bone, varying degrees of dorsal subluxation, and joint debris > 2 mm in diameter. The STT joint is normal.
Stage IV	There is complete deterioration of the CMC1 joint as in stage III and, in addition, the STT joint is narrowed with apparent sclerotic and cystic changes.

Limited association between pathophysiology and symptoms

Most people with objective evidence of osteoarthritis on radiographs (pathophysiology) do not experience symptoms or reduced hand capability.^{3,31} They do not even realize its presence and do not report thumb related problems.^{4,32} The majority seems able to adapt to their basal thumb osteoarthritis. This is supported by multiple studies indicating much higher prevalence for radiographic (incidental) osteoarthritis than for symptomatic osteoarthritis.³³ In the Framingham study, only 3% of men and 5% of women aged 71 years and older had symptomatic thumb osteoarthritis (CMC1 osteoarthritis on radiographs with reported thumb pain), while 89% of men and 94% of women had radiographic evidence of osteoarthritis.⁵ Two other studies showed that only one out of three people with radiographic CMC1 osteoarthritis reported thumb pain.^{3,31} In another study, only five of 122 (4%) people with CMC1 osteoarthritis had sought care for thumb pain.⁴ A study that evaluated wrist radiographs of patients presenting with a distal radial fracture found that three of 2324 people with radiographic CMC1 osteoarthritis had signs of prior surgical treatment for CMC1 osteoarthritis.¹ Given the high prevalence of CMC1 osteoarthritis among older people, it is safe to assume that many people never seek care for this condition.

Nonoperative treatment

For those seeking care, the first step in management of CMC1 osteoarthritis is to offer nonoperative care – as recommended by national and international guidelines.^{34,35} Nonoperative treatment includes education, pain medication and splinting.³⁶ Most

people, up to 85%, are satisfied with these treatment options and do not request surgical interventions.³⁷ Oral analgesics, like nonsteroidal anti-inflammatory drugs, are commonly described and can provide pain relief.³⁸ Splints that immobilize the CMC1 joint can reduce pain but do not improve strength or hand function.³⁶ Exercise therapy aims to optimize thumb position, prevent hyperextension, and improve strength, but there is very limited evidence available supporting these beneficial effects.^{39–41} Intra-articular injections seem to have no place anymore in treatment of CMC1 osteoarthritis since they do not surpass placebo injections with respect to improvement in pain intensity and physical function.^{42,43} Some studies suggest that corticosteroid injections can even be detrimental to articular cartilage and have the potential harm of skin-related adverse events.^{44–46}

Surgical treatment

Many surgical options are available for people with ongoing symptoms despite nonoperative management (Table 2).⁴⁷ Before surgical care is discussed, people must be informed that symptoms usually vary overtime and are likely to regress as time passes. For example, in 33 people who were on a waitlist for CMC1 surgery, after seven months of supportive treatment, 23 patients (70%) cancelled their surgery.⁴⁸

Table 2. Surgical treatment options for thumb base osteoarthritis.

Trapeziectomy alone
Trapeziectomy with ligament reconstruction and/or tendon interposition
Trapeziectomy with suspension and interposition arthroplasty
(Arthroscopic) hemi-trapeziectomy
Metacarpal extension osteotomy
Volar ligament reconstruction
Arthroscopy with debridement of the CMC1 joint
Arthrodesis
Implant arthroplasty
Total joint replacement

The first surgical procedure for CMC1 osteoarthritis was a simple trapeziectomy (removal of the trapezium) described in 1949 by Gervis.⁴⁹ In the next decades, tendon interposition (TI) with or without ligament reconstruction (LR) were added^{50–52}, aiming to prevent proximal migration of the first metacarpal bone after removal of the trapezium. Usually the flexor carpi radialis, abductor pollicis longus or palmaris longus is harvested and used as tendon interposition but synthetic interpositions also exist. Other surgical techniques include metacarpal osteotomy⁵³, joint arthrodesis⁵⁴, and a variety of total or partial arthroplasties.⁵⁵ It remains unclear which surgical

intervention is most effective. High quality evidence on this topic is scarce. Two systematic reviews could not identify one surgical procedure with benefits over the others in terms of pain intensity, physical function, range of motion or strength.^{56,57} Nowadays, a trapeziectomy with LRTI is the most recommended technique among surgeons.⁵⁸⁻⁶⁰

THESIS OUTLINE

Part One | Patient's perspective

Many people misperceive symptomatic CMC1 osteoarthritis as an acute problem or injury.¹⁵ Wrong ideas about the etiology may be reinforced through information on CMC1 osteoarthritis available on the internet. Previous studies showed that quality of online information on common medical topics varied considerably.⁶¹⁻⁶⁵ However, nine out of ten people indicated that they perceive health care related websites as a reliable source of information.⁶¹ In **Chapter 1** we aim to determine the quality of website information on thumb base osteoarthritis. It is important to understand what kind of information people obtain before they visit a doctor because inaccurate information may establish misconceptions about CMC1 osteoarthritis and influence treatment decisions in an unfavorable way. Moreover, some people may implicitly associate more invasive care with better quality care. They may be disappointed if advice and reassurance alone are offered by the doctor instead of surgical or physical treatment. In **Chapter 2** we will test this assumption by measuring people's implicit and explicit preferences towards two treatment options: supportive care (education, reassurance) *versus* physical care (surgery, injection).

Part Two | Surgeon's perspective

In the second part of this thesis, we focus on surgeons' perspectives on CMC1 osteoarthritis treatment. There is substantial surgeon-to-surgeon variation in treatment recommendations for CMC1 osteoarthritis.^{58,66,67} This treatment variation is unwarranted as it implies that many people are overtreated or undertreated.⁶⁸ Studies suggest that surgeon characteristics and preferences influence treatment decisions more than is merited.^{6,58} In order to reduce treatment variation, it is first of all important to understand what drives it. In **Chapter 3** we aim to gain more insight into treatment variation by assessing the prevalence of, and factors associated with, radiographs and intra-articular injections. In **Chapter 4** we focus on variation in surgeon's treatment recommendations for people with CMC1 osteoarthritis and varying characteristics.

In **Chapter 5** we hone in on surgeons' attitude towards the psychosocial aspects of CMC1 osteoarthritis. Recall that most people with CMC1 osteoarthritis do not seek care, and that some people experience pain and others, with the same pathophysiology, do not to the same extent. Symptom intensity is best explained through the bio-psycho-social model, in which variation in symptom intensity is largely accounted for by variation in mental and social health. There is notable evidence that people seeking care have greater symptoms of depression and less effective coping strategies compared to those with incidental CMC1 osteoarthritis.^{31,69-72} For other musculoskeletal conditions, such as chronic back pain, there is accumulating evidence that training in effective coping strategies reduces pain intensity and improves capability.⁷³ Therefore, psychosocial treatment opportunities may be an efficacious step in treatment of CMC1 osteoarthritis too.^{69,74,75} In **Chapter 5** we assess surgeons' willingness to offer psychological interventions for people with CMC1 osteoarthritis seeking specialty care.

Part Three | Surgical interventions for thumb carpometacarpal osteoarthritis

In the third part of this thesis, we focus on outcomes of existing and novel surgical treatments for CMC1 osteoarthritis. One of the many available surgical options is a pyrocarbon disc interposition arthroplasty. The biconvex disc made of pyrolytic carbon was introduced in 2005 to maintain thumb-axis length, strength and motion. It can be placed after partial trapeziectomy and is fixated with a tendon strip.^{76,77} Available studies on outcomes after pyrocarbon disc placement are mainly small cohort studies with a maximum of 46 people.^{76,78,79} In **Chapter 6** we will analyze a retrospective cohort of 137 people (164 thumbs) after pyrocarbon disc placement. Patient reported outcome measures, patient satisfaction, thumb strength and motion are assessed at a minimum of five years after surgery (median 7.2 years, range 5 to 11). A potential disadvantage of pyrocarbon disc interposition is the risk of (sub)luxation. Previous studies report rates of disc displacement between 11% and 21%, but only two of 39 people in these series requested revision surgery.^{77,78} These findings raise the question of whether the position of the disc affects treatment outcomes after pyrocarbon interposition arthroplasty. In **Chapter 7** we will evaluate the severity of radiographic disc displacement on patient reported outcomes (Michigan Hand Questionnaire [MHQ]) and other factors including pain intensity and thumb strength.

For people with persisting symptoms of CMC1 osteoarthritis desiring surgical intervention at a relatively young age, minimal invasive techniques that preserve the joint may be advantageous. Joint distraction is a joint sparing treatment for relatively young patients (generally before 65 years of age) with symptoms of osteoarthritis and

aims to postpone or prevent an invasive surgical intervention.⁸⁰⁻⁸³ Previous evidence on ankle and knee osteoarthritis shows that joint distraction can result in sustained clinical improvement with actual repair of joint cartilage after treatment.^{80,82-85} Joint distraction is also feasible for the osteoarthritic CMC1 joint.⁸⁶ In 2017 Spaans *et al.* published a pilot study on CMC1 joint distraction among five people with ongoing thumb pain despite nonoperative treatment.⁸⁶ One year after distraction treatment, all five patients experienced sufficient pain relief (mean pain score improved from 48 [range 25 to 71] to 14 [range 0 to 38] on scale from 0 to 100) and improved hand capability (mean MHQ scores improved from 48 [range 33 to 61] to 76 [range 64 to 96], on a scale 0 to 100). In **Chapter 8** we aim to assess the effect of CMC1 joint distraction in a larger cohort including 20 patients with a minimum period of two years after surgery.

Joint distraction is quite a new treatment for CMC1 osteoarthritis and much is still unknown, including optimal duration of the distraction. As with knee distraction, it is possible that lowering the distraction period from eight to six weeks may result in less adverse events and still achieve sufficient clinical benefits for people. In **Chapter 9**, we therefore describe a study protocol for a randomized controlled non-inferiority trial to compare six weeks with eight weeks of CMC1 joint distraction.

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Abbreviations

APL	Abductor Pollicis Longus
CI	Confidence Interval
CMC	Carpometacarpal
CPT	Current Procedural Terminology
CT	Computed Tomography
DASH	Disabilities of the Arm, Shoulder and Hand
FCR	Flexor Carpi Radialis
HON	Health On the Net
HT	Hemi-Trapezium
IAT	Implicit Association Test
ICC	Intraclass Correlation Coefficient
ICD	International Classification of Diseases
IQR	Interquartile Range
LRTI	Ligament Reconstruction and Tendon Interposition
MC	Metacarpal
MCID	Minimal Clinically Important Difference
MHQ	Michigan Hand Outcomes Questionnaire
MRI	Magnetic Resonance Imaging
OA	Osteoarthritis
OMERACT	Outcome Measures in Rheumatology Clinical Trials
OR	Odds Ratio
PA	Posteroanterior
PCS	Pain Catastrophizing Scale
PHQ	Patient Health Questionnaire
PP	Proximal Phalanx
PROM	Patient Reported Outcome Measure
PROMIS UE	Patient Reported Outcomes Measurement Information System for Physical Function of the Upper Extremity
PRWHE	Patient Rated Wrist/Hand Evaluation
REDCap	Research Electronic Data Capture
SD	Standard Deviation
SE	Standard Error
SOVG	Science of Variation Group
STT	Scapho-Trapezio-Trapezoidal
TI	Tendon Interposition
TMC	Trapeziometacarpal
TOMS	Thumb Base Osteoarthritis MRI Scoring System
VAS	Visual Analogue Scale





Part one

PATIENT'S PERSPECTIVE



Chapter 1

FACTORS ASSOCIATED WITH QUALITY OF ONLINE INFORMATION ON TRAPEZIOMETACARPAL ARTHRITIS

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ABSTRACT

Background: People increasingly search the Internet for information about common medical problems such as trapeziometacarpal (TMC) joint arthritis. But this information can be biased, inaccurate, and misleading. Medical professionals should be aware of what patients may be reading about their condition because concepts and beliefs can affect symptoms, limitations, and decision making.

Objectives: To determine what factors are associated with the quality and content of online information on trapeziometacarpal osteoarthritis.

Methods: This was a descriptive study. Using 3 search engines we entered "thumb arthritis" and measured the quality of design and content of websites using the DISCERN and LIDA tools, dominant tones using the IBM Watson Tone Analyzer, readability, and we recorded website characteristics.

Websites: We included 67 websites with mean scores for LIDA (\pm Standard Deviation) of 61 ± 13 ; for DISCERN 45 ± 12 . Nineteen (28%) were nonprofit and 14 (21%) HON code-accredited. All but 1 website exceeded the recommended sixth-grade reading level.

Results: In multivariable analysis, the website not having a clear preference for treatment was independently associated with greater design and content quality measured by DISCERN. Health On the Net (HON) code certification—a code of conduct for medical websites—and nonprofit websites had higher LIDA scores.

Conclusion: Online information on TMC arthrosis is difficult to read, often biased in favor of a particular treatment and influenced by profit and HON code. Hand surgeons should prepare to gently correct misconceptions established or reinforced, in part, by material found on the Internet.

INTRODUCTION

People increasingly search the Internet for information about medical problems. Seventy-four percent of adults in the United States have searched online for medical information.¹ There is a great deal of information available online for common illnesses such as trapeziometacarpal (TMC) arthritis.²⁻⁴ The American Medical Association and the National Institutes of Health recommend that patient information be written at a sixth-grade reading level.^{5,6} However, a recent article found that TMC arthritis online information uniformly exceeds this recommended reading level.⁷

The quality of online information varies.⁷⁻¹⁰ The information patients find can be biased, inaccurate, or misleading.⁹ Although there is a risk of misinformation and misunderstanding, many people are not aware of the accuracy or trustworthiness of the information they obtain. One study found that 9 out of 10 people describe the information they find as reliable.¹

It can be helpful for medical professionals to know the quality, tone and readability of online information most commonly read by their patients. There may be greater risk of incorrectly identifying patient preferences (going with preferences based on misconceptions rather than preferences based on values) if people have preconceptions and misconceptions that are influenced by online information.¹¹ This study addressed factors independently associated with TMC osteoarthritis online information design and content quality measured using the (1) DISCERN and (2) LIDA instruments.

MATERIALS & METHODS

Data source

Because our study involves no participants, it was exempt from institutional review board approval. On July 31st, 2017, we searched for “thumb arthritis” in 3 of the most popular Web search engines (Google, Yahoo!, and Bing) (Appendix 1).¹² Because results can be influenced by search history, we searched with the browser in privacy mode after deleting our search history and cookies. We recorded the first 50 hits of each search engine. After excluding duplicates ($n = 57$) and irrelevant websites ($n = 26$, eg, blogs, web-shops, research journals, videos), 67 websites were included.

Measurements

We recorded what treatment options were discussed (operative, nonoperative, both, or none), if there was a clear preference for 1 treatment and if the website was profit or nonprofit. For U.S. websites we used Nonprofit Explorer, a website that registers tax-exempt organizations, to look for nonprofit organizations.¹³ In addition, we registered if websites had a Health On the Net (HON) code. The Health On the Net Foundation is an internationally recognized organization that provides certification of conduct, a HONcode, for medical websites.¹⁴ A HON seal is accredited when a website meets their 8 principles: authoritative, complementary, privacy, attribution, justifiability, transparency, financial disclosure, and advertising policy.¹⁴ The HONcode is an accepted quality measure for online health sites.¹⁴⁻¹⁶

Readability is defined as the ease with which a reader can understand a written text.¹⁷ We used 3 of the most reliable scores for readability: the Flesch Reading Ease Score (FRES), the Flesch-Kincaid Grade Level (FKGL), and the Gunning Fog Index (GFI). We used the spelling and grammar tool in Microsoft Word (Microsoft Corp., Redmond, WA) to determine the FRES and FKGL. We used an online calculator to assess the GFI.¹⁸

The FRES rates text on a 100-point rating scale with higher scores representing easier readability. The FKGL reflects the required U.S. grade level to comprehend text, for example, a score of 7.2 indicates that text is expected to be understandable for an average student in seventh grade. It ranges from 3 to 12, with greater score indicating more difficult readability.¹⁹ The GFI is a measure of text readability based on the use of difficult words and the length of sentences.²⁰ Scores range from 0 to 15 and represent the estimated years of school education that is required to understand text on first reading.

Table 1. Definition of dominant tones.

	Definition
Emotional tones	
Anger	Is evoked due to injustice, conflict, humiliation, negligence, or betrayal. If anger is active, a person attacks the target, verbally or physically. If passive, a person silently sulks and feels tension and hostility.
Disgust	A feeling of revulsion or strong disapproval aroused by something unpleasant or offensive.
Fear	Fear is a response to impending danger. It is a survival mechanism that is triggered as a reaction to some negative stimulus. Fear can be a mild caution or an extreme phobia.
Joy	Joy or happiness has shades of enjoyment, satisfaction and pleasure. There is a sense of well-being, inner peace, love, safety and contentment.
Sadness	Indicates a feeling of loss and disadvantage. When a person can be observed to be quiet, less energetic and withdrawn, it may be inferred that sadness exists.
Language styles	
Analytical	A person's reasoning and analytical attitude about things.
Confident	A person's degree of certainty.
Tentative	A person's degree of inhibition.
Social tendencies	
Openness	The extent to which a person is open to experiencing a variety of activities.
Conscientiousness	A person's tendency to act in an organized or thoughtful way.
Extraversion	A person's tendency to seek stimulation in the company of others.
Agreeableness	A person's tendency to be compassionate and cooperative toward others.
Emotional range	The extent to which a person's emotions are sensitive to the individual's environment.

From IBM Cloud Docs. Personality Insights. Available at: <https://console.bluemix.net/docs/services/personality-insights/models.html#models>. Assessed June 2, 2018.

The IBM Watson Tone Analyzer measures tones that are present in written text in 3 categories: emotion (tones of anger, disgust, fear, joy, or sadness), language style (language that is analytical, confident, or tentative), and social tendencies (language reflecting openness, conscientiousness, extraversion, agreeableness, or emotional range) (Table 1). Scores of each tone range from 0 to 1.0 with scores greater than 0.5 indicating likely present, and scores greater than 0.75 indicating very likely present tones.²¹ We copied all website texts in the analyzer and used the document level to get a sense of the dominant tones of the website.

The DISCERN and LIDA tools gauge health information quality (Appendix 2). The DISCERN contains 16 questions, 8 on reliability and 7 on treatment information and choices, and 1 question on overall quality. Each question is rated on a 5-point Likert scale with answers from 1 'no' to 5 'yes' with a maximum score of 80. A higher score indicates greater overall quality.²² The LIDA measures 3 domains: accessibility, usability and reliability. It consists of 27 questions scored on a 4-point Likert scale, with scores ranging from 0 'never' to 3 'always'. Total scores range between 0 and 100 with a higher score indicating greater quality.²³ We rated usability and reliability because the online calculation for accessibility is no longer available.

Reliability

To assess intra-observer reliability, the DISCERN and LIDA were scored twice by a single reviewer (J.S.E.O.) with 2 weeks in between evaluations. The DISCERN and LIDA scores are the mean of both ratings. The intra-observer reliability, measured by intraclass correlation coefficient, of DISCERN was 0.91 (95% confidence interval [95% CI] = 0.85 – 0.94) and LIDA was 0.85 (95% CI = 0.77 – 0.90) (Table 2). Bland-Altman plots showed small difference in agreement between the 2 ratings and minimal systematic differences (Appendix 3).

Table 2. Reliability scores.

Variables scored	ICC* (95% CI)	P value
Intra-observer reliability		
DISCERN	0.91 (0.85 - 0.94)	<0.001
LIDA	0.85 (0.77 - 0.90)	<0.001
Inter-observer reliability		
DISCERN	0.95 (0.91 - 0.98)	<0.001
LIDA	0.88 (0.78 - 0.94)	<0.001
Inter-observer agreement**		
Treatment options discussed	Kappa ± SE	
	1.00 (0.17)	<0.001
Clear preference for treatment	1.00 (0.13)	<0.001
Nonprofit website	1.00 (0.17)	<0.001

ICC = intraclass correlation coefficient. **Bold** indicates statistically significant difference ($P < 0.05$). *Two-way mixed-effects model for ICC with 95% CI. **Inter-observer agreement as kappa with standard error.

To assess inter-observer reliability, a second reviewer (J.T.P.K.) rated 30 websites on DISCERN, LIDA, profit *versus* nonprofit, clear preference for 1 treatment or not, and what treatment options were discussed. The inter-observer reliability, measured by intraclass correlation coefficient, for DISCERN was 0.95 (95% CI = 0.91 – 0.98) and for

LIDA was 0.88 (95% CI = 0.78 – 0.94) (Table 2). The inter-observer reliability, measured by kappa, for nonprofit was 1.00 (standard error [SE], 0.17), for discussed treatment options 1.00 (SE = 0.17), and for clear preference for treatment 1.00 (SE, 0.13) (Table 2).

The IBM Watson Tone Analyzer was developed to analyze tones in customer service conversations. It is based on 96,000 customer service Twitter conversations, rated by 5 trained annotators for tone. IBM trained a machine-learning model based on this dataset. IBM states the model demonstrated high accuracy compared with a benchmark dataset, but they do not mention actual numbers to gauge the reliability of the machine-learning program.²⁴

Website characteristics

Of the 67 websites, 19 (28%) were nonprofit and 14 (21%) HONcode-accredited (Table 3). Mean readability scores for FRES were $53 \pm$ standard deviation (\pm SD) 9.7 (indicating "difficult to read"); for FKGL, 10 ± 1.7 (corresponds with 10th-grade reading level); and for GFI, 13 ± 2.0 (indicating 13 years of education required to understand text). Only 1 website was written below seventh-grade level (FKGL 4.7), as recommended by The National Institution of Health and The American Medical Association.^{6,7} The most likely present tones in websites texts were openness (0.85 ± 0.09) and tentative (0.72 ± 0.19). The mean LIDA score was 61 ± 13 , the mean DISCERN was 45 ± 12 .

Statistical analysis

Continuous variables are reported as mean and standard deviation (SD) and discrete variables as number and percentage. We used Student t-test to compare continuous and dichotomous variables, and Pearson correlation for 2 continuous variables.

We created 2 backward stepwise regression models to identify independent predictors of websites' quality of information measured with DISCERN and LIDA. We included all factors with *P* less than 0.10 on bivariate analysis (Table 4) in the final multivariable models (Table 5). Adjusted R^2 indicates the proportion of variability in the outcome variable (either DISCERN or LIDA score) that is accounted for by the model. Semipartial R^2 expresses the specific variability of a given independent variable in the model.

An *a priori* sample size estimate indicated that a sample of 65 websites would provide 80% statistical power, with alpha set at 0.05, for a regression with 5 independent variables if a single variable would account for 10% or more of the variability in quality, and our complete model would account for 20% of the overall variability in quality.

Table 3. Website characteristics.

Variables	Values
Websites	67
HONcode, n (%)	14 (21)
Nonprofit, n (%)	19 (28)
Both treatment options discussed, n (%)	53 (79)
Clear preference for treatment, n (%)	
None	44 (66)
Nonoperative treatment	15 (22)
Operative treatment	8 (12)
Readability scores	
FRES	53 ± 9.7
FKGL	10 ± 1.7
GFI	13 ± 2.0
Website tone	
Anger	0.07 ± 0.05
Disgust	0.08 ± 0.08
Fear	0.26 ± 0.13
Joy	0.35 ± 0.18
Sadness	0.61 ± 0.04
Analytical	0.63 ± 0.14
Confident	0.00 ± 0.00
Tentative	0.72 ± 0.19
Openness	0.85 ± 0.09
Conscientiousness	0.29 ± 0.14
Extraversion	0.09 ± 0.07
Agreeableness	0.13 ± 0.10
Emotional range	0.24 ± 0.12
Quality of information	
DISCERN	45 ± 12
LIDA	61 ± 13

Continuous variables as mean (\pm SD); discrete variables as number (percentage). HON: Health On the Net code; FRES: Flesch Reading Ease Score; FKGL: Flesch-Kincaid Grade Level; GFI: Gunning Fog Index.

Table 4. Bivariate analyses.

Variables	DISCERN	P value	LIDA	P value
HONcode				
Yes	51 ± 10	0.032	71 ± 11	0.0017
No	43 ± 12		59 ± 13	
Non-profit				
Yes	50 ± 11	0.033	69 ± 12	0.0020
No	43 ± 12		58 ± 13	
Both treatment options discussed				
Yes	47 ± 11	0.0022	62 ± 14	0.17
No	36 ± 12		57 ± 10	
Clear preference for treatment				
None	49 ± 10	0.0004	64 ± 13	0.019
Nonoperative treatment	36 ± 12		55 ± 13	
Operative treatment	39 ± 12		55 ± 9.5	
Readability scores (r)				
FRES	-0.063	0.61	-0.2	0.10
FKGL	-0.1	0.42	0.086	0.49
GFI	-0.1562	0.21	0.046	0.71
Website tone (r)				
Anger	-0.1811	0.14	-0.1355	0.27
Disgust	0.17	0.18	0.13	0.31
Fear	0.2828	0.020	0.18	0.14
Joy	-0.04	0.75	-0.16	0.18
Sadness	-0.1815	0.14	-0.12	0.32
Analytical	0.11	0.39	-0.13	0.32
Confident	0.00	0.00	0.00	0.00
Tentative	0.23	0.059	0.27	0.030
Openness	-0.042	0.74	-0.14	0.26
Conscientiousness	-0.0304	0.81	-0.17	0.16
Extraversion	-0.2337	0.057	-0.11	0.38
Agreeableness	-0.0175	0.89	0.07	0.58
Emotional range	-0.2124	0.084	-0.18	0.14

Bold indicates statistically significant difference ($P < 0.05$). Pearson correlation indicated by r ; continuous variables as mean (\pm SD); discrete variables as number (percentage).

RESULTS

DISCERN

Accounting for potential interaction of variables using multivariable analysis, greater website quality measured by DISCERN was independently associated with not having a clear preference for treatment, compared with having a clear preference (preference for either nonoperative treatment: β regression coefficient [β] = -12; 95% CI = -19 to -6.0; semipartial R^2 = 0.18, P < 0.05; or preference for operative treatment: β = -9.7; 95% CI = -18 to -1.4, semipartial R^2 = 0.068, P < 0.05) (adjusted R^2 = 0.19) (Table 5). Dominant website tone of fear (r = 0.29, P < 0.05), being HONcode-certified (P = 0.032), and nonprofit websites (P = 0.033) were significant in bivariate analysis but were not retained in the final model (Table 4).

LIDA

Greater website quality, measured by LIDA, was independently associated with being HONcode-certified (β = 11; 95% CI = 4.3 to 18; semipartial R^2 = 0.12; P < 0.05) and being nonprofit (β = 10; 95% CI = 3.7 to 16; semipartial R^2 = 0.12; P < 0.05) (adjusted R^2 = 0.23) (Table 5). Dominant tentative tone (r = 0.27, P = 0.030) and clear preference for treatment (P = 0.019) were significant in bivariate analysis but were not retained in the final model (Table 4).

Table 5. Stepwise regression for predictors of quality of information.*

Dependent variables	Predictors	Regression coefficient (95% confidence interval)	Standard error	P value	Semipartial R^2	Adjusted R^2
DISCERN	Clear preference for treatment					
	None	<i>reference value</i>				
	Nonoperative treatment	-12 (-19 to -6,0)	3.2	<0.001	0.18	0.19
Operative treatment	-9.7 (-18 to -1.4)	4.1	0.022	0.068		
LIDA	HONcode	11 (4.3 to 18)	3.5	0.002	0.12	0.23
	Nonprofit	10 (3.7 to 16)	3.2	0.002	0.12	

Bold indicates statistically significant difference (P < 0.05). *Variables inserted in the stepwise regression for DISCERN model: HONcode, nonprofit, treatment options, treatment preference, website tones: fear, tentative, extraversion, emotional range. For LIDA model: HONcode, nonprofit, treatment preference, website tone: tentative.

DISCUSSION

Information that patients find online about common health conditions like TMC arthritis can be difficult to read, biased, and misleading.^{1,7-10} This study addressed factors associated with the design and content quality of TMC arthritis online information measured by DISCERN and LIDA.

We acknowledge some study limitations. First, this study is limited to websites that were written in English and available on the date of search, July 31, 2017. The Internet is changing quickly, and its dynamic character makes it impossible to predict when and how online information will be edited or updated. Our study might not reflect the most recent available online information regarding TMC arthritis. Second, we used the search term "thumb arthritis" and no other medical terms such as "carpometacarpal" or "trapeziometacarpal osteoarthritis." Different terms would have produced a wider range of websites; however, the term "thumb arthritis" may be more commonly used by patients than sophisticated medical terms. Third, the quality of videos, images, and other multimedia factors were not assessed, although these materials might contribute to overall comprehension and better understanding of health information. Fourth, the DISCERN and LIDA quality assessment tools rely on subjective input, despite strict criteria for assessment of each rating. This may lead to bias of the observers, although our study showed good intra- and inter-observer reliability scores. Fifth, we addressed the quality and not the accuracy of the content based on current best evidence. It is possible to present quality content that is not evidence-based. Sixth, the reliability of the Watson tone analyzer for medical websites is unknown. In addition, language assessment tools only give an estimation of the likelihood of dominant tones and emotions in written text. It does not address the purposes of the author nor the existence of possible bias. Although little is studied about the correlation between language assessment tools and patient information websites, tone analyzers are increasingly used by communication experts in the field of marketing, customer service, and education.

The finding that lower website quality measured by DISCERN was independently associated with a clear preference for treatment, compared with no clear preference, can be explained by the fact that the DISCERN tool focuses specifically on the quality of written information about treatment choices.^{22,25} The DISCERN instrument can be used to assess the quality of a website that discusses 1 particular treatment choice, as long as it is clear that other treatment choices are available (Questions 6 and 14) and that only 1 treatment option is discussed by the authors (Question 1). Websites that only focus on 1 treatment option and are not clear about other available treatments

score lower on the DISCERN measure. A previous study investigated TMC arthritis information websites for their readability and quality.⁷ To assess quality, they used more limited and less often used measures with fewer answer options, such as the HONcode Site Evaluation Form,²⁶ instead of DISCERN and LIDA tools.^{23,25,27} In addition, they did not analyze website tones or performed multivariable analysis to assess factors associated with the quality of information. They found that health information on TMC arthritis is of generally poor quality, is predominantly posted by physician authors and too hard to read. Of the 60 websites analyzed, only three contained a HONcode.⁷ Of the 60 websites analyzed, only 3 contained a HONcode.⁷

The finding that greater website quality measured by LIDA, was associated with being HONcode-certified, is in line with previous findings. Several studies on the quality of online information about colorectal cancer information, chronic pain, asthma, and scoliosis indicate HON certification as a factor associated with greater website quality.^{10,28-31} Conversely, other studies on TMC arthritis, vascular anomalies and vertebroplasty, including HON certification as an independent variable, did not find this association,^{7,17,32} possibly owing to the low number of HON-certified websites in the latter studies' samples. Nonprofit websites showed better quality, probably because they have no commercial aims to sell products or services. Two studies on the quality and readability of online colorectal cancer information¹⁰ and of online cauda equina syndrome information³⁰ indicate a similar relationship between greater website quality and government-authored websites. Whereas DISCERN assesses the presentation of treatment options, the LIDA tool focuses more on usability and reliability. Specific tones were significant in bivariate analysis suggesting that they might be clues to lower quality, but were not independent of the profit status and HONcode. Readability was not associated with quality scores, perhaps because the websites on average were written for relatively highly educated people.^{7,9,28,33-35} Another explanation is that LIDA and DISCERN tools do not sufficiently assess and capture readability levels of websites. The DISCERN instrument does not contain any question regarding readability, the LIDA tool only contains 1 (2.1.2.: Is the level of detail appropriate to their level of knowledge?). This lack of readability items should be kept in mind when using these outcome measures to rate website quality.

This study found that web-based information on TMC arthritis is difficult to read, often biased in favor of a particular treatment, and influenced by profit and HONcode. Improved websites and decision aids (tools providing unbiased information to patients and that help clarify patients' preferences) could help ensure that patient decisions about TMC arthritis and other common health conditions are based on their values and not on misconceptions. Measures of design, content, tone, and readability can assist with the development of improved patient information.

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APPENDICES

Appendix 1: Included and excluded websites.

Included websites

Engine	Website
Yahoo	AAHS
Google	AAOS
Yahoo	AAOS
Google	AgilityOrthopedics
Google	Arthritis Foundation
Yahoo	ArthritisFoundation
Google	ArthritisHealth
Bing	ArthritisRelieved
Yahoo	ASSH
Google	BelMarra
Google	BioPro
Google	BoneTalks
Google	BSSH
Google	BurlingtonFreePress
Google	C.NoelHenly
Google	ChicagoTribune
Google	ClevelandClinic
Yahoo	ConsumerHealthDigest
Google	DailyMail
Google	DallasNews
Yahoo	DicksonDiveley
Google	Dr.Sinner
Google	Drugs.com
Google	EatonHand
Google	EverydayHealth
Yahoo	Fitzmaurice

URL

<http://handsurgery.org/multimedia/files/public/thumbarthritis.pdf>

<http://orthoinfo.aaos.org/topic.cfm?topic=A00210>

<http://orthoinfo.aaos.org/topic.cfm?topic=A00224>

<http://www.agilitydoctor.com/learning/agility-magazine/200-thumb-arthritis-what-can-be-done-about-it>

<http://www.arthritis.org/living-with-arthritis/treatments/joint-surgery/types/other/new-thumb-surgery-options.php>

<http://www.arthritis.org/living-with-arthritis/treatments/medication/drug-types/other/oa-thumb-treatment.php>

<https://www.arthritis-health.com/types/rheumatoid/hand-rheumatoid-arthritis-signs-and-symptoms>

<http://arthritisrelieved.com/arthritis-thumb-pain-thumb-arthritis/>

<http://www.assh.org/LinkClick.aspx?fileticket=AsKorJBUZsw%3d&portalid=1>

<http://www.belmarrahealth.com/thumb-arthritis-pain-causes-treatments/>

<http://bioproimplants.com/portfolio-view/thumb-arthritis>

<http://www.bonetalks.com/thumbarthritis/>

http://www.bssh.ac.uk/patients/conditions/24/basal_thumb_arthritis

<http://www.burlingtonfreepress.com/story/life/2017/03/13/thumb-arthritis-treatment-symptoms-mikolyzk-manitowoc-hfm/99124612/>

<http://noelhenley.com/arthritis-base-of-the-thumb/>

<http://www.chicagotribune.com/suburbs/highland-park/community/chi-ugc-article-5-main-causes-you-must-know-about-thumb-joint-2014-05-15-story.html>

<https://my.clevelandclinic.org/health/articles/arthritis-thumb-base>

<https://www.consumerhealthdigest.com/joint-pain/thumb-arthritis.html>

<http://www.dailymail.co.uk/health/article-3952498/Blast-arthritis-Exocet-thumb-implant-Using-latest-technology-joint-replacement-restore-mobility.html>

<https://www.dallasnews.com/life/healthy-living/2013/11/04/is-that-pain-in-your-thumb-arthritis>

<https://www.dd-clinic.com/thumb-cmc-arthritis/>

<http://sinnerchiropractic.com/z-thumb-arthritis/>

<https://www.drugs.com/mcd/thumb-arthritis>

<http://www.eatonhand.com/hw/hw003.htm>

<https://www.everydayhealth.com/arthritis/0404/thumbs-down-thumb-arthritis-on-the-rise.aspx>

<http://www.fitzhand.com/thumb-arthritis/>

Appendix 1: Continued.

Included websites	
Engine	Website
Google	Gibaud
Bing	HandAndWristClinic
Bing	HandToShoulderCenter
Google	HealthCentral
Google	Healthline
Google	Healthline
Google	HoustonMethodist
Google	HSS
Google	IrishTimes
Google	JohnMuir
Yahoo	JointPainSolutions
Yahoo	LawrenceLi
Yahoo	Lifescript
Google	LondonOrthopaedicClinic
Google	MayoClinic
Yahoo	MHS
Google	MichiganMedicine
Google	MyHand
Google	MyHealthAlberta
Yahoo	Nebraska
Bing	NHS
Yahoo	NorthwellHealth
Google	OhMyArthritis
Yahoo	OhMyArthritis
Google	OrthoBullets
Yahoo	Orthopod
Bing	PHS
Google	Prolotherapy
Google	Regenexx
Google	TaluneUniversity
Google	TheHandandWristInstitute

URL

<https://www.gibaud.com/EN/pathology/hand-wrist/basal-thumb-arthritis.htm>
<http://www.handandwristclinic.com/article.asp?article=107>
<https://handtoshoulderwisconsin.com/our-specialties/hand/thumb-arthritis/>
<https://www.healthcentral.com/article/oh-my-aching-hands-the-thumb>
<http://www.healthline.com/health/osteoarthritis/thumb#overview1>
<http://www.healthline.com/health/basal-joint-arthritis>
<http://www.houstonmethodist.org/orthopedics/where-does-it-hurt/hand/arthritis-of-the-thumb/>
https://www.hss.edu/conditions_basal-joint-arthritis-overview.asp
<http://www.irishtimes.com/business/innovation/new-implant-could-improve-treatment-of-thumb-arthritis-1.2991175>
<https://www.johnmuirhealth.com/health-education/conditions-treatments/bones-joints/thumb-arthritis.html>
<http://www.joint-pain-solutions.com/thumb-joint-pain.html>
<https://www.orthopedicshoulder.com/services/hand/thumb-arthritis/>
http://www.lifescript.com/health/a-z/mayo/t/thumb_arthritis.aspx
<http://www.londonorthopaedic.com/thumb-arthritis/>
<http://www.mayoclinic.org/diseases-conditions/thumb-arthritis/basics/treatment/con-20027798>
<http://www.midwesthand.com/specialty-treatment/thumb-arthritis/>
<https://medicine.umich.edu/dept/orthopaedic-surgery/patient-care-services-hand-upper-extremity/basilar-thumb-arthritis>
<http://www.myhand.com.au/handouts/anatomy/joint/basal-thumb-arthritis-joint>
<https://myhealth.alberta.ca/health/pages/conditions.aspx?Hwid=hw125723>
<http://www.carpaltunnelrelief.net/Basilar%20Thumb%20Arthritis>
<http://www.nhs.uk/conditions/osteoarthritis/Pages/Introduction.aspx>
<https://www.northwell.edu/find-care/conditions-we-treat/arthritis-thumb>
<http://www.blog.ohmyarthritis.com/my-thumb-hurts-do-i-have-thumb-arthritis/>
<http://www.ohmyarthritis.com/Learn/About-Health-Conditions/CMC-thumb-arthritis.html>
<http://www.orthobullets.com/hand/6054/basilar-thumb-arthritis>
<http://eorthopod.com/arthritis-of-the-thumb/>
<http://phsurgery.com/thumb-arthritis/>
<http://www.prolotherapy.org/thumb-arthritis/>
<https://www.regenexx.com/hand-basal-joint-cmc-arthritis-treatment/>
<https://medicine.tulane.edu/find-doctor/orthopaedics-clinics/problems-conditions/thumb-arthritisbasal-thumb-arthritis>
<http://www.handandwristinstitute.com/basal-thumb-arthritis/>

Appendix 1: Continued.

Included websites

Engine	Website
Google	TheRheumatologist
Google	UWMedicine
Google	UWMedicine
Yahoo	VeryWell
Yahoo	VeryWell
Google	ViveHealth
Google	Wellington
Yahoo	Wikipedia
Yahoo	Ygoy
Bing	YourHealthyJoints

Excluded websites:

Engine	Website
Yahoo	Amazon
Yahoo	Ebay
Bing	Pinterest
Bing	Pinterest
Google	PubMed
Yahoo	PubMed
Bing	Walmart
Yahoo	Youtube
Bing	Youtube
Bing	Youtube
Google	BoulderCentre
Google	3PointProducts
Google	MayoClinic
Google	MayoClinic

URL

<http://www.the-rheumatologist.org/article/nonsurgical-treatments-can-relieve-pain-improve-hand-function-in-thumb-carpometacarpal-joint-osteoarthritis/>

<http://www.orthop.washington.edu/?q=patient-care/hand/thumb-arthritis.html>

<http://www.uwmedicine.org/health-library/Pages/thumb-arthritis.aspx>

<https://www.verywell.com/thumb-arthritis-2549457>

<https://www.verywell.com/thumb-osteoarthritis-what-you-need-to-know-2552320>

<https://www.vivehealth.com/blogs/resources/thumb-brace-for-arthritis>

<http://www.wellington-hand-physiotherapy.co.nz/thumb-pain-and-arthritis.html>

<https://en.wikipedia.org/wiki/Arthritis>

<http://arthritis.ygoy.com/remedies-for-thumb-arthritis/>

<http://yourhealthyjoints.com/thumb-arthritis/>

URL**Reason for exclusion**

<https://www.amazon.com/arthritis-thumb-splint/s?ie=UTF8&page=1&rh=i%3Aaps%2Ck%3Aarthritis%20thumb%20splint>

webshop

https://www.ebay.com/sch/i.html?_nkw=arthritis+thumb+splint

webshop

<https://nl.pinterest.com/studiomaya2/thumb-arthritis/>

pictures only

<https://nl.pinterest.com/loriakm/thumb-arthritis/>

pictures only

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2599975/>

research journal

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684204/>

research journal

<https://www.walmart.com/c/ep/thumb-braces>

webshop

<https://www.youtube.com/watch?v=3V3YEUYRvg0>

video

https://www.youtube.com/watch?v=XZ_Gy35DGPk

video

<https://www.youtube.com/watch?v=SfOAOq5QPZk>

video

<https://bouldercentre.com/thumb-arthritis/>

video

<http://www.3pointproducts.com/design-line-thumb-arthritis-splint>

webshop

<http://www.mayoclinic.org/diseases-conditions/thumb-arthritis/basics/definition/con-20027798>

overlapping

<http://www.mayoclinic.org/diseases-conditions/thumb-arthritis/basics/symptoms/con-20027798>

overlapping

Appendix 1: Continued.

Excluded websites	
Engine	Website
Google	ASSH
Bing	ClickBank
Yahoo	DJOGlobal
Yahoo	Healthline
Yahoo	HeraldTimesReporter
Yahoo	HSS
Google	NYHandandWristCenter
Yahoo	OhMyArthritis
Bing	PureNaturalHealing
Yahoo	UconnHealth
Yahoo	WebMD
Google	OrthoCare

AAHS, American Association for Hand Surgery; AAOS, American Academy of Orthopaedic Surgeons; ASSH, American Society for Surgery of the Hand; BSSH, British Society for Surgery of the Hand; HSS, Hospital for Special Surgery; MHS, Midwest Hand Service;

URL	Reason for exclusion
http://www.assh.org/handcare/hand-arm-conditions/thumb-arthritis	overlapping
http://hiddensurvivalmuscle.com/?hop=indy2559	not relevant
http://www.djoglobal.eu/en_UK/index.html	not relevant
http://www.healthline.com/health/osteoarthritis/thumb	overlapping
http://www.htrnews.com/story/life/2017/06/08/ask-doctor-thumb-arthritis-there-such-thing/381549001/	overlapping
https://www.hss.edu/conditions_basal-joint-arthritis-therapy.asp	overlapping
http://www.handsurgeonsnewyork.com/arthritis-of-the-thumb/	overlapping
http://www.blog.ohmyarthritis.com/my-thumb-hurts-whats-wrong/	overlapping
http://www.purenaturalhealing.com/go/	not relevant
http://uconnsportsmed.uhc.edu/injury/handwrist/arthritis_thumb.html	overlapping
http://www.webmd.com/rheumatoid-arthritis/guide/trigger-finger#1	not relevant
https://www.ortho-care.eu/en/hand-and-wrist/disorders/basal-thumb-arthritis	not operational anymore

NHS, National Health Service; PHS, Public Health Service; UWMedicine, University of Washington Medicine; DJOGlobal, DJ Orthopedics Global; NYHandandWrist-Center: New York Hand and Wrist Center.

Appendix 2: DISCERN and LIDA questionnaires.

DISCERN questions:

- 1 Are the aims clear?
 - 2 Does it achieve its aims?
 - 3 Is it relevant?
 - 4 Is it clear what sources of information were used to compile the publication (other than the author or producer)?
 - 5 Is it clear when the information used or reported in the publication was produced?
 - 6 Is it balanced and unbiased?
 - 7 Does it provide details of additional sources of support and information?
 - 8 Does it refer to areas of uncertainty?
 - 9 Does it describe how each treatment works?
 - 10 Does it describe the benefits of each treatment?
 - 11 Does it describe the risks of each treatment?
 - 12 Does it describe what would happen if no treatment is used?
 - 13 Does it describe how the treatment choices affect overall quality of life?
 - 14 Is it clear that there may be more than one possible treatment choice?
 - 15 Does it provide support for shared decision-making?
 - 16 Based on the answers to all the above questions, rate the overall quality of the information about treatment choices.
-

LIDA questions:

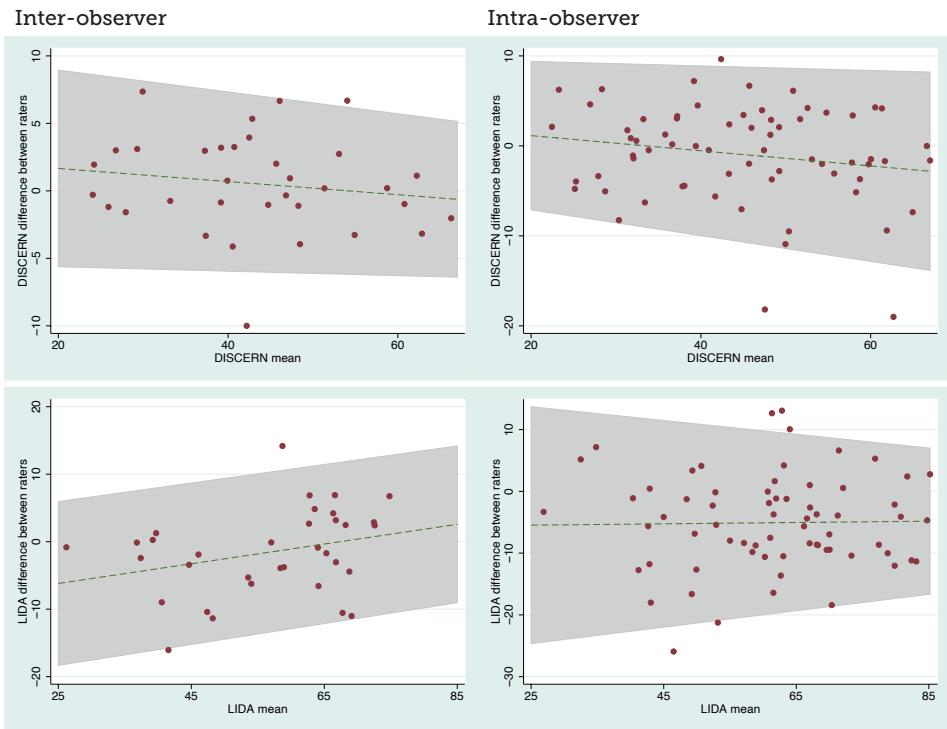
Usability

- 1.1 Is there a clear statement of who this web site is for?
 - 1.2 Is the level of detail appropriate to their level of knowledge?
 - 1.3 Is the layout of the main block of information clear and readable?
 - 1.4 Is the navigation clear and well structured?
 - 1.5 Can you always tell your current location in the site?
 - 1.6 Is the colour scheme appropriate and engaging?
 - 2.1 Is the same page layout used throughout the site?
 - 2.2 Do navigational links have a consistent function?
 - 2.3 Is the site structure (categories or organisation of pages) applied consistently?
 - 3.1 Does the site provide an effective search facility?
 - 3.2 Does the site provide effective browsing facilities?
 - 3.3 Does the design minimise the cognitive overhead of using the site?
 - 3.4 Does the site support the normal browser navigational tools?
 - 3.5 Can you use the site without third party plug-ins?
 - 4.1 Can the user make an effective judgment of whether the site applies to them?
 - 4.2 Is the web site interactive?
 - 4.3 Can the user personalise their experience of using the site?
 - 4.4 Does the web site integrate non-textual media?
-

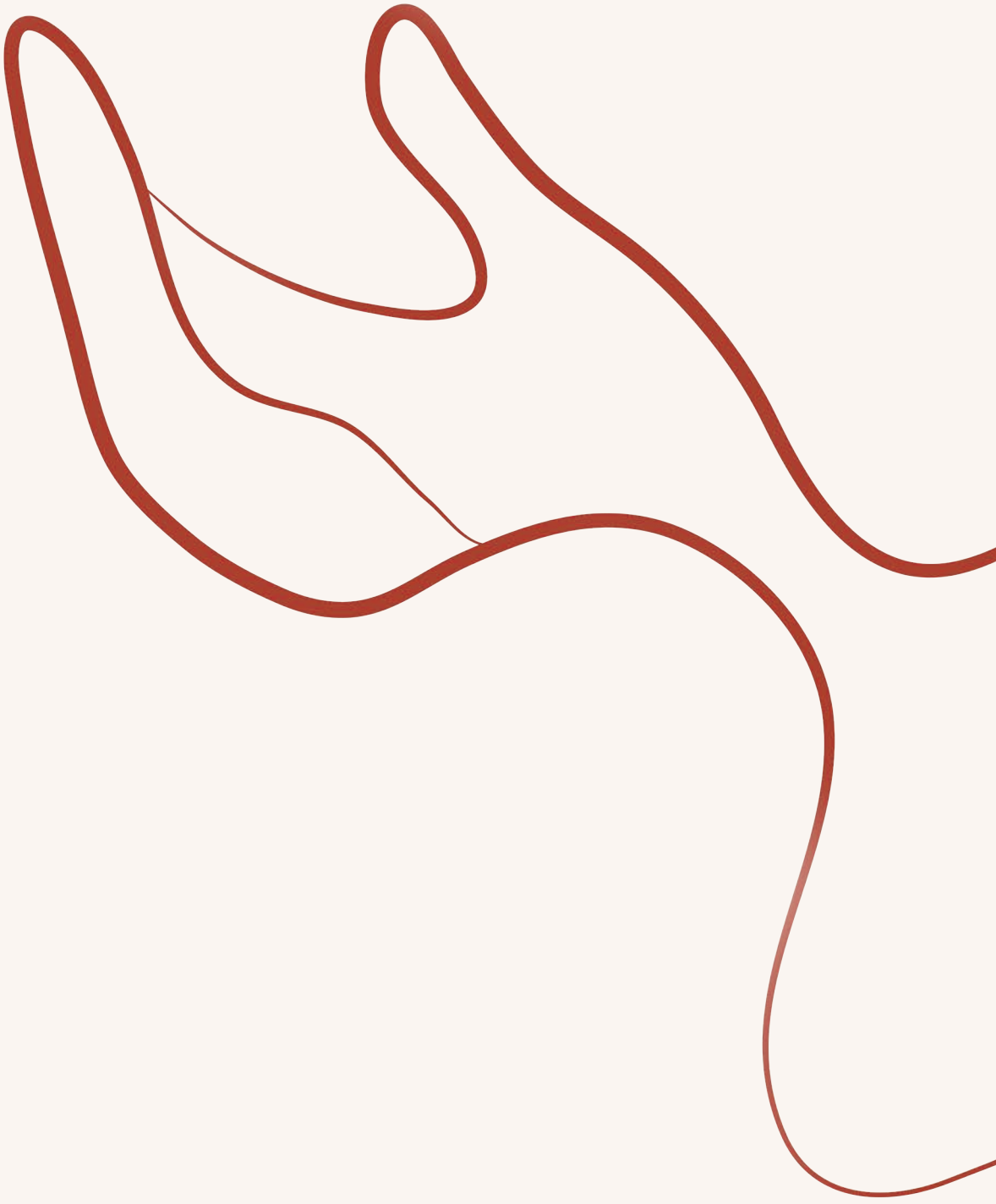
Appendix 2: Continued.

Reliability

- 1.1 Does the site respond to recent events?
- 1.2 Can users submit comments on specific content?
- 1.3 Is site content updated at an appropriate interval?
- 2.1 Is it clear who runs the site?
- 2.2 Is it clear who pays for the site?
- 2.3 Is there a declaration of the objectives of the people who run the site?
- 3.1 Does the site report a clear content production method?
- 3.2 Is this a robust method?
- 3.3 Can the information be checked from original sources?



Appendix 3: Bland-Altman plots for inter- and intra-observer reliability.



Chapter 2

DO PATIENTS UNCONSCIOUSLY ASSOCIATE
SUGGESTIONS FOR MORE-INVASIVE
TREATMENT WITH BETTER CARE?

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Clinical Orthopaedics and Related Research

2019;477(3):514-522

ABSTRACT

Background: It seems common for patients to conceive of care in physical terms, such as medications, injections, and procedures rather than advice and support. Clinicians often encounter patients who seem to prefer more testing or invasive treatments than expertise supports.

Objectives: To determine whether patients unconsciously associate suggestions for invasive treatments with better care.

Methods: This was a cross-sectional observational cohort study conducted among six surgeon offices in a large urban area. Patients completed a survey of demographics and their expressed preference about receiving either physical treatment or support. Physical treatment was defined as any procedure, surgery, injection, or medication; support was defined as reassurance, conversation, and education, but no physical treatment. Patients then completed the Implicit Association Test (IAT), specifically designed for this study, to evaluate implicit preferences toward treatment or support. Scores (D scores) range from -2 to 2, where 0 indicates no implicit preference. Positive scores indicate a preference toward "receiving a physical treatment is good care", and negative scores indicate a preference toward "receiving supportive care is good care".

Patients: 125 new patients with a mean age of 50 ± 15 years (range 18 to 79) and 56 (45%) were men. Patients had a broad spectrum of upper and lower extremity musculoskeletal conditions, ranging from trigger finger to patellofemoral syndrome.

Results: There was a slight implicit association of good care with support ($D = -0.17 \pm 0.62$; range, -2 to 1.2) and an expressed preference for physical treatment (mean score = 0.63 ± 2.0 ; range, -3 to 3). Patients who received both physical and supportive treatment had greater implicit preference for good care, meaning supportive care, than patients receiving physical care alone ($b = -0.42$; 95% CI, -0.73 to -0.11; $p = 0.008$; semipartial $R^2 = 0.04$). Gender was independently associated with a greater expressed preference for physical treatment, with men expressing this preference more than women ($b = 1.0$; 95% CI, 0.31–1.7; $p = 0.005$; semipartial $R^2 = 0.06$). An expressed preference for treatment was not associated with implicit preference ($b = 0.01$; 95% CI, -0.04 to 0.06; $p = 0.721$).

Conclusion: Although surgeons may sometimes feel pressured toward physical treatments, based on our results and cutoff values, the average patient with upper or lower extremity symptoms has a slight implicit preference for supportive treatment and would likely be receptive.

INTRODUCTION

Patients commonly conceive of care in physical terms, such as medications, injections, and procedures. To some, compassion, advice, and reassurance may not seem like adequate care. For example, a retrospective study with data from 7,800 general practices in the United Kingdom using the General Practice Patient Survey (GPPS), the national Quality and Outcomes Framework, and standardized measures of antibiotic prescribing volumes in 2012 to 2013, found that clinicians who resisted prescribing antibiotics received lower ratings for patient satisfaction.¹ In the setting of surgical specialty care, a patient who thinks an operation is the key to improved health may consider a "good doctor" as one who offers surgery and might be disappointed by a doctor who offers advice and reassurance alone. Surgeons may perceive their role similarly and feel more satisfied and rewarded by intervention.

Preference can be divided into explicit (expressed) and implicit (unconscious) preference. An expressed preference is influenced by an individual's self-presentational goals, such as social desirability. Implicit attitudes are manifest as actions or judgments that are automatic and unconscious.⁷ Computer-based Implicit Association Tests (IAT), introduced in 1998, can be used to measure implicit preferences.⁹ The IAT is based on the time it takes people to match certain words with certain categories. The IAT measures implicit preferences in the speed that people connect categories in their minds. Faster connections are consistent with a person's implicit preferences. For example, if a patient associates a good doctor with surgical treatment and a bad doctor with supportive therapy, they will more quickly match words associated with these combinations than they will match words associated with the opposite (good doctor and supportive therapy *versus* bad doctor and surgical therapy).

A recent systematic review identified several patient characteristics associated with unconscious preference of clinicians toward patients, including age, gender, race, socioeconomic status, and weight.⁵ For instance, physicians tend to have an implicit preference for recommending some specific treatment interventions to white patients more than black patients, such as greater use of thrombolytic therapy and coronary artery bypass surgery.^{5,6,17} It seems likely that implicit preference affects how patients assess expert information and make decisions, but this is less studied. Clinicians often encounter patients who would like more testing or invasive treatments than expert supports. This gives us the sense that patients may have an implicit preference for these types of physical treatments

over reassurance and supportive treatment. If this concern is inaccurate, it might combine with the awkwardness of correcting misconceptions, less training in effective communication strategies, surgeon preferences, and other factors to increase the risk of an error in diagnosis of patient preferences.

In this study, we asked: (1) Do patients have (A) an implicit preference and (B) an expressed preference for a physical intervention (such as a pill, an injection, or surgery) over supportive care (such as reassurance and education)? (2) What factors are independently associated with both an implicit and an expressed preference for a physical intervention over supportive care? (3) Is there a relationship between a patient's implicit preference toward or away from a physical intervention and his/her expressed preference on that subject?

PATIENTS & METHODS

Study design

After institutional review board approval of this cross-sectional, observational cohort study, we prospectively enrolled 125 adult patients between November 28, 2017 and February 26, 2018. Patients were seen at six orthopaedic upper and lower extremity specialist offices in a large urban area. We considered all new, English-speaking patients who were 18 to 89 years old, visiting one out of 13 participating orthopaedic surgeons for any upper or lower extremity problem. Patients had to be able to provide informed consent, to understand the IAT, and to know how to use a laptop (read a computer screen and use a keyboard). We excluded patients who were not able to use the laptop. We did not have exclusion criteria for certain conditions; patients included had a broad spectrum of upper or lower extremity conditions, ranging from trigger finger to patellofemoral syndrome. Five research assistants (three of whom were authors: J.T.P.K., J.S.E.O., T.T.H.T.), who were not involved with patient treatment, described the study to patients before or after the visit with the surgeon. We were granted a waiver of written informed consent. Patients indicated their consent by completing the questionnaire and the IAT.

Measurements

Patients were asked to complete a questionnaire and the IAT at the beginning or end of their visits. The questionnaire consisted of (1) demographics: age, gender, race/ethnicity, marital status, education level, work status, comorbidities (cardiovascular, musculoskeletal, mental, other, or none), appointment type (first visit or second opinion), diagnosis type (traumatic or nontraumatic orthopaedic condition); and (2) a question for the self-reported (explicit) preference for treatment, measured on a 7-point Likert scale, with scores of 1, 2, and 3 for "slight/moderate/strong preference for physical treatment," such as an injection, medication, surgery, or physical therapy, respectively, scores of -1, -2, and -3 for "slight/moderate/strong preference for supportive treatment," including support, education, or reassurance, respectively, and a score of 0 indicating "no preference for physical or supportive treatment." The research assistant who enrolled the patient advised the office and surgeon on the questionnaire. The surgeon entered diagnosis and treatment (physical, supportive, or both). All questionnaires were administered on an encrypted tablet via secure, HIPAA compliant electronic platform: Research Electronic Data Capture (REDCap; Nashville, TN, USA), which is a secure web-based application for building and managing online surveys and databases.¹³ After completing the questionnaire, the patients completed the IAT to test implicit bias toward treatment.

The IAT

People's expressed preferences do not always match their implicit associations. For example, many people believe that men and women are equally suited to science. However, many people completing an IAT associate men with science more than women.⁸ The IAT measures unconscious or unacknowledged associations.¹⁹ As mentioned earlier, the IAT is based on the time it takes people to match certain words with certain categories. The idea is that making a response is easier when closely related items share the same response key.¹⁹ When completing an IAT, patients are asked to quickly sort words into categories (for example, to put "Injection" with "Treatment" or "Reassurance" with "Support") by using two response keys, which were the left and right arrow keys in our study. Faster connections are consistent with a person's implicit associations. Patients were shown two combinations of four categories. Words (items) assigned to one of the four categories were displayed on the screen. They then quickly sorted items into categories using the two response keys. We downloaded free IAT software from Meade AW on an encrypted laptop.¹⁴ The IAT measures the latencies between the two response keys for the four categories of stimuli (Table 1).⁹

Table 1. Sequence of steps in the IAT.

Steps	Number of trials	Function	Categories assigned to left-key response	Categories assigned to right-key response
1	10	Practice	Treatment	Support
2	10	Practice	Good care	Bad care
3	10	Test	Treatment + Good care	Support + Bad care
4	10	Practice	Support	Treatment
5	10	Test	Support + Good care	Treatment + Bad care

For 50% of the cohort, the left and right items were switched to reduce the typical effect of order in which the two combined tasks are performed; IAT = Implicit Association Test.

We created an IAT consisting of five steps (including three practice steps) with up to 10 trials per step. The categories were: "Treatment", "Support", "Good care", and "Bad care" (Table 1). We assigned items associated with each category (Table 2). We defined treatment as any surgery, procedure, injection, or medication, and we defined support as reassurance, conversation, and education but no physical treatment. Patients were shown "Treatment" and "Good care" versus "Support" and "Bad care" first. Analyses of website IAT data showed that IAT measures tend to indicate that associations have greater strength when they are tested in the first combined task (Table 3, step 3) than in the second combined task (step 5).^{9,15} As previously suggested, to reduce this typical effect of order in which the two combined tasks are performed, we created another IAT in which "Treatment" and "Bad care" versus "Support" and "Good care" appeared first.^{9,14} We aimed to administer both tests for 50% of the total cohort.

Although other IATs have been validated in numerous studies, the IAT we used was specifically made for this study. Scores (D scores) range from -2 to 2, where 0 indicates no implicit association, positive scores indicate association of receiving a physical treatment with good care, and negative scores indicate association of supportive care with good care. According to the original IAT, break points for no preference (± 0 to 0.15), slight preference (± 0.15 to 0.35), moderate preference (± 0.35 to 0.65), and strong preference ($\pm > 0.65$ to 2) were selected conservatively according to psychological conventions for effect size.^{15,18}

Study population

Of the 129 patients approached, 125 (97%) consented and were included in the study. One patient (< 1%) declined to participate, and three patients (2%) were excluded because they were not able to read the laptop screen. None of the final cohort of patients enrolled were excluded from the analysis. The mean age was 50 ± 15 years (range 18 to 79 years) and 56 (45%) were men (Table 4). Sixty-five patients (52%) completed version 1 of our IAT (Appendix 1). When comparing baseline patient characteristics between the two versions of our IAT, we found that more white people and more people with a traumatic orthopaedic condition completed version 1 of the IAT (Appendix 1). In both IAT versions, patients matched more items to their associated categories correctly when the combinations "Treatment" plus "Bad care" and "Support" plus "Good care" were displayed (step 5 in version 1; step 3 in version 2; Table 3). The IAT showed a moderate-to-strong internal correlation ($r = 0.47$, $P < 0.001$; Table 3). We found a variety of upper and lower extremity diagnoses in our cohort (Appendix 2).

Statistical analysis

We used Student t-test to assess differences and associations between continuous variables, Fisher exact test for discrete variables, Pearson's correlation to test for internal consistency of the IAT and to test for associations between continuous variables, and one-way ANOVA tests for the associations of nominal and continuous variables. Internal consistency for the IAT was calculated by a scoring algorithm where for each candidate, two-part measures were created using two mutually exclusive subsets of the IAT's combined-task trials. The correlation between these two part-measures, across respondents, provided a measure of internal consistency.¹⁴ We primarily treated the expressed preference as a continuous variable with scores ranging from -3 to 3. In a secondary analysis, we treated the expressed preference as a categorical variable (Appendix 3), without differences regarding the continuous scale. We created two multivariable linear regression models to assess factors associated with (1) the implicit preference for treatment (IAT score) and (2) with the expressed preference for treatment. Variables with $P < 0.10$ on bivariate analysis (Appendix 4) were included

Table 2. Items assigned to each category in the IAT.

Categories	Item 1	Item 2	Item 3
Treatment	Pharmaceutical	Intervention	Medication
Support	Reassurance	Understand	Adaptation
Good care	Recommend to friends	Compassionate	Competent
Bad care	Do not recommend to friends	Incompetent	Insensitive

IAT = Implicit Association Test.

in the final models. We also included expressed preference for treatment in the final model with the IAT score since this was our variable of interest. The adjusted R-squared (R^2) indicated how much variability in the outcome variable for which the model accounts. Semipartial R^2 expresses the specific variability of a given independent variable in the model. We considered $P < 0.05$ as significant.

An *a priori* power analysis indicated that a sample of 123 subjects would provide 90% statistical power, with alpha set at 0.05, for a regression with 10 predictors if the expressed preference for treatment would account for 7% or more of the variability in the implicit association (IAT score), and our complete model would account for 20% of the overall variability.

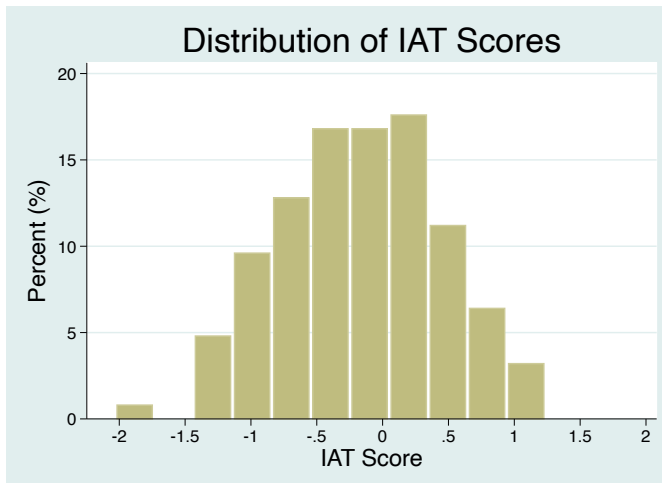


Figure 1. IAT scores show a broad distribution of implicit preferences toward good care being both support and physical intervention; IAT = Implicit Association Test.

Item 4	Item 5	Item 6	Item 7
Procedure	Injection	Surgery	Pill
Resiliency	Patience	Support	Educate
Attentive	Listens	Cares	-
Dismissive	Interrupts	Arrogant	-

Table 3. Implicit Attitude Test (IAT).

Variables	Version 1 ("treatment + good care" first in step 3)	Version 2 ("treatment + bad care" first in step 3)	P value
Frequency (n = 125 [%])	65 (52)	60 (48)	
Times per step (seconds)*			
Step 3	27 ± 12 (11 to 56)	33 ± 23 (12 to 137)	0.044
Step 5	22 ± 10 (8.6 to 73)	32 ± 14 (13 to 78)	<0.001
Correct answers per step†			
Step 3	7.5 ± 1.5 (4 to 10)	8.8 ± 1.3 (2 to 10)	<0.001
Step 5	8.3 ± 1.5 (3 to 10)	8.0 ± 1.6 (4 to 10)	0.413
Final IAT score separate‡	-0.17 ± 0.57 (-1.2 to 1.0)	-0.17 ± 0.68 (-2.0 to 1.2)	0.973
Final IAT score combined‡	-0.17 ± 0.62 (-2.0 to 1.2)		
Internal consistency (r)	0.47; P = < 0.001		

Bold indicates statistically significant difference; Pearson's correlation indicated by *r*; Continuous variables as mean ± SD (range), unless otherwise indicated; discrete variables as number (percentage). *Steps 1, 2, and 4 are practice rounds; steps 3 and 5 are measured rounds. †Higher score represents more preference for combination "treatment" with "good care" and "support" with "bad care".

Table 4. Patient and clinical characteristics.

Variables	N = 125
Age (years)	50 ± 15 (18 to 79)
Men (%)	56 (45)
Race/ethnicity (%)	
White	87 (70)
Non-white	38 (30)
Marital status (%)	
Married/unmarried couple	76 (61)
Divorced/separated/widowed	18 (14)
Single	31 (25)
Level of education (%)	
High school or less	26 (21)
(Some) college	67 (54)
Postcollege graduate degree	32 (26)
Work status (%)	
Employed	93 (74)
Retired	20 (16)
Other (student, unemployed, unable to work)	12 (9.6)
Comorbidities (%)	
Cardiovascular	30 (24)
Musculoskeletal	25 (20)
Mental	10 (8.0)
Other	14 (11)
None	61 (49)
Appointment type (%)	
First visit	121 (97)
Second opinion	4 (3.2)
Type of diagnosis (%)	
Traumatic	67 (54)
Nontraumatic	58 (46)
Treatment given	
Physical treatment (for example, pill, shot, surgery)	62 (50)
Supportive treatment (such as, self-care, reassurance, education)	44 (35)
Both	19 (15)
Expressed preference for physical treatment (for instance, pill, shot, surgery) or supportive treatment (including, self-care, reassurance, education)*	0.63 ± 2.0 (-3 to 3)

Continuous variables as mean ± SD (range); discrete variables as number (percentage). *Higher positive score represents more preference for treatment, negative for support.

RESULTS

Preferences for physical intervention and supportive care

Patients had a slight implicit association of good care with support ($D = -0.17 \pm 0.62$; Table 3). Score distribution ranged from very strong association of good care with support to very strong association with physical treatment (range -2.0 to 1.2; Figure 1). In contrast, patients indicated a slight preference favoring physical treatment over support on the expressed preference scale (score = 0.63 ± 2.0 ; range -3 to 3; Table 4).

Factors associated with preference for physical intervention and supportive care

Patients who eventually received both physical and supportive treatments were independently associated with implicit association of good care with support, accounting for potential interaction of variables using multivariable analysis (regression coefficient $[\beta] = -0.42$; 95% confidence interval [95% CI], -0.73 to -0.11; $P = 0.008$; semipartial $R^2 = 0.04$; adjusted R^2 full model = 0.13; Table 5). Patients having a psychological comorbidity had an implicit preference for physical treatment being good care ($\beta = 0.44$; 95% CI, 0.03 to 0.85; $P = 0.035$; semipartial $R^2 = 0.02$; Table 5). After controlling for potential confounding variables like gender and eventual treatment received, we found that men were more likely to have an expressed preference for physical treatment ($\beta = 1.0$; 95% CI, 0.31 to 1.7; $P = 0.005$; semipartial $R^2 = 0.06$; adjusted R^2 full model = 0.08; Table 5). Patients who eventually received supportive treatment also had more expressed preference for support ($\beta = -0.13$; 95% CI, -1.1 to 0.87; $P = 0.801$; semipartial $R^2 = 0.05$; Table 5).

Are expressed preferences associated with implicit preferences?

We also assessed whether patients' expressed preferences corresponded with their implicit preferences. Discordance would emphasize the importance of helping patients become aware of their values to ensure that their preferences are not based on misconceptions. Our analysis revealed that patients' expressed preferences for treatment were not associated with their implicit preferences ($\beta = 0.01$; 95% CI, -0.04 to 0.06; $P = 0.72$; Table 5).

Table 5. Multivariable regression analyses of factors associated with IAT and expressed preference.

Dependent variables	Retained variables
IAT score*	Race/Ethnicity White Non-White Level of education High school or less (Some) College Post-college graduate degree Comorbidities Mental No Yes Other No Yes None No Yes Treatment given Biomedical Biopsychosocial Both Expressed preference ¹
Expressed preference¹	Sex Women Men Treatment given Biomedical Biopsychosocial Both

Bold indicates statistically significant difference; only the semipartial R^2 is displayed for significant variables and for expressed preference; CI = confidence interval; IAT = implicit attitude test.

Regression coefficient [β] (95% CI)	Standard error (SE)	P value	Semipartial R-squared (R ²)	Adjusted R ²
<i>reference value</i> -0.20 (-0.43 to 0.04)	0.12	0.098		
<i>reference value</i> -0.26 (-0.54 to 0.01)	0.14	0.062		
0.03 (-0.28 to 0.34)	0.16	0.856		
<i>reference value</i> 0.44 (0.03 to 0.85)	0.21	0.035	0.02	0.13
<i>reference value</i> 0.13 (-0.22 to 0.49)	0.18	0.465		
<i>reference value</i> -0.06 (-0.30 to 0.17)	0.12	0.596		
<i>reference value</i> 0.10 (-0.14 to 0.34)	0.12	0.413		
-0.42 (-0.73 to -0.11)	0.16	0.008	0.04	
0.01 (-0.04 to 0.06)	0.03	0.721	0.002	
<i>reference value</i> 1.0 (0.31 to 1.7)	0.35	0.005	0.06	0.08
<i>reference value</i> -0.98 (-1.7 to -0.23)	0.38	0.011	0.05	
-0.13 (-1.1 to 0.87)	0.50	0.801		

*Higher score represents more preference for combination "treatment" with "good care" and "support" with "bad care". †Higher positive score represents more preference for treatment, negative for support.

DISCUSSION

People have both expressed and implicit preferences.⁷ Patients with orthopaedic issues often place their hopes on a mechanical fix of their problems and have an expressed preference for a physical intervention. An expressed preference for intervention is often based on misconceptions about the problem's etiology (for example, that it was caused by injury rather than normal aging), natural history (whether it is self-limited rather than progressive and disabling), and treatment (whether it is necessary *versus* discretionary). Expert advice correcting these misconceptions can bolster resiliency and hope, but may be difficult to believe and may be, at least initially, unwelcome. This may in part be caused by an unconscious association linking physical intervention with good care. This study sought to determine whether patients seeing an orthopaedic surgeon unconsciously associate suggestions for invasive treatments with better care than supportive treatment. We also tested whether their expressed and implicit preferences aligned.

We acknowledge some study limitations. First, because it uses complementary pairs of words (here: "Treatment" and "Support"; "Good care" and "Bad care"), the IAT is limited to measuring the relative strengths of pair-wise associations rather than absolute strengths of single associations. In other words, with the results from this study, we can only state patients' implicit associations of good care with physical treatment or supportive treatment, rather than determining whether patients have an implicit preference for physical treatment or supportive treatment by itself. However, the IAT is useful because many important categories form complementary pairs such as good *versus* bad.⁸ Second, the categories "Treatment" and "Support" might have been interpreted variably since some patients think support is a type of treatment and others do not. To address this issue, patients were instructed that treatment would mean any physical intervention, such as an injection or pill, and support was only meant to capture treatments more in the psychosocial realm (education, reassurance, bolstering resilience). Third, we assessed the explicit preference before the implicit preference, which could have resulted in more implicit preference toward the expressed preference. However, a study by Nosek *et al.* did not find any order effect of expressed preference and implicit preference.¹⁶ Fourth, an order effect was found in multiple studies favoring more implicit preference (higher D scores) toward the first set of combinations in the IAT compared with the second set of combinations.^{9,11,14-16} To account for this, it is suggested to either increase the number of practice steps and/or items per step,^{11,16} or to create another IAT with reversed category combinations.^{9,14,15} Since we used a free IAT software that lacked the capacity to increase practice steps or exceed 10 items per step, we chose the latter strategy. Fifth, some patients completed

the IAT rapidly and some very slowly. To account for this, the IAT omitted answers with response times less than 300 milliseconds for more than 10% of the trials, and answers with response times over 10,000 milliseconds, as previously studied.^{11,14} Another limitation may pertain to the timing of the questionnaire. Some patients completed the questionnaire and IAT before the visit and some patients completed it after. It might be that patients' preferences – expressed preferences in particular – changed during the course of the visit and the information provided by the surgeon. Additionally, we did not assess if patients were new to the clinic or were established patients presenting with a new problem. It might be that patients have different preferences based on the fact that they have an established relationship with a physician. Finally, we enrolled consecutive patients – limiting selection bias – from one large urban area only, which might limit generalizability to other specialties or even to other orthopaedic clinics. However, we aimed to keep our inclusion criteria as broad as possible to get a complete spectrum of orthopaedic conditions and patient factors in our cohort. It is likely that other patient factors, such as coping strategies or a patient's activity level, influence preferences as well. This merits further study with an increase in power and sample size to account for all possible confounding variables of interest.

Patients had a slight implicit association of good care with supportive treatment, such as reassurance and guidance, rather than physical treatments, like injection, surgery, or medication. The expressed preference pointed in the other direction showing a slight preference for physical treatment. Although the IAT has no clear score interpretations, we believe the results can be interpreted with the proposed cutoff values that were conservatively selected according to psychological conventions for effect size, as mentioned in the Methods section. Extreme values of -2 and 2 are rare using the IAT and that may be one of the reasons that interpretations of strong preferences start from a D score of ± 0.65 . In our cohort, we had only 17 patients (14%) with scores over ± 1.0 , of which only one patient reached the most extreme score of -2 (maximum implicit preference for supportive care). This gives reason to assume our mean score of -0.17 falls within the true value of having a slight implicit preference. Our finding contrasts with some studies of expressed preferences, which found that people seeking care with their general practitioners were more satisfied on average when they received antibiotics¹, and that patients prefer any treatment resulting in relief of day-to-day symptoms.⁴ Streufert *et al.* also found that patients who participated in high-risk activities and previously had a shoulder dislocation favored surgery.²⁰ The dissonance in study results might reflect a difference in populations studied. It is possible that patients visiting a general practitioner, who is often more accessible than a surgeon, have different values or see more routine problems, resulting in different preferences.

Our study looked at a full range of orthopaedic problems. Compared with Streufert *et al.*²⁰, it is also possible that preferences depend on their specific circumstances and motivations, such as activity level. This merits further study. As patients' expressed preferences for physical interventions are often based on misconceptions about their conditions, surgeons should set aside their own – often surgical – preferences and take time to connect with patients, creating a trusting relationship in which misconceptions can be gently and gradually corrected to increase the likelihood that patients' expressed diagnostic and treatment preferences are consistent with their values.

People who opted for both a physical intervention and supportive treatment were more likely to have a measured implicit preference for supportive treatment. What this seems to capture is that a patient who receives a physical intervention, such as an injection, also wants to have the supportive treatment and peace of mind. Said differently, physical treatments cannot substitute for supportive treatment that provides reassurance and hope. A study of implicit preferences for treating multiple sclerosis found that, on average, patients prioritize symptom relief, and physicians want to slow disease progression.⁴ For many diseases like multiple sclerosis, there may not yet exist a physical treatment that can reliably alleviate symptoms, but it is possible that symptoms will diminish over time despite the lack of an effective treatment. Patients may decline all physical interventions – or there may not be any effective interventions – but they might seek understanding and peace of mind to help them adapt. Our finding that men expressed greater explicit preference for physical treatment is consistent with other studies. One study of 395 patients found that men (and older patients) were more likely to choose discretionary spinal surgery, but no relationship was observed between the measured patient-reported outcomes and decision to undergo spinal surgery within 18 months of the index visit.² A study of shared-decision making in 7009 patients with multiple sclerosis found that women had a greater preference for shared-decision making, indicating that men either might take their physician's opinion less into consideration or men may defer more to their doctor, or both.³ These results suggest that surgeons might need to help patients explore their values, men in particular. Tools such as decision aids might help gently correct misconceptions and improve awareness of one's values.

The lack of correlation between explicit and implicit preferences observed in the current study is common when socially sensitive topics are studied with the IAT.^{8,9} For socially sensitive topics, people may not feel comfortable expressing preferences consistent with their values and, therefore, their implicit preferences.¹⁰ A systematic review of 122 studies found wide variability of implicit-explicit correlations, stating that

the predictive value of explicit measures is limited, particularly for socially sensitive topics.¹² The discordance of explicit and implicit preference we observed in the context of an orthopaedic consultation may reflect the fact that musculoskeletal disease is a frequent somatic focus for stress and distress. Somatization is thought to occur in part due to a sense that it is socially acceptable to discuss physical pain and physical treatments, but discussion of symptoms such as depression and anxiety and their treatment may be associated with feelings of stigma and shame. If one makes the seemingly safe assumption that a person's automatic associations align with their core values, the IAT data suggest that expressed preferences may sometimes be based on misconceptions. Orthopaedic surgeons probably ought to interpret requests for invasive treatments as a measure of the magnitude of the impact of the problem on a person's life, while maintaining focus on helping people correct misconceptions and ensure their choices are aligned with their values.

Surgeons often encounter patients who would like more testing or physical treatments than expertise or evidence supports. Although surgeons may sometimes feel pressured toward physical treatments, our data suggest that overall, patients with upper or lower extremity symptoms associate supportive treatment with good care. This indicates that people are likely to be receptive to supportive treatment. It may be important to practice effective communication strategies to ensure that supportive treatment does not feel like denying intervention or otherwise creating conflict with a person's expressed preferences. These findings should give surgeons and all specialists confidence that if they can establish a sufficiently comfortable and trusting relationship with a patient – which may occur over several interactions and with incremental care – patients may feel more comfortable expressing preferences for supportive forms of treatment, including treatments that address stress and distress that are being expressed as physical symptoms.

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APPENDICES

Appendix 1. Comparison of patient and clinical characteristics *versus* IAT version.

Variables	Version 1 (n = 65)	Version 2 (n = 60)	P value
Age (years)	49 ± 14 (18 to 79)	52 ± 17 (18 to 78)	0.449
Men (n, %)	27 (42)	29 (48)	0.476
Race/ethnicity (n, %)			
White	39 (60)	48 (80)	0.019
Nonwhite	26 (40)	12 (20)	
Marital status (n, %)			
Married/unmarried couple	40 (62)	36 (60)	0.174
Divorced/separated/widowed	6 (9.2)	12 (20)	
Single	19 (29)	12 (20)	
Level of education (n, %)			
High school or less	14 (22)	12 (20)	0.343
(Some) college	38 (58)	29 (48)	
Postcollege graduate degree	13 (20)	19 (32)	
Work status (n, %)			
Employed	52 (80)	41 (68)	0.111
Retired	6 (9.2)	14 (23)	
Other (student, unemployed, unable to work)	7 (11)	5 (8.3)	
Comorbidities (n, %)			
Cardiovascular	14 (22)	16 (27)	0.535
Musculoskeletal	10 (15)	15 (25)	0.189
Mental	4 (6.2)	6 (10)	0.519
Other	5 (7.7)	9 (15)	0.259
None	34 (52)	27 (45)	0.475
Appointment type (n, %)			
First visit	64 (98)	57 (95)	0.350
Second opinion	1 (1.5)	3 (5.0)	
Type of diagnosis (n, %)			
Traumatic	41 (63)	26 (43)	0.032
Nontraumatic	24 (37)	34 (57)	

Appendix 1. Continued.

Variables	Version 1 (n = 65)	Version 2 (n = 60)	P value
Treatment given (n, %)			
Physical treatment (for example, pill, shot, surgery)	32 (49)	30 (50)	0.858
Supportive treatment (such as, self-care, reassurance, education)	22 (34)	22 (37)	
Both	11 (17)	8 (13)	
Expressed preference for physical treatment (including, pill, shot, surgery) or supportive treatment (for example, self-care, reassurance, education)*	0.85 ± 2.0 (-3 to 3)	0.40 ± 2.0 (-3 to 3)	0.214

*Higher positive score represents more preference for treatment, negative for support; **bold** indicates statistically significant difference; continuous variables as mean ± SD (range); discrete variables as number (percentage); IAT = implicit attitude test.

Appendix 2. Diagnoses and frequencies.

Diagnoses	Frequency (%)
Knee osteoarthritis	9 (7.2)
Lateral epicondylitis	5 (4.0)
Trigger finger	5 (4.0)
Wrist fracture	5 (4.0)
Shoulder pain	4 (3.2)
Ankle fracture	4 (3.2)
Ankle sprain	3 (2.4)
Carpal tunnel syndrome	3 (2.4)
Cervical radiculopathy	3 (2.4)
Distal fibula fracture	3 (2.4)
Distal radius fracture	3 (2.4)
Meniscus tear	3 (2.4)
Rotator cuff tear	3 (2.4)
Thumb arthritis	3 (2.4)
Dupuytren's disease	2 (1.6)
Knee pain	2 (1.6)
Mallet finger	2 (1.6)
Patella fracture	2 (1.6)
Shoulder dislocation	2 (1.6)
Achilles tendon rupture	1 (0.80)
Acromioclavicular joint arthropathy	1 (0.80)

Appendix 2. Continued.

Diagnoses	Frequency (%)
Acromioclavicular joint arthrosis	1 (0.80)
Benign thumb tumor	1 (0.80)
Biceps tendon tear	1 (0.80)
Bursitis unspecified	1 (0.80)
CMC-1 arthritis	1 (0.80)
Calcaneus fracture	1 (0.80)
Carpal tunnel syndrome and cubital tunnel syndrome	1 (0.80)
Carpal tunnel syndrome and lateral epicondylitis	1 (0.80)
Clavicle fracture	1 (0.80)
Cubital tunnel syndrome	1 (0.80)
De Quervain's tenosynovitis	1 (0.80)
Displaced clavicle fracture	1 (0.80)
Distal humerus fracture	1 (0.80)
Distal phalanx fracture	1 (0.80)
Elbow and hand sprain	1 (0.80)
Elbow joint effusion	1 (0.80)
Finger extensor tendon laceration	1 (0.80)
Finger tendinitis	1 (0.80)
Foot soft tissue contusion	1 (0.80)
Frozen shoulder	1 (0.80)
Hand pain	1 (0.80)
Hip osteoarthritis	1 (0.80)
Hip bursitis	1 (0.80)
Humerus fracture	1 (0.80)
Knee contusion	1 (0.80)
Lateral epicondylitis and medial epicondylitis	1 (0.80)
Lumbar radiculopathy	1 (0.80)
Malunion distal radius fracture	1 (0.80)
Median nerve neuroma	1 (0.80)
Metacarpal fracture	1 (0.80)
Multiple toe fractures	1 (0.80)
Neck pain	1 (0.80)
Nonspecific shoulder pain	1 (0.80)
PIP arthritis	1 (0.80)
PIP sprain	1 (0.80)
Patella tendon strain	1 (0.80)
Patellofemoral syndrome	1 (0.80)

Appendix 2. Continued.

Diagnoses	Frequency (%)
Pelvis fracture	1 (0.80)
Possible meniscus tear	1 (0.80)
Radial neck fracture	1 (0.80)
Rotator cuff tendinopathy	1 (0.80)
Scaphoid fracture	1 (0.80)
Shoulder impingement	1 (0.80)
Shoulder subluxation and rotator cuff strain	1 (0.80)
Suspected nerve-related arm pain	1 (0.80)
Tendinitis unspecified	1 (0.80)
Tibial plateau fracture	1 (0.80)
Traumatic ankle pain	1 (0.80)
Traumatic knee pain	1 (0.80)
Trigger finger and carpal tunnel syndrome	1 (0.80)
Trigger thumb	1 (0.80)
Trigger thumb and carpal tunnel syndrome	1 (0.80)
Unspecified articular cartilage disorder	1 (0.80)
Unspecified muscle rupture	1 (0.80)
Wrist pain	1 (0.80)
Wrist sprain	1 (0.80)
Wrist tendinitis	1 (0.80)

Discrete variables as number (percentage).

Appendix 3. Bivariate analyses of explicit preference as categorical vs IAT score.

Options	Frequency	IAT score'	P value
Strong preference for treatment	27 (22)	-0.10 ± 0.51	
Moderate preference for treatment	24 (19)	-0.28 ± 0.56	
Slight preference for treatment	19 (15)	-0.15 ± 0.63	
Neutral about treatment or support = no preference	26 (21)	-0.05 ± 0.73	0.232
Slight preference for support	8 (6.4)	-0.54 ± 0.52	
Moderate preference for support	2 (1.6)	-0.90 ± 0.21	
Strong preference for support	19 (15)	-0.08 ± 0.69	

Continuous variables as mean ± SD; discrete variables as number (percentage).

'Higher score represents more preference for combination "treatment" with "good care" and "support" with "bad care"; IAT = implicit attitude test.

Appendix 4. Bivariate analyses of factors associated with the IAT score and expressed preference for treatment.

Variables	IAT score	P value	Expressed preference	P value
Age (r)	0.05	0.565	-0.05	0.606
Sex				
Women	-0.24 ± 0.62	0.173	0.23 ± 2.2	0.012
Men	-0.09 ± 0.62		1.1 ± 1.6	
Race/ethnicity				
White	-0.10 ± 0.60	0.062	0.53 ± 2.0	0.384
Nonwhite	-0.33 ± 0.64		0.87 ± 2.0	
Marital status				
Married/unmarried couple	-0.20 ± 0.61	0.212	0.58 ± 2.0	0.796
Divorced/separated/widowed	0.07 ± 0.61		0.50 ± 2.0	
Single	-0.23 ± 0.64		0.84 ± 2.0	
Level of education				
High school or less	-0.13 ± 0.69	0.021	0.85 ± 2.1	0.821
(Some) college	-0.30 ± 0.63		0.60 ± 1.9	
Postcollege graduate degree	0.07 ± 0.47		0.53 ± 2.2	
Work status				
Employed	-0.22 ± 0.63	0.220	0.75 ± 1.9	0.497
Retired	0.04 ± 0.65		0.20 ± 2.3	
Other (student, unemployed, unable to work)	-0.13 ± 0.42		0.42 ± 2.2	
Comorbidities				
Cardiovascular				
No	-0.21 ± 0.65	0.202	0.68 ± 2.0	0.605
Yes	-0.04 ± 0.52		0.47 ± 2.1	
Musculoskeletal				
No	-0.16 ± 0.64	0.801	0.73 ± 2.0	0.275
Yes	-0.20 ± 0.54		0.24 ± 2.1	
Mental				
No	-0.20 ± 0.63	0.096	0.57 ± 2.0	0.272
Yes	0.14 ± 0.38		1.3 ± 1.3	
Other				
No	-0.21 ± 0.62	0.047	0.65 ± 1.9	0.794
Yes	0.14 ± 0.61		0.50 ± 2.5	
None				
No	-0.07 ± 0.54	0.067	0.58 ± 2.1	0.759
Yes	-0.28 ± 0.69		0.69 ± 2.0	

Appendix 4. Continued.

Variables	IAT score	P value	Expressed preference	P value
Appointment type				
First visit	-0.16 ± 0.60	0.147	0.63 ± 2.0	0.905
Second opinion	-0.62 ± 1.2		0.75 ± 1.5	
Type of diagnosis				
Traumatic	-0.24 ± 0.59	0.205	0.69 ± 2.0	0.744
Nontraumatic	-0.09 ± 0.65		0.57 ± 2.0	
Treatment given				
Physical treatment (for example, pill, shot, surgery)	-0.13 ± 0.57	0.017	0.94 ± 1.9	0.082
Supportive treatment (such as, self-care, reassurance, education)	-0.07 ± 0.67		0.09 ± 2.1	
Both	-0.54 ± 0.56		0.89 ± 1.9	
Expressed preference for physical treatment or supportive treatment (r)*	0.01	0.912	-	-

*Higher positive score represents more preference for treatment, negative for support; **bold** indicates statistically significant difference; Pearson's correlation indicated by r; continuous variables as mean ± SD (range), unless otherwise indicated; IAT = Implicit Attitude Test.





Part two

SURGEON'S PERSPECTIVE



Chapter 3

NEW PATIENT VISIT FOR CARE OF
IDIOPATHIC TRAPEZIOMETACARPAL
OSTEOARTHRITIS: FACTORS ASSOCIATED
WITH INJECTION AND RADIOGRAPHS

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ABSTRACT

Background: Radiographs may have limited utility in the diagnosis and management of trapeziometacarpal osteoarthritis (TMC OA). In the trials performed to date, intra-articular steroid injection does not relieve symptoms better than simulated steroid injection.

Objectives: To assess the prevalence of, and factors associated with obtaining radiographs and performing intra-articular injection at new patients visits for idiopathic TMC OA.

Methods: This was a retrospective database study. Patients with TMC OA were identified in a national administrative claims database for commercially insured patients from October to December 2015. The following categories were analyzed for each patient: age, gender, geographic region (within the United States), work status, and employment classification. We created two multivariable logistic regression models to identify independent factors associated with (1) radiograph and (2) injection at first visit.

Participants: 2961 patients were eligible, including 2199 (74%) women.

Results: Approximately half of the patients (1549 of 2961; 52%) had a radiograph during their first evaluation of TMC OA by a surgeon. In multivariable analysis, patients from the Southern United States correlated with greater rates of radiographs obtained at first visit (Odds Ratio [OR] = 1.3, 95% Confidence Interval [95% CI] = 1.1 to 1.6, semipartial R^2 = 0.0036, P = 0.009). Nearly one quarter of the patients (758 of 2961; 26%) had an injection during their first evaluation of TMC OA by a surgeon. In multivariable analysis, women were associated with a lower likelihood to receive an injection during a new patient visit (OR = 0.83, 95% CI = 0.69 to 1.0, semipartial R^2 = 0.0014, P = 0.044).

Conclusion: Our study showed a high prevalence of radiographs and intra-articular injections among patients with TMC OA coded as a new visit. The discordance between daily practice and current best evidence merits attention.

INTRODUCTION

Trapeziometacarpal osteoarthritis (TMC OA) is an expected part of human aging.¹⁻³ Studies identify incidental, advanced, and well adapted TMC arthrosis as a common finding among people seeking care for other problems.^{1,2} The true prevalence of patients with TMC OA seeking specialty care is unknown but evidence suggests that most people adapt to their condition.^{1,2,4,5} With respect to knee OA, population based studies of people over 65 years of age demonstrate a high prevalence of osteoarthritis but most people seem to adapt to their condition, even with advanced disease. For instance, less than half of the patients with the most advanced radiographic findings of knee OA qualified as having symptomatic arthritis.⁶ Based on this, and the high prevalence of radiographic TMC OA found in prior studies, it seems reasonable to infer that population-based studies of TMC OA would have similar findings.¹ Studies of people with crepitation of the TMC joint ("incidental TMC OA") who are being seen by a hand specialist for other medical reasons suggest that – as with knee arthritis – TMC OA may be generally well-accommodated.³

Radiographs seem to have limited value in the management of TMC OA. The high prevalence of TMC OA and the characteristic symptoms and signs make diagnosis reliable and accurate without radiographs.^{1,2} Additionally, radiographs are not helpful in the treatment decision-making process, given the limited correspondence of radiographic severity of TMC OA with pain intensity and magnitude of physical limitations.^{4,7} Thumbs with crepitation during axial pressure and circumduction of the TMC joint (the so-called grind test) have advanced arthrosis.⁸

Intra-articular injections – with either corticosteroids or hyaluronic acid – provide brief palliation at best and cannot modify the natural history of the disease.⁹⁻¹⁵ It is not clear that therapeutic injections outperform placebo injection.⁹⁻¹⁵ A level I randomized controlled trial comparing hylan, steroid and placebo injections for TMC OA did not show significant differences in outcome.¹⁶ The only other study of corticosteroid injection compared to simulated steroid injection (saline) also showed no differences.¹⁰ A prior database study among three affiliated urban hospitals documented wide (51-fold) surgeon-to-surgeon variation in the rate of injections for TMC OA.¹⁷ There is evidence that treatment offerings are influenced by surgeon values and surgeon personality.¹⁸⁻²¹ Ideally, variation in treatments for TMC OA is based on patient values and preferences, not on surgeon bias.

This study assessed the prevalence of, and factors associated with obtaining radiographs and performing intra-articular injections for idiopathic TMC OA at new patient visits.

PATIENTS & METHODS

Study design

This study was exempt from institutional review board approval since no identifiable health information was reviewed. We used an administrative claims database for commercially insured patients (Truven Health Analytics Marketscan®) from October to December 2015. Inclusion criteria were patients with a diagnosis (International Classification of Diseases, Tenth Revision (ICD-10) code) of TMC OA and Current Procedural Terminology (CPT) codes for a new outpatient office visit (99201-99205) (Appendix 1). We used CPT codes on the same date to identify injection of small/intermediate joint (20600, 20604, 20605), and radiograph of the hand/finger (73120, 73130, 73140) (Appendix 1).

We included 3077 patients aged 18 years or older diagnosed with TMC OA at a new outpatient visit with a surgeon between October and December 2015. The following categories were analyzed for each patient: age, gender, geographic region (within the United States), work status, and employment classification. We excluded duplicate diagnoses claims (N = 36), claims with unknown region (N = 6), and those with a diagnosis of secondary (N = 29), or post-traumatic (N = 45) TMC OA.

Study population

Two thousand nine hundred sixty-one patients were eligible, including 2199 (74%) women (Table 1).

Statistical analysis

Continuous variables are reported as mean with standard deviations (SD) and discrete variables as number with percentage. We used Chi-squared test to compare categorical and dichotomous variables, and Student t-test for continuous and dichotomous variables. We created two multivariable logistic regression models to identify independent factors associated with (1) radiograph and (2) injection performed at first visit. We included all factors with $P < 0.10$ on bivariate analysis in the final models. C-statistic is a measure of goodness of fit in logistic regression model with scores between 0.50 and 1.00. Higher scores indicate a better fit. Semipartial R^2 expresses the specific variability of a given independent variable in the model.

Table 1. Demographic overview.

Variable	N = 2961 patients
Age (range)	59 ± 9.5 (18 to 97)
Gender, n (%)	
Men	762 (26)
Women	2199 (74)
Region, n (%)	
North-East	569 (19)
North-Central	713 (24)
South	1240 (42)
West	439 (15)
Work status, n (%)	
Employed	1573 (53)
Retired	694 (23)
Unable to work/other	694 (23)
Employee classification, n (%)	
Fulltime	688 (23)
Parttime	675 (23)
Other	1598 (54)
Injection at new patient visit	758 (26)
Radiograph at new patient visit	1549 (52)

Continuous variables as mean ± SD; discrete variables as number (percentage).

RESULTS

Radiograph at new patient visit

Just over half of the patients (1549 of 2961; 52%) had a radiograph during a new patient evaluation of TMC OA. In bivariate analysis, there was a significant difference of radiograph rates between regions ($P < 0.001$) (Table 2). Accounting for potential interaction of variables using multivariable analysis, patients from the Southern United States (Odds Ratio [OR] = 1.3; 95% Confidence Interval [95% CI] = 1.1 to 1.6; semipartial $R^2 = 0.0036$; $P = 0.009$) correlated with greater rates of radiographs obtained at a new patient visit (Table 3).

Injection at new patient visit

Approximately one quarter of the patients (758 of 2961; 26%) had an injection during their new patient evaluation of TMC OA. In bivariate analysis, younger patients were associated with a greater likelihood of an injection at new patient visit ($P = 0.028$) (Table 2). Accounting for potential interaction of variables using multivariable analysis, women (OR = 0.83; 95% CI = 0.69 to 1.0, semipartial $R^2 = 0.0014$, $P = 0.044$) correlated with lower injection rates at new visits (Table 3).

Table 2. Bivariate analyses of factors associated with injection or radiograph.

Variables	Injection at new patient visit			Radiograph at new patient visit		
	Yes	No	<i>P</i> value	Yes	No	<i>P</i> value
Age (years)	58 ± 8.2	59 ± 9.9	0.028	59 ± 8.8	59 ± 10	0.057
Gender, n (%)						
Men	215 (28)	547 (72)	0.055	401 (53)	361 (47)	0.84
Women	543 (25)	1656 (75)		1148 (52)	1051 (48)	
Region, n (%)						
North-East	134 (24)	435 (76)	0.074	280 (49)	289 (51)	<0.001
North-Central	164 (23)	549 (77)		382 (54)	331 (46)	
South	344 (28)	896 (72)		693 (56)	547 (44)	
West	116 (26)	323 (74)		194 (44)	245 (56)	
Work status, n (%)						
Employed	417 (27)	1156 (73)	0.098	835 (53)	738 (47)	0.55
Retired	156 (22)	538 (78)		351 (51)	343 (49)	
Unable to work/other	185 (27)	509 (73)		363 (52)	331 (48)	
Employee classification, n (%)						
Fulltime	177 (26)	511 (74)	0.37	360 (52)	328 (48)	0.38
Parttime	186 (28)	489 (72)		338 (50)	337 (50)	
Other	395 (25)	1203 (75)		851 (53)	747 (47)	

Values are reported as numbers (row percentage) or as mean ± SD. **Bold** indicates statistical significance.

Table 3. Multivariable logistic regression of factors associated with injection or radiograph at new patients visits for TMC OA.*

Dependent variable	Retained variables	OR
Radiograph at new visit	Age	0.99
	Region	
	North-East	
	North-Central	1.2
	South	1.3
	West	0.81
Injection at new visit	Age	0.99
	Women	0.83
	Region	
	North-East	
	North-Central	0.98
	South	1.2
	West	1.1
	Work status	
	Employed	
Retired	0.89	
	Unable to work/other	1.0

*TMC OA = Trapeziometacarpal Osteoarthritis; SE = Standard Error. **Bold** indicates statistically significant difference. Only the semipartial R^2 of variables with $P < 0.05$ is reported.

DISCUSSION

Radiographs and injections have arguably limited utility in the diagnosis and management of TMC OA.^{12,17,19,22-25} Wide surgeon-to-surgeon variation in the use of radiographs and injections was observed in a prior study of six surgeons.¹⁷ This study assessed the prevalence of, and factors associated with radiographs and intra-articular injection for idiopathic TMC OA at new patient visits using a large national claims database.

We acknowledge several limitations to our study. We relied on a claims database and could not determine the completeness or accuracy of the data. Database studies cannot address effectiveness or satisfaction. We cannot tell from the database what substance was injected, but it seems safe to assume that the vast majority were corticosteroid injections. The database did not have surgeon level data, so we could only test variation among the four recorded geographic divisions of the United States.

Regression coefficient (95% confidence interval)	SE	P value	Semipartial R ²	C-statistic
0.98 to 1.0	0.0039	0.095		
<i>reference value</i>				0.55
0.96 to 1.5	0.14	0.11		
1.1 to 1.6	0.13	0.009	0.0036	
0.63 to 1.0	0.10	0.10		
0.98 to 1.0	0.0052	0.16		
0.69 to 1.0	0.078	0.044	0.0014	
<i>reference value</i>				
0.75 to 1.3	0.13	0.89		
0.97 to 1.5	0.14	0.085		0.54
0.86 to 1.5	0.17	0.36		
<i>reference value</i>				
0.70 to 1.1	0.11	0.36		
0.81 to 1.2	0.11	0.94		

The observation that more than half of the patients (52%) had a radiograph during a new patient evaluation of TMC OA suggests that radiographs are obtained routinely in many practices. The percentage of patients with TMC arthrosis that have a radiograph of the hand at some point in their care is likely larger, given that we could not account for patients that had a radiograph prior to this visit (from their primary care doctor or another specialist) or at subsequent visits. It is notable that in such a large percentage of patients with TMC OA radiographs are obtained when it offers few potential benefits and incurs costs and some potential harms. On the one hand, symptoms and physical examination are sufficient for accurate diagnosis of TMC OA in such a high-prevalence setting (after the age of 50 nearly half of all humans have some TMC OA).^{1,2,4,26,27} On the other hand, radiographic severity does not correlate well with symptoms and physical limitations and therefore will not be particularly helpful in the treatment decision-making process.^{27,28} In a recent review published in the New England Journal of Medicine the authors explain

how symptom intensity and the magnitude of self-reported activity limitations are influenced by the way a (medical) condition is described and framed.²⁹ In other words, the meaning or context attributed to the symptoms, often referred to placebo and nocebo effects. For example, mentioning potential side effects of an intervention can result in a more unpleasant experience.^{29,30} With respect to people presenting with symptoms of TMC OA, without radiographs, it might be easier to consider themselves as having age-appropriate changes in their thumb instead of suffering from thumb OA.^{1,17,26} An adaptive interpretation of symptoms and limitations from thumb arthritis can potentially help to diminish pain intensity and improve self-reported activity level through psychosocial effects that are increasingly well understood.^{3,28,31,32} We suggest to increase the attention towards social and mental health in surgeon offices and offer psychosocial interventions to patients with TMC OA seeking care. In our opinion, patients with pain at the base of the thumb might consider asking their doctor about the potential benefits and potential harms associated with radiographs and whether they are worth the cost.

The finding that one in four patients with TMC OA received an injection during their new visit merits attention given that injections are palliative at best and may not outperform placebo injections.^{10,12,15,33} Keeping in mind that some patients likely received an injection prior to this visit (from their primary care doctor or another specialist) or at subsequent visits, the percentage of patients with TMC arthrosis that receive an injection at some point in their care is likely to exceed 26%. It is notable that such a large percentage of patients with TMC OA receive an injection when the evidence suggests no benefit.^{10,16} It is also important to consider the potential harms of injection. Corticosteroid injections can be detrimental to articular cartilage and are associated with skin-related adverse events.^{9,12-15} We wonder if people would choose an injection if they were more aware of these aspects and if this would lead to less surgeon-to-surgeon variation in injection rates. It is important that clinicians help patients consider what matters most to them to ensure that decisions are based on patient values rather than on misconceptions and not on surgeon bias. Common misconceptions to be vigilant for include the belief that the injection can cure the problem or is in some way necessary. Given the evidence that injections are over-utilized relative to the available evidence, combined with the knowledge that injections have potential physical and psychosocial harm, injection for TMC OA might be considered for inclusion on the Choosing Wisely campaign.³⁴ We recommend that physicians inform their patients to seek unbiased information – e.g. by reviewing a decision aid³⁵ – and be prepared with questions if their doctor offers an injection for TMC OA.

Our study showed a high prevalence of radiographs obtained and intra-articular injections given at new visits among patients seen for TMC OA. Given the weak correspondence of radiographic severity and TMC OA symptom intensity, and the knowledge that steroid injections do not provide greater relief than placebo injections, these might represent areas for cost savings. Besides that, it is important to consider the strong influence of cognitive biases regarding pain (e.g. catastrophic thinking and fear of painful movement) and the influence of context effects (e.g. placebo and nocebo) on patient symptom severity and the magnitude of self-reported activity limitations. We recommend that patients presenting to a hand surgeon with base of thumb pain ask their surgeon whether and how diagnostic tests, like radiographs, are helpful and to which degree injections or other recommended interventions fit their goals and values.

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APPENDICES

Appendix 1. CPT codes.

CPT codes for radiograph:

73120 (X-ray hand 2 views)

73130 (X-ray hand 3 views)

73140 (X-ray finger)

CPT codes for injection:

20600 (Arthrocentesis, aspiration and/or injection, small joint or bursa (e.g. fingers, toes); without ultrasound guidance)

20604 (Arthrocentesis, aspiration and/or injection, small joint or bursa (e.g. fingers, toes); with ultrasound guidance, with permanent recording and reporting)

20605 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g. temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance)

CPT codes for new patient office visit

99201 - Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.

99202 - Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.

99203 - Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or

coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.

99204 - Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.

99205 - Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.






Chapter 4

VARIATION IN OFFER OF OPERATIVE TREATMENT TO PATIENTS WITH TRAPEZIOMETACARPAL OSTEOARTHRITIS

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ABSTRACT

Background: Operative treatment of trapeziometacarpal osteoarthritis (TMC OA) is discretionary. There is substantial surgeon-to-surgeon variation in offers of surgery.

Objectives: To determine factors associated with variation in recommendation of operative treatment to patients with TMC OA. Secondly, we studied factors associated with preferred operative technique and surgeon demographic factors variability in recommendation for operative treatment.

Methods: This was a cross-sectional survey study. All hand surgeon members of the Science of Variation Group (SOVG) were invited to review 16 scenarios of patients with TMC OA. Surgeons were asked whether they would recommend surgical treatment for each patient and, if yes, which surgical technique they would offer (trapeziectomy, trapeziectomy with ligament reconstruction and/or tendon interposition (LRTI), joint replacement, or arthrodesis). Scenarios varied in pain intensity, relief after injection, radiographic severity, and psychosocial symptoms.

Participants: 126 hand surgeon members of the SOVG; 10 (8%) were women, most specialized in orthopaedic surgery (106; 84%) and practiced in North America (80; 63%).

Results: Patient characteristics associated with greater likelihood to recommend surgical treatment were: substantial pain, a previous injection that did not relieve pain, radiograph with severe TMC OA, and few symptoms of depression. Practice region was the only factor associated with preferred surgical technique and trapeziectomy with LRTI the most commonly recommended treatment (89; 72%). There was low agreement among surgeons regarding treatment recommendations (Kappa 0.22; 95% Confidence Interval 0.11-0.33; $P < 0.05$).

Conclusion: The notable variation in offers of operative treatment for TMC OA is largely associated with variable attention to subjective factors. Surgeons' awareness of the potential influence of subjective factors on their recommendations might contribute to efforts to ensure that patient choices reflect what matters most to them and are not based on misconceptions.

INTRODUCTION

Radiographic trapeziometacarpal osteoarthritis (TMC OA) is an expected part of human aging. The prevalence of radiographic TMC OA is around 90% for adults aged 80 years and older and 100% aged 90 and older.¹ The correlation between radiographic TMC OA and pain intensity or magnitude of physical limitations is weak.² Patients with more adaptive coping strategies have fewer symptoms and limitations.³⁻¹⁰ Among the subset of people that seek specialty care for TMC arthrosis, most are satisfied with a single visit and most choose supportive care.¹¹ The majority of people seem to adapt and a small percentage request operative treatment.^{1-3,11,12}

There is substantial variation in the rate of surgery and operative techniques for TMC OA.¹³⁻¹⁸ Such variation often arises, in part, from dissatisfaction with alleviation of symptoms and limitations. A recent online survey study among hand surgeons found that surgeons tend to recommend a specific surgical technique for TMC OA based on personal experience rather than best evidence.¹⁶ The most offered surgical treatment for TMC OA is ligament reconstruction and tendon interposition (LRTI), which is associated with more adverse events, whereas alleviation of pain and maintenance of function is comparable with simple trapeziectomy.^{19,20} Other studies found that surgeon training, experience, and personality influence treatment recommendations.^{17,21} One out of four surgeons changed their preferred procedure for TMC OA over the last five years¹⁶, which suggests that surgeons may not be completely satisfied with the results of operative treatment.

Treatment variation in the rate and type of surgery in general is primarily based on variation in surgeon attitudes and beliefs and on the extent to which patient preferences are included in the decision-making process.²² Better knowledge of factors associated with recommendation of operative treatment to patients with TMC OA may help reduce variation based on surgeon beliefs and preferences.

This study tested the primary null hypothesis that there are no factors independently associated with recommendation of operative treatment to patients with TMC OA. Second, we sought surgeon characteristics associated with a preferred operative technique and assessed surgeon demographic factors associated with variability in recommendation of operative treatment.

MATERIALS & METHODS

After institutional review board approval of this cross-sectional study, we invited all hand surgeon members of the Science of Variation Group (SOVG) to participate. The SOVG is a web-based collaborative that aims to study variation in definition, interpretations, classification, and treatment of illnesses without financial incentives.²³ Invitations were sent on September 8, 2018, followed by three reminders after one, two, and three weeks to those who had not responded. Surgeons were presented 16 different clinical scenarios of patients with TMC OA, developed in an online survey tool (SurveyMonkey, Palo Alto, CA).

Each scenario varied four patient characteristics: (1) pain, (2) injection (3) radiograph, and (4) psychosocial symptoms (Appendix 1). Each characteristic had two alternatives: A and B. The alternatives for pain were (1A) mild occasional and minimal interfering with work and hobbies and (1B) substantial and interfering with work and hobbies. For injections, the alternatives were (2A) pain relieved for nearly a year by injection and (2B) pain not relieved by injection. The alternatives for radiograph were (3A) severe TMC arthrosis and (3B) mild to moderate TMC radiographic arthrosis. Psychosocial symptoms had alternatives (4A) substantial symptoms of depression and catastrophic thinking (defined in the scenario as deflated, overwhelmed, hopeless etc.) and (4B) few symptoms of depression and catastrophic thinking (terms such as resilient, positive, or joyful). Sixteen cases were created to include all possible combinations of the clinical characteristics.

Surgeons were asked two questions per scenario: (1) Would you recommend surgical treatment for this patient? and (2) If yes to (1): Which surgical technique would you offer: trapeziectomy; trapeziectomy with LRTI; joint replacement; or arthrodesis? We calculated the "likelihood to recommend surgical treatment score" for each clinical characteristic. This is a score from 0 to 1, with 0 indicating that for none of the patients did the surgeon recommend surgical treatment and 1 indicating that for all patients the surgeon recommends surgical treatment. Subsequently we calculated the "likelihood to recommend surgical treatment score" per surgeon by dividing the number of patients they would operate on by 16 (the total number of patients).

Study sample

Of the 402 hand surgeons invited, 133 (33%) responded and participated. This rate does not represent the participation rate of people qualified and able to participate because the SOVG e-mail list is not confirmed or updated and participants decide whether the topic is in their area of expertise. Surgeons (n = 7) who did not complete all questions

were excluded, leaving 126 participants for analysis. Ten participants (8%) were women and most surgeons practiced in North America (80; 63%), specialized in orthopaedic surgery (106; 84%) and supervised trainees (94; 75%) (Table 1). On average, surgeons recommended operative treatment in six of 16 patient scenarios (Appendix 2). Two surgeons (1.6%) did not recommend surgery at all and two surgeons recommended surgical treatment in all patient scenarios (1.6%) (Appendix 2).

Table 1. Surgeon characteristics.

Variables	N = 126
Sex	
Male	116 (92)
Female	10 (8)
Region	
North America	80 (63)
Europe	24 (19)
Other	22 (17)
Subspecialty	
Orthopaedics	106 (84)
Trauma surgery	9 (7.1)
Plastic surgery	11 (8.7)
Years in independent practice	
0 - 5	35 (28)
6 - 10	27 (21)
11 - 20	44 (35)
21- 30	20 (16)
Supervision of trainees	
No	32 (25)
Yes	94 (75)
Preferred surgical technique*	
Trapeziectomy	23 (19)
Trapeziectomy with LRTI	89 (72)
Joint replacement	4 (3.2)
Arthrodesis	6 (4.8)
No clear preference	2 (1.6)

LRTI = ligament reconstruction and tendon interposition. All discrete variables as number (percentage). *Two surgeons did not recommend surgery at all.

Sample size calculation

A priori, we calculated that a minimum sample size of 126 participants would provide 80% statistical power ($\beta = 0.20$; two-tailed $\alpha = 0.05$) to detect a difference in likelihood to recommend surgical treatment score of 0.1 assuming a standard deviation (SD) of 0.2 in both groups using a paired t-test.

Statistical analysis

Continuous variables are reported as mean with standard deviation and discrete variables as absolute numbers with percentages. We used Student t-test to compare continuous with dichotomous variables, analysis of variance for continuous and nominal variables, and Fisher exact test to compare nominal and dichotomous variables or two nominal variables. We used the paired t-test to compare the difference between the "likelihood to recommend surgical treatment score" based on the four dichotomous clinical characteristics. For example: the "recommendation for surgical treatment score" for severe TMC OA on radiograph ($n = 8$) was compared with mild/moderate TMC OA on radiograph ($n = 8$), as judged by all surgeons.

We assigned preferred surgical technique per surgeon based on the answer to question 2. Surgeons with multiple favorite techniques ($n = 2$) and surgeons without choosing surgery at all ($n = 2$) were omitted because no preferred technique could be established.

We used Fleiss kappa to assess the inter-observer agreement and calculated 95% confidence intervals (95% CI) and *P* values by using the bootstrap method (number of resamples = 1000).²⁴ Kappa is a quantitative measure of agreement and takes into account the possibility of (dis)agreement occurring simply by chance.²⁵ A kappa of 1 indicates perfect agreement, whereas a kappa of 0 indicates agreement equivalent to change. *P* values less than 0.05 were considered statistically significant.

Table 2. Bivariate analyses.

Variables	Likelihood to recommend surgical treatment*	<i>P</i> value
Surgeon characteristics		
Sex		
Male	0.37 ± 0.19	0.43
Female	0.42 ± 0.16	
Region		
North America	0.34 ± 0.19	<0.05
Europe	0.43 ± 0.21	
Other	0.43 ± 0.16	

Table 2. Continued.

Variables	Likelihood to recommend surgical treatment*	P value
Subspecialty		
Orthopaedics	0.38 ± 0.19	0.48
Trauma surgery	0.41 ± 0.18	
Plastic surgery	0.31 ± 0.17	
Years in independent practice		
0 - 5	0.38 ± 0.17	0.45
6 - 10	0.34 ± 0.17	
11 - 20	0.36 ± 0.22	
21 - 30	0.43 ± 0.19	
Supervision of trainees		
No	0.33 ± 0.15	0.11
Yes	0.39 ± 0.20	
Preferred surgical technique		
Trapeziectomy	0.37 ± 0.16	0.87
Trapeziectomy with LRTI	0.38 ± 0.19	
Joint Replacement	0.45 ± 0.29	
Arthrodesis	0.35 ± 0.17	
No clear preference	0.47 ± 0.17	
Patient characteristics		
Pain		
Mild	0.16 ± 0.23	<0.05
Substantial	0.59 ± 0.24	
Previous injection		
Relieved pain for nearly 1 year	0.27 ± 0.24	<0.05
Did not relieve pain	0.48 ± 0.21	
Radiograph		
Mild/moderate TMC OA	0.33 ± 0.20	<0.05
Severe TMC OA	0.41 ± 0.23	
Psychosocial symptoms of depression		
Few symptoms	0.46 ± 0.24	<0.05
Substantial symptoms	0.28 ± 0.25	

LRTI = ligament reconstruction and tendon interposition; TMC OA = trapeziometacarpal osteoarthritis. Continuous variables as mean (\pm SD); **bold** indicates statistically significant difference ($P < 0.05$).

*Likelihood to recommend surgical treatment is a score from 0 to 1, with 0 indicating that for none of the cases the surgeon recommends surgical treatment, and 1 indicating that for all of the cases the surgeon recommends surgical treatment.

RESULTS

Factors associated with the decision to offer operative treatment

In bivariate analysis, the only surgeon characteristic related to recommendation of surgical treatment was region: surgeons from North America (0.34 ± 0.19) recommended surgical treatment less often than European surgeons (0.43 ± 0.21) or those from other regions (0.43 ± 0.16) ($P = 0.035$) (Table 2). The patient characteristics associated with greater likelihood to recommend surgical treatment were substantial pain (1B) ($P < 0.05$), a previous injection that did not relieve pain (2B) ($P < 0.05$), radiograph with severe TMC OA (3B) ($P < 0.05$), and few symptoms of depression (4A) ($P < 0.05$) (Table 2). Having substantial pain had a relatively high influence on surgeon decision to recommend surgery (0.59 ± 0.24) compared to patients with mild pain (0.16 ± 0.23) (Table 2).

Surgeon characteristics associated with preferred surgical technique

Practice region was the only factor associated with preferred surgical technique ($P < 0.05$) in bivariate analysis (Table 3). Trapeziectomy with LRTI was the preferred technique in all regions and most favored among surgeons from North America ($n = 65$, 84%) compared with European ($n = 14$, 58%) or surgeons from other regions ($n = 10$, 48%) (Table 3). Joint replacement was least favored and not preferred in any scenario by surgeons from outside North America or Europe (Table 3).

Inter-observer agreement to offer surgical treatment

We found low agreement in surgeon recommendation of treatment (kappa 0.22; 95% CI = 0.11 – 0.33; $P < 0.05$) (Table 4). There were no demographic factors associated with agreement (Table 4).

Table 3. Bivariate analyses on preferred surgical technique.

Variables	Preferred surgical technique				P value
	Trapeziectomy	Trapeziectomy with LFTI	Joint replacement	Arthrodesis	
Sex					
Male	2 (20)	7 (70)	0 (0)	1 (10)	0.68
Female	21 (19)	82 (73)	4 (3.6)	5 (4.5)	
Region					
North America	9 (12)	65 (84)	1 (1.3)	2 (2.6)	<0.05
Europe	6 (25)	14 (58)	3 (13)	1 (4.2)	
Other	8 (38)	10 (48)	0 (0)	3 (14)	
Subspecialty					
Orthopaedics	15 (15)	78 (76)	3 (2.9)	6 (5.9)	0.10
Trauma surgery	4 (44)	4 (44)	1 (11)	0 (0)	
Plastic surgery	4 (36)	7 (64)	0 (0)	0 (0)	
Years in independent practice					
0 - 5	6 (18)	27 (79)	1 (2.9)	0 (0)	0.07
6 - 10	4 (16)	20 (80)	1 (4.0)	0 (0)	
11 - 20	8 (18)	33 (75)	0 (0)	3 (6.8)	
21- 30	5 (26)	9 (47)	2 (11)	3 (16)	
Supervision of trainees					
No	7 (23)	20 (65)	2 (6.5)	2 (6.5)	0.42
Yes	16 (18)	69 (76)	2 (2.2)	4 (4.4)	

LRTI = ligament reconstruction and tendon interposition. All discrete variables as number (percentage); percentage reported as relative frequency of every row; **bold** indicates statistically significant difference ($P < 0.05$).

Table 4. Inter-observer agreement.

Variables	Kappa (95% CI)*
Overall Kappa	0.22 (0.11 to 0.33)
Sex	
Male	0.21 (0.11 to 0.32)
Female	0.23 (0.11 to 0.35)
Region	
North America	0.29 (0.14 to 0.43)
Europe	0.13 (0.05 to 0.20)
Other	0.14 (0.07 to 0.22)
Subspecialty	
Orthopaedics	0.22 (0.11 to 0.32)
Trauma Surgery	0.14 (0.02 to 0.26)
Plastic Surgery	0.24 (0.07 to 0.42)
Years in independent practice	
0 - 5	0.27 (0.15 to 0.39)
6 - 10	0.20 (0.09 to 0.30)
11 - 20	0.23 (0.10 to 0.35)
21- 30	0.12 (0.03 to 0.20)
Supervision of trainees	
No	0.24 (0.11 to 0.37)
Yes	0.21 (0.11 to 0.31)

CI = Confidence Interval.

*All *P* values were statistically significant; *P* < 0.05.

DISCUSSION

Recommendations for operative treatment of TMC OA vary widely according to surgeon attitude and beliefs.^{13,14,16,18,22} To help ensure that treatment choices are consistent with what matters most to individual patients and are not based on misconceptions or surgeon bias, this study assessed factors associated with variation in offer of operative treatment to patients with TMC OA. We also studied the surgeon characteristics associated with preferred technique.

We acknowledge some study limitations. First, patient characteristics based on clinical scenarios cannot fully represent a clinical encounter because patient scenarios fail to capture all the elements of patient-physician interaction. We intentionally simplified the scenario, and other approaches might yield different results. A series of such simplified experiments might help identify the key factors influencing variability of recommendation or offer of surgery. Second, we included 4 different patient factors (pain, response to injection, radiographic appearance, and psychosocial symptoms) we deemed most important, but other characteristics such as occupation, age, or physical examination might also merit study. Each additional trait doubles the number of necessary cases. To limit survey burden, we did not increase case load from 16 to 32. Third, participating members of the SOVG may not be representative of the average hand surgeon. Also, only 10 out of 126 (8%) participating surgeons were women and our findings may not be representative of all female surgeons. The SOVG periodically invites new members both in the United States and internationally. The group seems to represent the subset of surgeons that corresponds well via e-mail and that feel their time is well invested in surveys. The SOVG surveys are designed to look for sources of variation within the participant group and may or may not be externally valid. Because we assess common human traits and biases, we believe there are important and useful findings that apply outside this setting. Fourth, the wording of the survey is part of the experiment. Our study specifically addresses the relatively paternalistic approach of "recommending" surgery rather than the more shared approach of "offering" surgery. The importance of this wording can be tested in a series of future experiments. Fifth, the majority of hand surgeons were orthopaedic surgeons from North America and the lack of observed differences between subgroups might be spurious.

Surgeons were more likely to recommend surgery to patients with substantial pain, more severe osteoarthritis on radiographs, and prior ineffective injections. All are often regarded as signs of greater pathophysiology. Yet, there is mounting evidence

that pain intensity and dissatisfaction with treatment are related to symptoms of depression and less effective coping strategies.²⁶⁻²⁸ Moreover, the correlation between symptom intensity and radiographic severity of TMC OA is limited.^{2,29,30} Evidence also suggests that intra-articular injections do not outperform simulated injections.³¹⁻³⁶

This raises the possibility that surgeons might be underappreciating and undertreating psychosocial determinants of illness, overemphasizing radiographic findings, and being unhelpfully influenced by dissatisfaction with a treatment. Attention to psychosocial factors among patients with disabling musculoskeletal pain might be beneficial.³⁷⁻⁴² Future studies could assess whether screening for ineffective coping strategies and depression, and addressing this, for example through cognitive behavioral therapy-based treatment strategies, is a helpful adjunct in the treatment of TMC OA. Surgeons seem aware of the importance of mental health, given that they were less likely to recommend surgery to patients with substantial symptoms of depression. Future studies could also focus on addressing surgeon barriers for referral to psychosocial treatment.⁴³ A recent study found that surgeons are willing to discuss psychological factors but referrals are hindered by perceived lack of time, discomfort with discussion of the mental and social determinants of health, and stigma associated with mental health.⁴⁴

The finding that trapeziectomy with LRTI is the favored procedure (particularly among North American surgeons) is in line with other studies.^{16,18} This is in spite of notable evidence that the addition of LRTI adds complications and delays recovery with alleviation of symptoms and limitations comparable with trapeziectomy alone.^{20,45} This consistent finding suggests that factors other than best evidence are driving surgeon recommendations. We found no difference in years of practice and offered surgical technique, which is in line with previous research.^{21,46}

There was low inter-observer agreement in offer of surgery. This low agreement on the treatment of TMC OA is consistent with prior studies^{15,17}, and is in line with a documented 7-fold variation in surgery rate in a database study.¹⁴ Based on evidence from prior studies, the decision to offer surgery is influenced, in part, by factors such as surgeon experience, training, and personality.^{17,21} Surgeons are more likely to recommend surgery for their patient than for themselves.⁴⁷ And, when evidence for surgical treatments is inconclusive, they fall back on personal and cultural factors rather than on their patient's values and preferences.^{22,48} It is important to use communication strategies and tools that help people become aware of what matters most to them and ensure their decision is not affected by any of several common

misconceptions about arthritis.^{22,49} Mounting evidence suggests that TMC OA is particularly well-suited for use of a decision aid (a website or video that helps patients become aware of what matters most to them, correct common misconceptions, and clarify their preferences). One randomized controlled trial including 90 patients with TMC OA found that patients had less decisional conflict after using a decision-aid.⁵⁰ Because practice variation is associated with higher health care costs²², future studies could assess whether wide use of a decision aid reduces unwarranted variation and costs with no deficiency in patient-reported outcomes compared with care without a decision aid.

Our results identified notable variation in operative care for TMC OA, which seems associated with variable attention to mental health. Greater symptoms and physical limitations (such as substantial pain, radiographic severity, and previous injection without pain relief) do not correspond well with greater disease. Yet, they are often interpreted as reflecting more severe pathophysiology. This interpretation does not adequately account for the consistent finding that much of the variation in symptoms and physical limitations is accounted for by the psychological and social aspects of human illness. The treatment of TMC OA might benefit from addressing stress, distress, and less-effective coping strategies, and also by clarifying what is most important to the patient. This can include empathetic communication strategy training for doctors, incorporating mental health professionals in the treatment program, and decision aids. Future research might address the ability to offer treatment strategies that focus on mental health opportunities and foster effective coping strategies to improve outcomes using fewer resources.

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APPENDICES

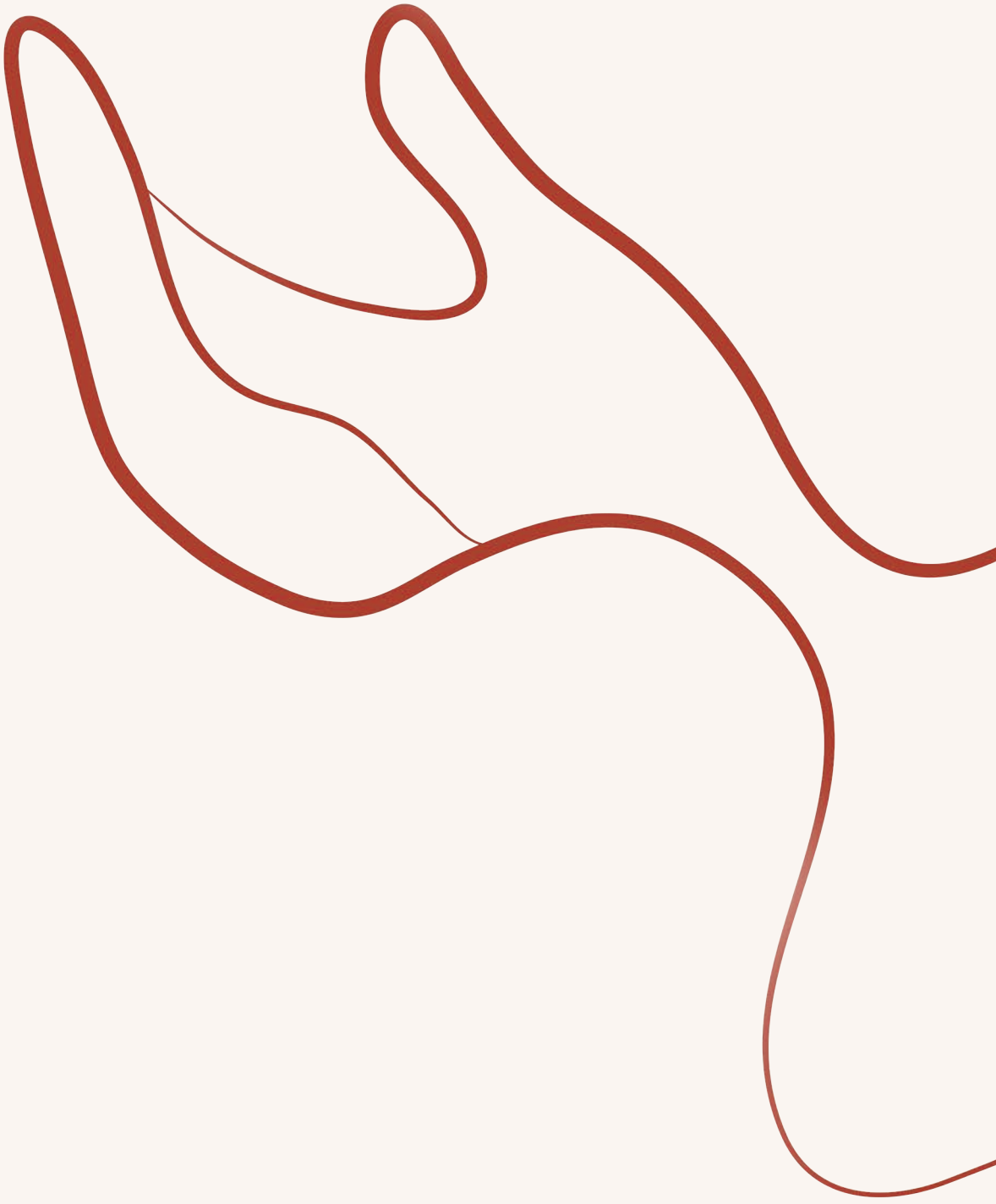
Appendix 1: Scenario.

A 55-year old woman is not satisfied with education, orthosis wear, and medication and is considering surgery. The pain is (*mild occasional and minimal interfering with work and hobbies* versus *substantial and interfering with work and hobbies*). A previous injection (*relieved the pain for nearly a year* versus *provided a day or 2 of pain relief*). Radiographs show (*severe TMC arthrosis* versus *mild to moderate TMC arthrosis*). The patient seems (*overwhelmed, negative and deflated [or synonym]* versus *positive, cheery and active [or synonym]*).

Appendix 2. Surgical treatment recommended.

Number of times a surgeon recommend surgery	Number of surgeons*
0	2 (1.6)
1	1 (0.80)
2	14 (11)
3	5 (4.0)
4	28 (22)
5	10 (8.0)
6	15 (12)
7	12 (9.5)
8	19 (15)
9	6 (4.8)
10	3 (2.4)
11	5 (4.0)
12	3 (2.4)
13	1 (0.80)
14	0 (0.0)
15	0 (0.0)
16	2 (1.6)
Mean (\pm SD)	6.0 (3.0)

*Discrete variables as number (percentage).



Chapter 5

SURGEONS ATTITUDE TOWARD PSYCHOSOCIAL ASPECTS OF TRAPEZIOMETACARPAL OSTEOARTHRITIS

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ABSTRACT

Background: There is notable evidence that unhelpful thoughts (symptoms of anxiety and depression) increase symptom intensity among patients with trapeziometacarpal osteoarthritis (TMC OA). Surgeons may or may not be mindful of this line of evidence when interacting with patients.

Objectives: In a survey-based experiment, we randomized surgeons to be prompted about the psychosocial aspects of TMC OA. We aimed to measure the influence of mindfulness of mental health on treatment recommendations and willingness to discuss mental health interventions.

Methods: This was a cross-sectional survey study. We randomized surgeons to read one of two paragraphs: (A) about biomedical treatment options for TMC OA, or (B) about the impact of mental and social aspects on TMC OA. Thereafter, surgeons were asked several questions about their opinions and treatment recommendations.

Participants: 121 hand surgeons, 83 were members of the Science of Variation Group. Most were practicing in Europe (48; 40%) or North America (54; 45%). Sixty-two surgeons (51%) were randomized to the biomedical paragraph (A) and 59 surgeons (49%) to the biopsychosocial paragraph (B).

Results: We found that prompting surgeons with information about the psychosocial aspects of TMC OA did not influence their attitudes or treatment recommendations. Most surgeons were willing to offer patients a workbook (92%) or psychologist referral (84%). Among the few surgeons declining to refer, their reasoning was "it would not be of any help" and "stigmatization".

Conclusion: The observation that a paragraph to encourage mindfulness about the psychosocial aspects of TMC OA, which had no influence on surgeon opinions, suggests that awareness may not be a major factor accounting the relatively limited implementation of this evidence in practice to date. Surgeons seem aware of the importance of psychological influence and barriers may include availability, stigma, and a sense of futility.

INTRODUCTION

Trapeziometacarpal osteoarthritis (TMC OA) is part of normal human aging.¹ Among people seeking specialty care for TMC OA and people seeing a hand specialist for another condition with incidental TMC arthrosis, radiographic severity is not associated with symptom intensity.²⁻⁴ It seems that people can accommodate the condition and it is likely a subset experiencing difficulty accommodating who seek specialty care.²⁻⁴

There is strong evidence that psychosocial factors, such as unhelpful feelings (symptoms of distress, meaning depression and anxiety) and unhelpful thoughts (e.g. worst case or catastrophic thinking), account for more of the variation in symptom severity and magnitude of physical limitations than measure of pathophysiology.^{3,5,6} There is also evidence that people who request surgery for TMC OA have greater catastrophic thinking in response to nociception and less self-reported personal control than those who are satisfied with nonoperative treatment.^{4,6,7} Offering interventions to reorient unhelpful thoughts and emotions in response to pathophysiology has proved helpful for other painful musculoskeletal conditions such as knee and hip osteoarthritis, back pain, and musculoskeletal trauma.⁸⁻¹² These lines of evidence suggest that addressing mental and social health opportunities can help people seeking care for TMC OA to feel better and do more.

It is not clear that this evidence has been implemented in the daily practice of hand surgery specialty care. Perhaps, surgeons are still becoming aware of and getting comfortable with this line of evidence. Some studies among surgical patients show high rates of undiagnosed or unaddressed mental health opportunities (opportunities to improve health by reorienting common misinterpretation of symptoms or alleviating worry or despair).^{13,14} Prior studies identified other factors such as perceived lack of time, social stigma, and surgeon uncertainty about how to refer.¹⁵ A systematic review among physicians with a broad variety of specialties noted that surgeons are less likely, and therefore an "at-risk group", to refer their patients for psychological care.¹⁶ The authors speculated that greater awareness might increase the number of referrals.¹⁶

Previous studies on semantic priming (influencing ideas through words or pictures) have demonstrated that written text can unconsciously influence attitude and behavior.¹⁷⁻²⁰ Positive priming through a questionnaire is associated with improvement in physical strength.²⁰ Whereas negatively phrased questions regarding pain intensity scores were associated with more limited capability.¹⁹ Priming surgeons by having them read information about the influences of psychosocial aspects on TMC OA, may change their attitude toward offering psychosocial treatment for patients with TMC OA.

This survey-based study randomized surgeons to read information about TMC OA from a biomedical or a biopsychosocial paradigm. We aimed to test if prompting surgeons with biopsychosocial information would influence their opinions about mental and social health opportunities for patients with TMC OA. This study also addressed reasons not offering psychological support.

Table 1. Surgeon characteristics.

Variables	N = 121
Men	101 (83)
Region of practice	
Europe	48 (40)
North America	54 (45)
Other*	19 (16)
Subspecialty	
Orthopaedic surgeon	78 (64)
Plastic surgeon	38 (31)
Trauma surgeon	5 (4.1)
Experience in independent practice	
0 - 5 years	32 (26)
6 - 10 years	34 (28)
11 - 20 years	34 (28)
21- 30 years	21 (17)
Supervision of trainees	91 (75)
Primed to paragraph	
A) Biomedical paradigm	62 (51)
B) Psychosocial paradigm	59 (49)

All discrete variables as number (percentage). *Specified in Appendix 3; consists of Asia, Australia, South-America.

MATERIAL & METHODS

Study design

This cross-sectional survey study was reviewed and approved by our institutional review board and a waiver of informed consent was obtained. Hand surgeon members of the Science of Variation Group (SOVG; a web-based collaborative that studies variation in care²¹) were invited (along with 39 nonmember colleagues) to participate in this survey-based experiment. An online tool (SurveyMonkey, Palo Alto, California, United States) was used to set up and conduct the survey. Variation within the sample is more important than response rate for such experiments. The associations are more likely to generalize than the absolute rates.

Measurements

After providing demographic information, physicians were randomly assigned to read one of two paragraphs (A or B). Paragraph A contained biomedical treatment options for TMC OA, such as: "Treatment includes splints, medications, injection, and surgery... Osteotomy, arthrodesis, and distraction are also considered" (full text with references can be found in Appendix 1). Paragraph B emphasized the important influence of mental and social health on symptoms and limitations from TMC OA, including information like: "The correlation between radiographic severity of TMC OA and pain intensity is surprisingly limited. Patients with fewer symptoms of depression and more adaptive coping strategies have fewer symptoms and limitations" (full text with references can be found in Appendix 1).

After reading the biomedical or biopsychosocial paragraph, surgeons were asked several questions about their thoughts and recommendations, starting with: "To what degree do you think psychosocial factors influence symptom intensity and magnitude of limitations associated with TMC arthrosis?" (Question 1; Appendix 2). Then, physicians were asked to read a clinical scenario of a 55-year old woman with symptoms of TMC OA (Appendix 2) and complete the remaining questions: (2) Would injection or surgical intervention address all of the patient's issues? If no, what would be helpful in this scenario? (options given; Appendix 2); (3) If the patient was interested in help with resiliency and adaptation and there was a workbook readily available in your office, would you offer it to the patient? If no, why not? (options given); (4) If the patient was interested in help with resiliency and adaptation and there was a psychologist or social worker readily available in your office, would you ask him or her to help? If no, why not? (options given); (5) Open text box to leave comments.

Study population

We sent invitations to the 388 hand surgeon members through e-mail in the SOVG database, but we do not know how many of those e-mails are still active and we also do not know which surgeons consider themselves active participants in the collaborative. We also sent e-mail invitations to 39 hand surgeons in the Netherlands. These 427 e-mails resulted in 121 participants in this randomized study. Sixty-two surgeons (51%) were randomized to the biomedical paragraph (A) and 59 surgeons (49%) to the biopsychosocial paragraph (B) (Table 1). Five surgeons (4.1%) did not complete the entire survey; however, no participants were excluded from analysis because all answered at least the first question.

Sample size calculation

A priori power analysis indicated that a sample size of 119 participants would provide 80% statistical power ($\beta = 0.20$; two-tailed $\alpha = 0.05$) for a regression with five predictors if priming would account for 5% or more of the variability in expected psychological influence, and our complete model would account for 25% of the overall variability.

Statistical analysis

Continuous variables are reported as mean with standard deviation and discrete variables as absolute numbers with percentages. We used Student t-test to compare continuous and dichotomous variables, analysis of variance for continuous and nominal variables, and Fisher exact test to compare nominal and dichotomous variables or two dichotomous variables. A *P* value of less than 0.05 was considered statistically significant.

We entered all variables with $P < 0.10$ in bivariate analysis into the multivariable analysis to control for potential confounders. We aimed to use a multivariable linear regression model to identify factors associated with the expected influence of psychosocial aspects, and multivariable logistic regression analysis to determine factors independently associated with (1) surgeon opinion on effectiveness of injection or surgery, and (2) surgeon willingness to offer psychological interventions.

Answers to questions 2B, 3B and 4B were dichotomized and analyzed separately. Surgeons comments mentioned at question 5 were categorized into themes by two investigators. After independently analyzing and assigning themes to every comment, consensus on the categories was reached by discussion.

RESULTS

Study population

Of the 121 participating surgeons, most were men ($n = 101$; 83%) and specialized in orthopaedic surgery ($n = 78$; 64%) (Table 1). Forty-eight surgeons (40%) were practicing in Europe and 54 (45%) in North America (Table 1; Appendix 3).

Prompting and expected psychosocial influence on TMC OA

Prompting surgeons with the biomedical paragraph (A) or biopsychosocial paragraph (B) was not associated with surgeon degree of expected psychological influence on symptom intensity among patients with TMC OA ($6.2 \pm$ standard deviation [SD] of 2.2 in paragraph A versus $6.4 \pm$ SD of 2.0 in paragraph B; $P = 0.67$) (Table 2). In bivariate analysis, no surgeon characteristics were associated with the expected influence of psychosocial factors (Question 1; Appendix 4). Therefore, we did not perform multivariable analysis.

Table 2. Association between priming and psychological influence on and treatment options for TMC OA.

Variables	Paradigm		P value
	Biomedical (A)	Biopsychosocial (B)	
Q1. To what degree do you think psychosocial factors influence symptom intensity and magnitude of limitations associated with TMC OA?*	6.2 ± 2.2	6.4 ± 2.0	0.67
Q2. Would injection or surgical intervention address all of the patient's issues? Answered with "yes".	11 (18)	6 (10)	0.30
Q3. If the patient was interested in help with resiliency and adaptation and there was a workbook readily available in your office, would you offer it to the patient? Answered with "yes".	57 (95)	52 (88)	0.20
Q4. If the patient was interested in help with resiliency and adaptation and there was a psychologist or social worker readily available in your office, would you ask him or her to help? Answered with "yes".	50 (86)	47 (81)	0.62

TMC OA = trapeziometacarpal osteoarthritis. All variables as number (percentage) if not otherwise specified. *Continuous score from 0-10 as mean (\pm SD).

Table 3. Other interventions and reasons for not offering psychological support.

Helpful options, other than injection or surgical intervention.	Q2B N = 102
Hand therapy	75 (74)
Splint	46 (45)
Psychological workbook	30 (29)
Referral to psychologist	16 (16)
More biomedical treatment (e.g. pain killers)	9 (8.8)
There are no more helpful options for this patient	9 (8.8)
Referral back to regular doctor	3 (2.9)

Q = question. Variables as number (percentage). More than one option could be selected for all questions.

Factors associated with surgeon opinion on effectiveness of injection or surgery

Accounting for potential interaction of variables using multivariable analysis, plastic surgeons (odds ratio [OR] = 0.12; standard error [SE] = 0.11; 95% confidence interval [CI] = 0.021 to 0.72; $P = 0.020$) were less likely to agree that injection or surgical intervention would address all of the patient's health opportunities than orthopaedic and trauma surgeons; surgeons from North America (OR = 0.23; SE = 0.17; 95% CI = 0.054 to 0.98; $P = 0.048$) were less likely to agree than surgeons from Europe or other continents. Most surgeons ($n = 102$; 86%) felt that injection or surgery would not address all the patient's health opportunities.

Factors associated with willingness to offer psychological interventions

In bivariate analysis, no factors, including priming, were associated with surgeon willingness to offer psychological help to patients with TMC OA (Question 3A and 4A; Appendix 4). Therefore, we did not perform multivariable analysis. There was a strong ceiling effect, with most surgeons willing to offer patients a workbook ($n = 109$; 92%) or refer them to a psychologist ($n = 97$; 84%).

Other treatment options and reasons for not offering psychological support

Surgeons ($n = 102$; 86%) who thought injection or surgery would not address all patient's issues suggested hand therapy ($n = 75$; 74%) and a splint ($n = 46$; 45%) most often as helpful other treatment options (Table 3). Offering a psychological workbook ($n = 30$; 29%) and referral to a psychologist ($n = 16$; 16%) were less often selected. Among the few surgeons not willing to offer these psychological interventions, primary reasons were "it would not be of any help/a waste of time" ($n = 14$) and because of "stigma associated with psychological factors" ($n = 10$) (Table 3).

Reasons for not offering psychological interventions.	Q3B N = 10	Q4B N = 19
It would not be of any help / waste of time	5	9
Stigma associated with psychological factors	2	8
Risk of dissatisfied patient	1	3
Lack of time	2	1
Uncomfortable feeling about raising such topics	1	1

Surgeon comments

The 27 comments made were categorized into six different themes; more than one theme could be selected per comment (Appendix 5). Nine comments were classified as biomedical (e.g.: "Surgery might well help with a big proportion of patients pain" or "I would consider corticosteroid injection"), and another nine as biopsychosocial (e.g.: "Offering resiliency training during a surgeon visit is challenging" or "I find working with a multidisciplinary pain team very useful"). The remaining comments were labeled as surgery is a reasonable last resort, psychosocial treatment is unavailable, surgery is financially more profitable to surgeons, or other (Appendix 5).

DISCUSSION

Evidence suggests that attention to mental and social health might help people adapt to symptoms of TMC OA,^{8-12,22} but not all surgeons are comfortable to discuss psychosocial issues or offer psychosocial care.^{15,16,23} More education and knowledge about the influence and presentation of psychological symptoms may contribute to greater awareness and a more positive attitude among surgeons.¹⁶ Therefore, this study randomized surgeons to read a biomedical or a biopsychosocial paradigm to test if prompting surgeons would influence their opinion about psychosocial health opportunities. We also aimed to measure the willingness to discuss mental health interventions and addressed reasons not offering psychological support.

The finding that prompting surgeons was not associated with surgeon degree of expected psychological influence might be explained by the overall agreement found in this and previous studies that psychological factors are relevant in the course of physical illness;^{23,26,27} more exposure to evidence-based information about the strong

influence of psychological factors does not seem to increase surgeon awareness or alter surgeon behavior. In other words, our results suggests that more education about the psychosocial aspects of TMC OA does not change surgeons' attitude toward treatment options. This means that surgeons seem aware of the existence and importance of this association. The average agreement of surgeons with expected psychological influence was 6.3 (SD = 2.2) in our study. In general, surgeons are tend to have a more negative attitude toward psychological problems than doctors from nonsurgical specialties.^{26,27} Studies demonstrate that surgeons, compared with physicians, more often disagree with the routinely assessment of psychosocial factors among in- and outpatients, indicate that emotional care of patients is impractical, and state that mental and social care does not have their interest.^{26,27} A study conducted at the St. George's Hospital in London found a difference in expectations between surgeons and physicians in the management of emotional care as a part of their practice; surgeons seem to value and prioritize the management of emotional problems less than physicians.²³ Despite these differences with other specialists, surgeon attitude has clearly changed in a positive way over the last decades: in 1986, only 67% of all surgeons agreed with the statement "Psychological factors are important in the course of physical illness" in a survey study, compared with 97% in 2003.²³ Nowadays, most surgeons seem to be quite aware of the importance of psychological needs of their patient and believe that biomedical treatment alone is not sufficient.¹⁵ Morgan and Killoughery attributed these differences in surgeon attitude to a shift in the culture of medical professionals, in part, due to a medical curriculum that is more focused on the patient-physician communication and biopsychosocial constructs of diseases.²³

However, surgeons can experience barriers to identify, discuss, and address mental health opportunities and referral rates remain low.^{15,16,23} A Dutch study found that only 48% of all hospital consultants – physicians and surgeons – frequently discuss patients' psychological issues.²⁶ A British study among physicians showed that 78% wanted more mental health expertise but referrals were avoided because of the social stigma associated with mental health.²³ The relatively high rates of surgeon willingness to offer a workbook (92%) or refer to a psychologist (84%) in our study contrasts with previous evidence of an overall negative attitude of surgeons toward offering psychosocial care.^{15,23,26} This could be partly explained by the way we phrased the questions "if the patient is interested" and "if psychological help is readily available", are both factors that could decrease surgeon barriers to discuss and offer help. Future studies could assess if increasing the direct availability of a social worker or psychologist in outpatient clinics will also increase referral rates among medical specialists for patients with TMC OA seeking specialty care.

The finding that plastic surgeons and surgeons from North America are less likely to agree that injection or surgical intervention would address all of the patient's issues is in line with prior studies documenting wide variation in treatment strategy for TMC OA.²⁸⁻³⁰ It is also in line with a recent study from our research team that found North American surgeons are less likely to recommend surgical treatment than European or surgeons from another region.²⁹ Birkmeyer *et al.* attributes variation in surgical rates across countries to differences in health care capacity, financial incentives, but also to physicians' beliefs about the indication for surgery.³¹ Treatment variation might be due to what is perceived as a dearth of high-quality evidence on best treatment for TMC OA or an emphasis on training and personal experience over evidence.³² Good evidence is necessary, but not sufficient to change practice.³³ The fact that most surgeons (86%) agreed with the statement that injection or surgery is not enough, suggests that there are opportunities – other than technical care – to expand on treatment strategies for TMC OA. There is strong evidence that biopsychosocial interventions can help patients with chronic illnesses, including OA, to adapt and improve their overall well-being.^{11,22} Screening for psychological factors and assessing patient's interest in help with adaptation, may help surgeons to discuss psychosocial topics more often. Future studies could focus on lowering surgeon barriers to refer by increasing the direct availability of psychosocial workers in surgeons' offices.

We acknowledge some study limitations. First, the study population consisted of participating SOVG members and hand surgeons from our personal network and may not be representative of the average hand surgeon. Also, most participants were orthopaedic surgeons and men and the results might not generalize to plastic surgeons and women. Second, we did not assess time spent on reading the priming paragraph; short reading time might decrease the impact of priming on surgeon attitude and could have resulted in a lack of observed differences between groups. Third, we did not measure surgeons' attitude toward psychosocial influences at baseline. Therefore, the impact of the priming stimulus remains unclear. However, previous literature is clear that semantic priming influences perceptions, behavior and a person's attitude.^{17,20,24} Fourth, a clinical patient scenario fails to capture all elements of the patient-physician interaction and therefore cannot fully represent a clinical encounter. Fifth, surgeon decision-making in a theoretical setting might differ from decision-making in an actual consultation. Social desirability bias²⁵, a common bias in self-administered questionnaires, and the awareness of participating in a survey may have influenced the answers. We did not account for potential differences in attitude between surgeons working in private clinics *versus* public settings.

CONCLUSION

Most surgeons agree that biomedical treatment alone is not sufficient for patients seeking specialty care for TMC OA. Surgeons seem aware of the importance of psychological influence and barriers to refer may include availability, stigma, and a sense of futility. Future studies could assess the impact of implementing psychosocial assistance in outpatient clinics on patient satisfaction, referral rates, and offer of surgical treatment.

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APPENDICES

Appendix 1. Priming paragraphs about treatment options for trapeziometacarpal osteoarthritis (TMC OA).

Paragraph A - Biomedical paradigm

"Treatment for TMC OA includes splints, medications, injection (steroid and hyaluronic acid), and surgery. Surgical variations involve the amount of trapezium resected; stabilization of the base of the metacarpal; and the use of interposition materials or prostheses.^{1,2} Osteotomy, arthrodesis, and distraction are also considered.^{3,4} There is no evidence that one technique achieves superior pain relief and improvement of physical abilities.⁵"

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Paragraph B - Biopsychosocial paradigm

"TMC OA is an expected part of human aging.^{1,2} Given the high rate of well-adapted incidental TMC OA in the hand surgeon's office, it seems that TMC OA is generally well-adapted.^{1,2} The correlation between radiographic severity of TMC OA and pain intensity or magnitude of physical limitations is surprisingly limited.^{1,2} Patients with fewer symptoms of depression and more adaptive coping strategies (e.g. less catastrophic thinking; greater self-efficacy) have fewer symptoms and limitations.³⁻⁶ Treatments based on cognitive behavioral therapy principles have proved useful for many painful conditions and might be a good option for patients with substantial pain and limitations associated with TMC OA.^{5,7"}

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Appendix 2. Questionnaire.

Question 1 – To what degree do you think psychosocial factors influence symptom intensity and magnitude of limitations associated with TMC arthrosis? Answered on an 11-point Likert scale ranging from “0” “not associated at all” to “10” “very much associated”.

Patient scenario:

A 55-year-old woman, an artistic painter, is not satisfied with education, splinting, and medication and is considering surgery. Radiographs show moderate TMC OA. A previous injection provided a day or two of pain relief. The patient expresses: ‘The pain is excruciating. I can’t hold a paintbrush for more than 5 minutes. I’m always dropping it.’

Question 2A – Would injection or surgical intervention address all of the patient’s issues? Yes/no

Question 2B – If no: which would you consider to be helpful in this scenario? (More than 1 option can be selected)

- Psychological workbook
- Referral back to regular doctor
- Referral to psychologist
- Splint
- Hand therapy
- More biomedical treatment (e.g. pain killers)
- There are no more helpful options for this patient

Question 3A – If the patient was interested in help with resiliency and adaptation and there was a workbook readily available in your office, would you offer it to the patient? Yes / no

Question 3B – If no, why not? (More than 1 option can be selected)

- Lack of time
- Stigma associated with psychological factors
- Uncomfortable feeling about raising such topics
- Risk of dissatisfied patient
- It would not be of any help / waste of time

Question 4A – If the patient was interested in help with resiliency and adaptation and there was a psychologist or social worker readily available in your office, would you ask him or her to help? Yes / No

Question 4B – If no, why not? (More than 1 option can be selected)

- Lack of time
- Stigma associated with psychological factors
- Uncomfortable feeling about raising such topics
- Risk of dissatisfied patient
- It would not be of any help / waste of time

Question 5 – Any other comments? (Open text box)

Appendix 3. Region of practice.

Country	N = 121	100%
Argentina	2	1.7
Australia	3	2.5
Austria	1	0.8
Belgium	1	0.8
Brazil	5	4.1
Colombia	7	5.8
France	1	0.8
Germany	2	1.7
Netherlands	39	32.2
New Zealand	1	0.8
Qatar	1	0.8
Sweden	1	0.8
Switzerland	1	0.8
United Kingdom	2	1.7
United States	54	44.6

Appendix 5. Themes for classifying comments.

Category	N = 27*
1. Biomedical emphasis	9
2. Biopsychosocial approach	9
3. Surgery is a reasonable last resort	6
4. Psychosocial treatment is unavailable	3
5. Surgery is financially more profitable to surgeons	3
6. Other	2

* More than 1 category was selected in 5 of the 27 comments.

Appendix 4. Influence of psychosocial factors on trapeziometacarpal osteoarthritis

Variables	Answer to Q1* N = 121	P value	Answer to Q2A* N = 119		
			Yes	No	P value
Gender					
Male	6.4 ± 2.1	0.53	14 (14)	85 (86)	1.0
Female	6.1 ± 2.1		3 (15)	17 (85)	
Region of practice					
Europe	6.1 ± 1.9	0.09	6 (13)	41 (87)	0.048
North America	6.8 ± 2.0		5 (9.3)	49 (91)	
Other	5.6 ± 2.7		6 (33)	12 (67)	
Subspecialty					
Orthopaedic surgeon	6.3 ± 2.2	0.99	15 (19)	62 (81)	0.093
Plastic surgeon	6.3 ± 2.0		2 (5.4)	35 (95)	
Trauma surgeon	6.2 ± 2.5		0 (0.0)	5 (100)	
Experience in independent practice					
0 - 5 years	6.1 ± 1.9	0.34	4 (13)	27 (87)	0.68
6 - 10 years	6.2 ± 2.2		3 (9.0)	30 (91)	
11 - 20 years	6.7 ± 1.8		6 (18)	28 (82)	
21- 30 years	6.3 ± 2.6		4 (19)	17 (81)	
Supervision of trainees					
Yes	6.4 ± 2.2	0.70	12 (13)	78 (87)	0.40
No	6.0 ± 1.9		5 (17)	24 (83)	
Primed to paragraph					
A: Biomedical paradigm	6.2 ± 2.2	0.67	11 (18)	49 (82)	0.30
B: Psychosocial paradigm	6.4 ± 2.0		6 (10)	53 (90)	

Variables as mean (± standard deviation) or number (row percentage); **bold** indicates statistically significant difference. *Questions:

Q1 = To what degree do you think psychosocial factors influence symptom intensity and magnitude of limitations associated with TMC arthrosis? [range 0-10]

Q2 = Would injection or surgical intervention address all of the patient's issues? [2 missing values]

Answer to Q3A* N = 119			Answer to Q4A* N = 116		
Yes	No	P value	Yes	No	P value
90 (91)	9 (9.1)	1.0	84 (87)	13 (13)	0.08
19 (95)	1 (5.0)		13 (68)	6 (32)	
42 (89)	5 (11)	0.16	36 (77)	11 (23)	0.18
52 (96)	2 (3.7)		46 (90)	5 (10)	
15 (83)	3 (17)		15 (83)	3 (17)	
73 (95)	4 (5.2)	0.12	64 (86)	10 (14)	0.27
32 (87)	5 (14)		28 (76)	9 (24)	
4 (80)	1 (20)		5 (100)	0 (0.0)	
28 (90)	3 (9.7)	0.91	21 (70)	9 (30)	0.097
30 (91)	3 (9.1)		30 (94)	2 (6.3)	
32 (94)	2 (5.9)		28 (85)	5 (15)	
19 (90)	2 (9.5)		18 (86)	3 (14)	
80 (89)	10 (11)	0.12	74 (84)	14 (16)	0.78
29 (100)	0 (0.0)		23 (82)	5 (18)	
57 (95)	3 (5.0)	0.20	50 (86)	8 (14)	0.62
52 (88)	7 (12)		47 (81)	11 (19)	

Q3 = If the patient was interested in help with resiliency and adaptation and there was a workbook readily available in your office, would you offer it to the patient? [2 missing values]

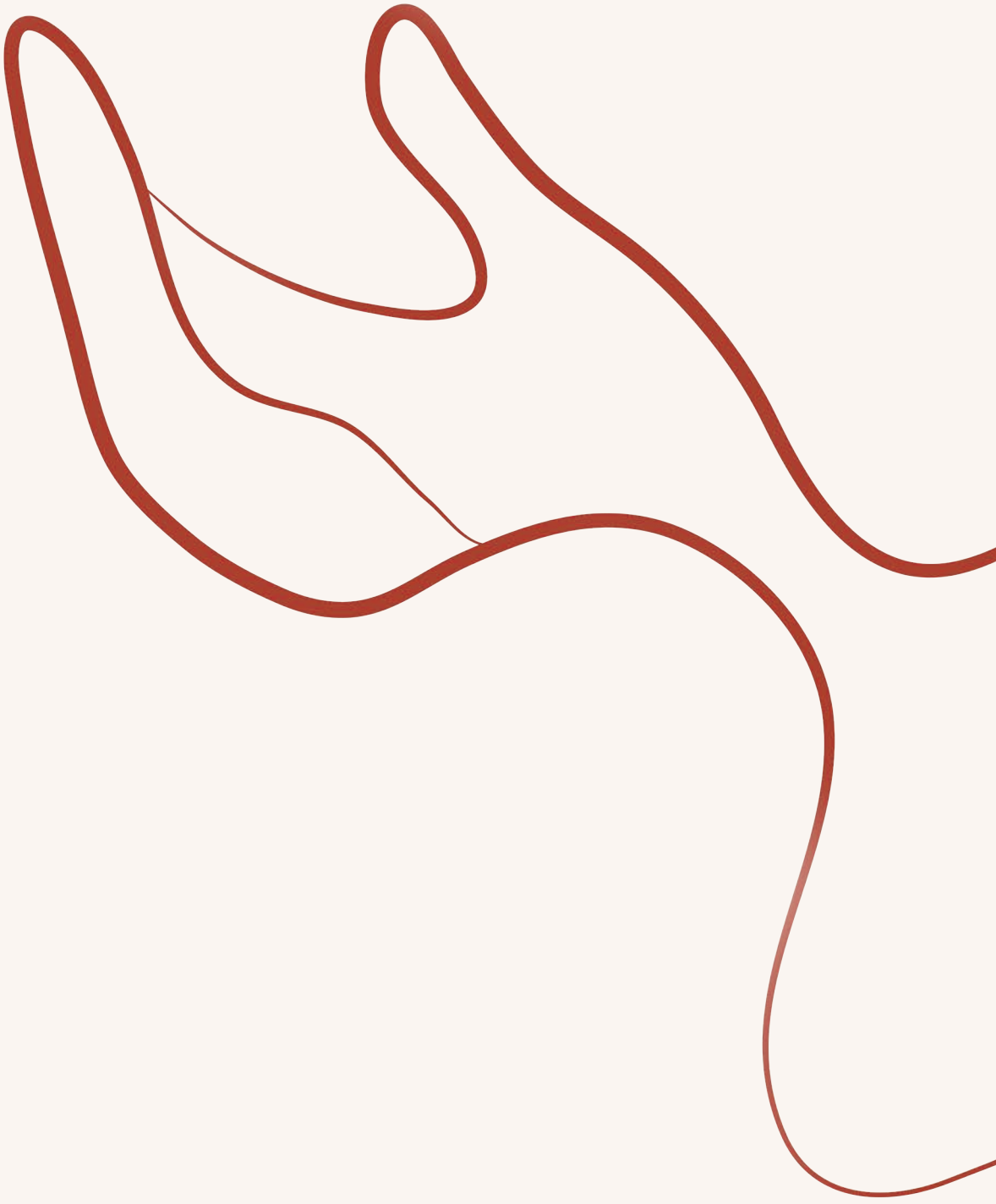
Q4 = If the patient was interested in help with resiliency and adaptation and there was a psychologist or social worker readily available in your office, would you ask him or her to help? [5 missing values]





Part three

SURGICAL INTERVENTIONS
FOR THUMB CARPOMETACARPAL
OSTEOARTHRITIS



Chapter 6

MEDIUM TO LONG-TERM FOLLOW-UP AFTER PYROCARBON DISC INTERPOSITION ARTHROPLASTY FOR TREATMENT OF CMC THUMB JOINT ARTHRITIS

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ABSTRACT

Background: Pyrocarbon disc interposition arthroplasty has been designed for the surgical treatment of Eaton-Glickel grade II/III carpometacarpal thumb joint arthritis. This study presents the results of this technique with a minimum five-year follow up.

Objectives: To determine patient-reported outcome measures (PROMs) after placement of a pyrocarbon disc with a minimum follow-up of five years. Secondly, implant survival, strength and motion measurements were assessed.

Methods: We assessed four questionnaires for patient-reported outcome measures in a cross-sectional study: the Patient-Rated Wrist and Hand Evaluation, Disabilities of Arm, Shoulder, and Hand questionnaire, Michigan Hand Questionnaire, and questions about satisfaction at the five-year follow up. We evaluated grip and pinch strength, range of motion, and the radiological position of the disc. Finally, a Kaplan-Meier survival analysis was performed.

Participants: Of the 234 operated thumbs (in 200 patients), 164 thumbs (in 137 patients) were available for follow-up varying from five to 12 years. All patients had been treated with pyrocarbon disc interposition arthroplasty for CMC1 OA between 2006 and 2014. Median age at operation 58 years (range 30 to 82) and most participants were women (121; 74%).

Results: Median Patient-Rated Wrist and Hand Evaluation, Disabilities of Arm, Shoulder, and Hand, and Michigan Hand Questionnaire scores were 17 (Interquartile range [IQR] 3 to 47), 18 (IQR 8.3 to 42), and 76 (IQR 63 to 91), respectively. The satisfaction score was 9 (Likert scale of 1 to 10). Grip and pinch strength reached nearly 100% compared with the contralateral hand. Range of motion resulted in a Kapandji score of 10. Thumb height showed a marginal loss and the Kaplan-Meier survival curve showed a survival rate of 91%.

Conclusion: Our study suggests that pyrocarbon disc interposition arthroplasty is a reliable and feasible treatment for carpometacarpal thumb joint arthritis at medium-term follow-up. It was associated with a high level of patient satisfaction; it maintained thumb height and the implant survived in 91% of patients. Strength and range of motion were comparable to the contralateral hand after a minimum follow-up of five years.

INTRODUCTION

Trapeziectomy, which was introduced by Gervis¹ in 1949, is still considered the reference standard for treatment of carpometacarpal (CMC) thumb joint arthritis. The technique achieves good results and has fewer complications than other more intricate techniques.^{2,3} However, simple trapeziectomy is not commonly performed alone because it may lead to proximal migration of the first metacarpal (MC1) with loss of thumb stability and power.⁴⁻⁶ Therefore, trapeziectomies are often combined with additional ligament reconstruction and tendon interposition (LRTI). Another option is to perform a distal hemi-trapeziectomy when the scapho-trapezio-trapezoidal (STT) joint is not affected. An interposition may be used to prevent impingement of the MC1 on the partially resected trapezium caused by proximal migration.^{7,8} Autologous tendon is the most widely used interposition substance with hemi-trapeziectomy, but it has been reported to have variable outcomes in terms of strength and range of motion.⁹ This is because the morphometric and biomechanical properties of autologous tendons used for interposition do not approach the volume or stiffness provided by the native trapezium bone.¹⁰

To overcome these disadvantages, the PyroDisk (Integra LifeSciences Corporation, Plainsboro, NJ) (Figure 1) was introduced for CMC thumb joint arthritis as an interposition possibly more stable than traditional techniques. The disc is a pyrolytic carbon interposition implant designed to be used after a distal hemi-trapeziectomy for radiological Eaton-Glickel stage II or III CMC thumb joint arthritis.¹¹ The biological tolerance of pyrolytic carbon is high, as has been known from its use in artificial heart valves since 1969.¹² The implant is a nonanatomic biarticular disc with convex smooth surfaces to allow movements along three axes. The disc is available in various diameters and heights to allow for optimal implant sizing. In contrast to other materials, pyrolytic carbon has an elastic modulus similar to cortical bone, to reduce the chance of subsidence into the underlying bone.^{13,14} This elastic modulus makes the disc itself resistant to wear, which contributes to preservation of thumb length. Finally, the implant can be placed without compromising the possibility for future revision surgery if necessary.

To date, reports on medium- to long-term results are scarce. Therefore, we conducted a cross-sectional study to evaluate medium- to long-term follow-up after hemi-trapeziectomy and pyrocarbon disc interposition arthroplasty for CMC thumb joint arthritis. The primary outcome was scores in patient-reported outcome measures (PROMs) for function, pain and satisfaction. Secondary aims included objective measurements of grip and range of motion, radiographic outcome, and implant survival.

PATIENTS & METHODS

Study design

From 2006 to 2014, four hand surgeons in two centers performed 234 pyrocarbon disc interposition arthroplasties in 200 patients (34 bilateral) after distal hemitrapeziectomy for CMC thumb joint arthritis. We designed a descriptive cross-sectional study with data obtained at a follow-up of five years or more. After approval of the institutional review board, we invited patients by mail to participate in the study between July 2017 and April 2018. After receiving signed written informed consent, we sent PROM questionnaires by mail and invited patients for conduct clinical measurements and radiographs. We reviewed all medical charts retrospectively for demographic characteristics, perioperative details, and complications.



Figure 1. The PyroDisk.

Patients

In our clinic, we perform CMC thumb joint arthroplasties when pain based on arthritis does not respond to nonsurgical therapy of at least three months duration. In the case of a radiological Eaton-Glickel stage II or III score, we offer pyrocarbon disc interposition arthroplasty in addition to other techniques. After discussion with the patient regarding all possible techniques, we make a shared decision on the final treatment. Contraindications include patients with STT arthritis,

hyperlaxity syndromes, or systematic inflammatory arthritis (rheumatoid arthritis, gout, or psoriasis). When necessary, we perform a computed tomography scan to exclude STT involvement before surgery.¹⁵

Surgical technique

Pyrocarbon disc interposition arthroplasty was previously described by Mariconda *et al.*¹⁶ using flexor carpi radialis (FCR) and by Barrera-Ochoa *et al.*¹⁷ using abductor pollicis longus (APL). General or regional anesthesia is used with tourniquet control. A dorsal longitudinal skin incision is made along the radial base of the MC1. After the joint capsule is opened, about 2 to 3 mm of the metacarpal base and the trapezial saddle is resected with a saw, with the transverse axis parallel to the metacarpophalangeal joint. Transosseous tunnels are created with an awl (average diameter: 3.0 mm) through the trapezium from dorsal-proximal to central-distal, and through the metacarpal base from central-proximal to dorsal-distal (Figure 2A). For proper disc placement, the tunnels should be placed exactly in the center of the metacarpal base and distal surface of the trapezium. This is required to prevent malalignment of the disc, which may lead to higher risk of subluxation. The proper disc diameter is determined using the trial implants. The correct size is one that fits the diameter of the metacarpal base without overhanging the trial implant. The thickness of the disc is selected in relation to the amount of bone resected. In addition, a shallow concave surface in the trapezium and the metacarpal base can be formed with a shaper to fit the disc snugly with its convex surface. To secure the disc, a strip of FCR or APL tendon is used (Figure 2B and 2C). The choice of tendon strip is determined by the surgeon's preference. Leaving the insertion of the tendon intact, a strip one-half to one-third wide and five to ten cm long is harvested. The tendon strip is then passed through the tunnel in the trapezium, the hole in the disc, and the tunnel in the MC1 bone (Figure 2D). Gentle traction is applied to the tendon to enhance stability. The residual tendon is folded back and sutured to itself and the periosteum of the metacarpal base, and incorporated into the capsular closure with absorbable sutures. The position of the disc is checked with postoperative radiography. The operated hand is placed in a thumb spica cast for four weeks. After the cast is removed, hand therapy commences. Emphasis is on active and passive range of motion exercises for the first two months, and strengthening thereafter.

Measurements

Patients completed the Patient-Rated Wrist/Hand Evaluation (PRWHE)^{18,19}, the Disabilities of Arm, Shoulder and Hand questionnaire (DASH)^{20,21}, the Michigan Hand Questionnaire (MHQ)²², and a questionnaire on patient satisfaction. The PRWHE and DASH do not differentiate between sides. Therefore, in the case of bilateral surgery,

patients were asked to complete the PRWHE twice (for both hands) and the DASH once. For the latter, we analyzed the score for the dominant hand. The satisfaction questionnaire (based on previous reports on patient satisfaction after treatment of CMC thumb joint arthritis) differentiated between sides.^{23,24} We asked patients why they sought treatment based on eight items: improvement of (1) thumb function, (2) thumb appearance, (3) power, (4) pain, (5) daily activities, (6) activities of leisure, (7) return to work, or (8) other. We evaluated questions regarding satisfaction with the outcome of the operation and treatment goal achievement (both on a 10-point Likert scale ranging from 1 = not satisfied at all to 10 = excellent satisfaction). For the secondary outcomes, strength, range of motion, radiographs and implant survival were analyzed. The average of three measurements of pinch and grip strength, thumb opposition (Kapandji score) and palmar abduction (using a Pollexograph, Erasmus MC, Rotterdam, the Netherlands^{25,26}) was used for analysis. Pinch strength (key, tip, and tripod pinch) was measured by a baseline pinch gauge (E-link H500 Hand Kit, Biometrics Ltd, Gwent, UK), and grip strength by using a hydraulic hand dynamometer in position two (E-link H500 Hand Kit). For comparison with the contralateral hand, strength was corrected for hand dominance with the 10% rule for right-hand patients; no correction was made for left-handedness.^{27,28}

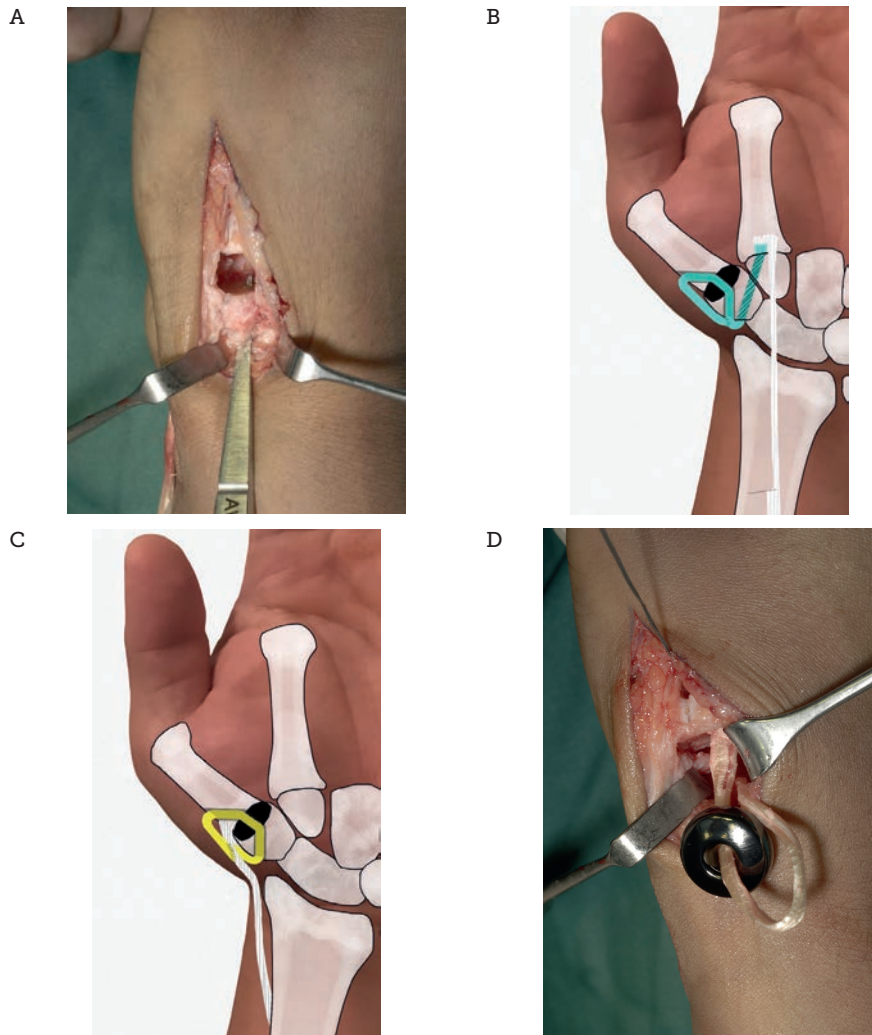


Figure 2. Intraoperative images.

A) With an awl, transosseous tunnels are created through the remaining trapezium from dorsal-proximal to central-distal (shown in the image) and through the metacarpal base from central-proximal to dorsal-distal. **B)** Use of the FCR tendon strip to secure the pyrocarbon disc. To harvest the FCR, two or three small incisions are made at the volar side of the forearm. The strip is cut proximally, released up to its insertion, and subsequently passed beneath the tendons of the first dorsal compartment to the proximal surface of the trapezium. **C)** APL tendon strip to secure the pyrocarbon disc. When harvesting the APL, the tendon strip is harvested under direct vision via the same incision as that used to expose the trapezium. The first extensor compartment is released and the APL strip is cut proximally, released to its distal insertion, and subsequently brought to the proximal surface of the trapezium. **D)** The tendon is brought to the proximal surface of the trapezium and passed through the tunnel of the trapezium, the PyroDisk, and the tunnel of the metacarpal consecutively.



Figure 3. Thumb height measurements.

The height of the hemi-trapezium (HT) is measured from the distal joint surface of the scaphoid to the proximal surface of the implant. The disc space (DS) is measured from the distal joint surface of the HT to the joint surface of the first metacarpal base. The trapezoidal space (TS) is measured between the distal joint surface of the scaphoid and the joint surface of the base of first metacarpal (MC1). The MC1 and proximal phalanx (PP) were measured from the midpoint of the proximal and distal joint surfaces.

Radiographs (lateral, posteroanterior and Bett's view) of the operated hand were obtained immediately after surgery and at the last follow-up visit. We analyzed the radiographs for STT arthritis, osteophytes, and disc luxation and measured thumb height. We calculated the total thumb height as the sum of the hemi-trapezium (HT), disc space and MC1 (Figure 3). We corrected for differences in hand size within patients and the magnification factor on radiography by calculating the ratios of the different heights with the proximal phalanx (PP) as a comparative standard, modified from the report by Downing and Davis.²⁹ Intra- and inter-rater reliability and agreement were assessed with the total thumb height ratio. The first author measured a subset of 62 thumb heights twice on two different time points a minimum of two weeks apart to assess intra-rater reliability; the second author repeated those measurements to assess inter-rater reliability.

For the survival analysis, we used the indication for revision as the end point based on ongoing pain with function loss caused by STT arthritis or disc dislocation, or without a specific cause. The difference in survival rate between men and women was also analyzed.

Statistical analysis

Kolmogorov-Smirnov test and histograms were used to assess distribution of the variables. We report descriptive statistics as means and standard deviation (SD) for normally distributed data, median and interquartile range (IQR) for nonnormal distributed data, or absolute values and proportions (%). The intraclass correlation coefficient (ICC) was used to calculate intra- and inter-rater reliability for thumb height (two-way mixed, absolute agreement). The ICC is reported with its 95% confidence interval. Bland Altman plots were used for agreement (Appendix 1). Normal variance of agreement was accepted when 90% of all differences was within the limits of agreement. We compared thumb height in time with the Student t-test. We used the Kaplan–Meier method to estimate implant survival.

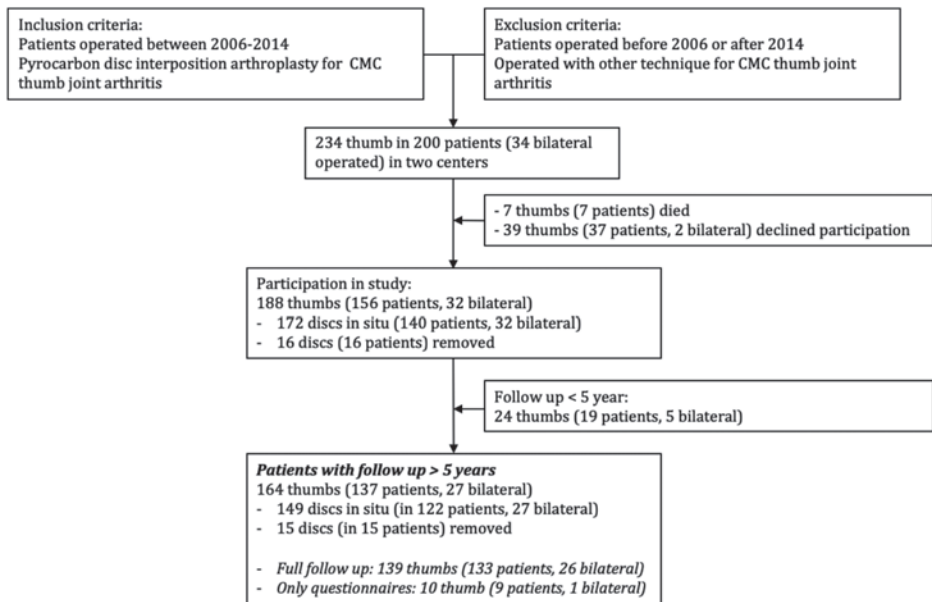


Figure 4. Flowchart of patients.

Table 1. Demographic data of patients with follow-up minimum of five years.

Variables	Disc <i>in situ</i>	%	Disc removed	%	Total cases, n (%)
Total discs (n = 164)	149	91	15	9	164 (100%)
Patients (n = 137)	122	89	15	11	137 (100%)
Bilateral operated*	50	93	4	7	54 (32.9%)
Single-side operated	99	90	11	10	110 (67.1%)
Dominant hand operated					
Yes	61	41	7	47	68 (41.5%)
No	88	59	8	53	96 (58.5%)
Operated side					
Left	87	53	11	6.7	98 (59.8%)
Right	62	37	4	2.4	66 (40.2%)
Dominance					
Left	26	16	3	1.8	29 (17.7%)
Right	126	77	12	7.3	138 (23.2%)
Use of tendon					
APL	120	90	14	10	134 (100%)
FCR	29	96	1	4	30 (100%)
Sex of patients, n					
Male	42		1		43 (26.2%)
Female	107		14		121 (73.8%)
Age at operation, years					
Median	58.2		56.0		58.0
Range	30 to 82		47 to 80		30 to 80
Follow-up, years					
Median	7.3		7.3		7.3
Range	5 to 12		5 to 10		5 to 12
Additional surgery					
MCP1 arthrodesis	6	4.0	1	1	5 (5%)
Interphalangeal arthrodesis	2	1.3	-	-	2 (1%)
Carpal tunnel release	7	4.7	1	1	8 (5%)
Trigger thumb release	6	4.0	1	1	7 (5%)

* Bilateral operated: 54 thumbs in 27 patients. In these patients, 23 patients were operated bilaterally with the disc still inside, and four in whom the disc remained in the thumb on one side and was removed on the other side. These four removals are shown in the group disc removals.

RESULTS

Clinical assessment

We analyzed 164 thumbs in 137 patients with more than five years of follow up (Figure 4). Table 1 shows the baseline characteristics. At final follow-up, 149 discs were still *in situ* (122 patients, 27 of whom had bilateral surgery) and 15 discs (in 15 patients) had been removed. The PROMs are listed in Table 2. The PRWHE showed a median of 17 (IQR 3 to 47) with the subscale for pain of 11 (IQR 0 to 25) and for function of 7 (IQR 2 to 22). The DASH and MHQ showed a median of 18.3 (IQR 8.3 to 42.5) and 76 (IQR 63 to 91) respectively. Satisfaction with the treatment goal and result were both high (9.0). Pain reduction was the main reason patients sought operative treatment. Measurements for strength and range of motion showed for all patients who underwent unilateral surgery that the operated hand reached a mean percentage of more than or nearly 100% compared with the contralateral (nonsurgical) hand (Table 3; Appendix 2, 3 and 4).

Radiological assessment

For 140 thumbs with the disc *in situ*, radiology results were available (Table 4). Thumb height measurements showed that the ratios for the HT/PP and MC1/PP were significantly decreased between time points (both $P \leq 0.05$) (Table 5). These ratios relate to a mean difference of 0.7 mm (SD 1.5 mm) of the HT and 1.1 mm (SD 4.2 mm) for the height of MC1. The total thumb height (sum of the HT, disc space, and MC1) ratio was significantly decreased in time ($P \leq 0.05$). This ratio relates to a mean difference of 2.2 mm (SD 5.0 mm). The measurement for total thumb height ratio showed excellent intra-rater and inter-rater reliability and agreement.

Survival analysis

The end point used for the survival analysis was indication for revision. The survival curve showed a survival of 91% with a minimum of five years of follow-up (Figure 5A). Implant survival was 97.7% for male patients and 88.4% for female patients ($P \leq 0.05$) (Figure 5B). For all revisions, we performed a total trapeziectomy with LRTI (with FCR strip or tendon transplant).

Table 6 shows revision surgery and other complications. One patient had additional surgery because of pain resulting from an osteophyte. The osteophyte was removed, and the disc remained in place, with a good outcome. Of the radiological findings, STT arthritis and subluxation with loss of thumb height could eventually lead to pain and/or function loss. At the time of analysis, there was no indication for revision in these patients.

Table 2. Scores for PRWHE, DASH, MHQ and satisfaction.*

PROM questionnaires and subscales	Pyrocarbon disc patients (n = 149)	
	Median	IQR
PRWHE †		
Pain	11	0 to 25
Function	7	2 to 22
Total	17	3 to 47
DASH‡	18.3	8.3 to 42.5
MHQ§		
Function of operated hand	70	50 to 85
Activities of daily living	83	69 to 95
Work	80	50 to 100
Pain	75	53 to 95
Aesthetics	100	75 to 100
Satisfaction	79	50 to 96
MHQ total	76	63 to 91
Satisfaction**		
Satisfaction with result	9	7 to 10
Main reason for operation solved	9	8 to 10
Reason for operation, n (%)		
Decrease pain	100	67
Improve function	25	17
Improve power	2	1
Being able to work again	1	1
Improve activities daily living	10	7
Improve activities of leisure	3	2
Missing	8	5

*Data are given as medians because of the nonnormal distribution of data.

†The PRWHE ranges from 0 to 50 for pain and function, in which 0 is the best outcome and 50 indicates the worst one. The total score ranges from 0 to 100, in which 0 is the best outcome and 100 indicates the worst one. ‡The DASH ranges from 0 to 100, in which 0 is the best outcome and 100 indicates the worst one. §In the MHQ, all scores range from 0 to 100, in which 100 indicates the best outcome and 0 indicates the worst one. **The satisfaction is scored on a Likert scale of 1 to 10, in which 1 = no satisfaction at all and 10 = excellent satisfaction.

Table 3. Power of grip, pinch and range of motion.

Hand Measurements	Operated hand (n = 139)	Contralateral hand** (n = 91)	Mean % Contralateral hand**
Jamar (kg)*	24.2 (12.3)	24.6 (12.2)	111.4 (67.0)
Key pinch (kg)*	4.5 (2.0)	4.7(2.0)	102.0 (36.9)
Tripod pinch (kg)*	4.1 (1.9)	4.5 (1.9)	94.6 (23.3)
Tip pinch (kg)*	3.4 (1.5)	3.7 (1.9)	98.5 (26.4)
Palmar abduction† (degrees)*	47 (10)	53 (11)	91.3 (17.1)
Opposition‡ (Kapandji)†	10 (9 to 10)	10 (9 to 10)	100 (90 to 100)

*Means and SD are given for normally distributed data.

†Medians and IQRs are given for nonnormally distributed data.

‡Palmar abduction was measured with the Pollexograph in degrees.

§Opposition was measured with the Kapandji score, ranging from 0 to 10.

**For contralateral hand measurements and the mean percentage of the contralateral hand, only data from single side-operated patients were used.

Table 4. Radiographic evaluation.

Radiographs of patients with disc still <i>in situ</i> (n = 140*)	Patients, n (%)
Normal radiograph	90 (64)
Moderate osteophyte formation around implant	5 (3.6)
Severe osteophyte formation around implant	18 (13)
Punched trapezium	5 (3.6)
STT arthritis	5 (3.6)
Subluxation with maintained thumb height	6 (4.3)
Subluxation with loss of thumb height	11 (7.9)

*Nine patients were not able to come to the hospital for follow-up.

Table 5. Measurements of thumb height upon radiology.

Thumb height ratio	Immediate follow-up (mean [SD])	Medium to long-term follow-up (mean [SD])	P value
Hemi-trapezium/Proximal phalanx*	0.28 (0.05)	0.26 (0.10)	< 0.05*
Disc space/Proximal phalanx*	0.25 (0.04)	0.25 (0.13)	0.23
Trapezial space/Proximal phalanx*	0.51 (0.06)	0.50 (0.11)	0.20
First metacarpal/Proximal phalanx*	1.38 (0.14)	1.34 (0.11)	< 0.05*
Total thumb height†/Proximal phalanx	1.91 (0.16)	1.83 (0.20)	< 0.05*

Reliability and agreement‡	ICC (95% CI)	Bland Altman agreement
Intra-rater	0.988 (0.981-0.993)	91.9%
Inter-rater	0.983 (0.972-0.990)	98.4%

*All ratios of the true measurements were calculated in millimeters.

†Total thumb height was calculated as the sum of the hemi-trapezium, disc space, and metacarpal height.

‡Reliability was calculated by the intercorrelation coefficient (ICC) and 95% confidence intervals (two-way mixed, absolute agreement) with the total thumb height ratio. Excellent reliability was set on reliability greater than 0.900. Bland – Altman plots were used to analyze agreement on the total thumb height ratios; good agreement was when 90% of all measurements were within the limits of agreement.

Table 6. Revision surgery and complications.

Revision/complication	Patients, n (%)	Revision surgery/treatment
Reason for disc removal		
Disc dislocation	3 (2)	Disc removal and T+ LRTI*
Tendon rupture owing to trauma	2 (1)	
Tendon loosening	1 (1)	
STT arthritis	7 (4)	Disc removal and T+ LRTI*
Persisting pain	5 (3)	Disc removal and T+ LRTI*
Other complications:		
Complex regional pain syndrome	1 (1)	Vitamin C and hand therapy
Pain owing to remaining osteophyte	1 (1)	Operative removal of osteophyte, no disc removal
Superficial wound infection	1 (1)	Oral antibiotics

* T+LRTI: Full trapeziectomy with ligament reconstruction and tendon interposition with flexor carpi radialis (FCR) tendon or autologous tendon.

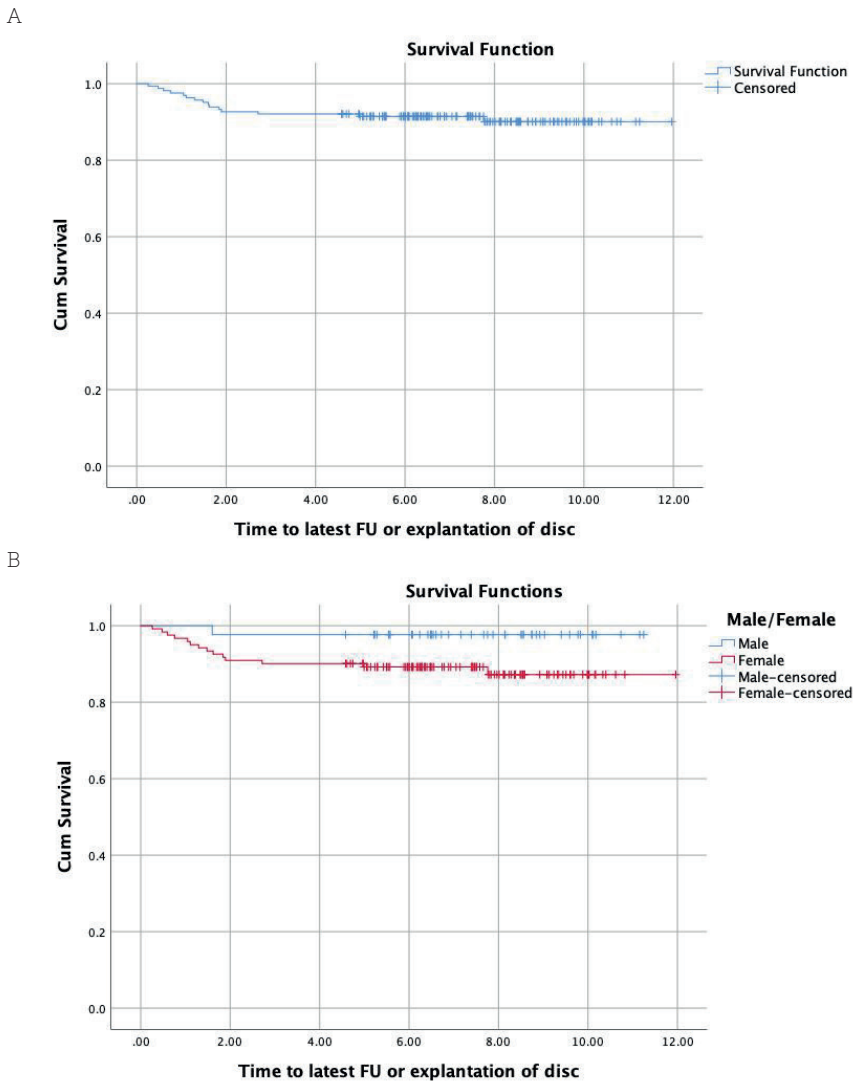


Figure 5. Survival curves.

A) Kaplan–Meier survival curve. The survival curve was 90.9%, with removal of the implant from any cause (condition-related or implant-related problems). A total of 15 discs had to be removed (among 164 thumbs in 137 patients with more than five-year follow-up). In three patients, disc luxation led to removal. In two patients, the cause was hand trauma with tendon rupture (after four and 14 months); one patient experienced tendon loosening (after 19 months). Seven patients (seven thumbs) developed painful STT arthritis (six months to almost eight years) that caused implant removal. In five other patients (five thumbs), persistent pain without a specified cause led to implant removal between six and 22 months. **B)** Survival curve between men and women. Implant survival was 97.7% for male patients and 88.4% for female patients ($P = 0.05$). Cum = cumulative; FU = follow-up.

DISCUSSION

We investigated the mid- to long-term results of hemi-trapeziectomy and pyrocarbon disc interposition arthroplasty for surgical treatment of CMC thumb joint arthritis. The main findings were high patient satisfaction, good implant survival, and preserved thumb height based on radiological assessment. Furthermore, all hand measurements (grip, pinch and range of motion) of the operated hand came close to or reached more than 100% compared with the contralateral side after correction for dominance.

The outcome of using pyrocarbon discs to treat CMC thumb joint arthritis was previously reported. Mariconda *et al.*¹⁶ studied 27 discs in 25 patients with a minimum follow-up of two years. Barrera-Ochoa *et al.*¹⁷ described 19 patients (19 discs) with a mean follow-up of 68 months. The results of these studies were used in a meta-analysis by Ganhewa *et al.*³⁰ on failure rates of thumb arthritis surgery. The pyrocarbon disc failure rate was 1.0 per 100 procedure-years, which was on the low side of the failure rate of any implant surgery of this study. Recently, long-term results of the pyrocarbon disc were reported by Smeraglia *et al.*³¹ by combining the data from previous pyrocarbon disc studies. They calculated the failure rate for the pyrocarbon disc to be 0.68. The failure rate calculated for our study was slightly higher, but both rates were lower than for any implant surgery. The authors of that study did not address clinical outcomes or PROMs in relation to the failure rate. The failure rate should correlate to the clinical performance before final conclusions are reached.

The PROMs in the current study were measured only after a follow-up of five years or more, so no changes over time were measured. Other studies reporting the PRWHE, DASH, or MHQ after trapeziectomy with or without LRTI and other arthroplasties showed results similar to ours at the same follow-up point.³²⁻³⁵ Moreover, the median DASH score of 18 found in our study is comparable to normative data for populations aged 50 to 65 years in European countries (a DASH score of 14 to 19).³⁶

Currently, trapeziectomy with or without LRTI is considered the reference standard.⁵ Studies describing these techniques show results similar to those from our study regarding clinical hand measurements and PROMs.^{32,37-39} Gangopadhyay *et al.*³⁹ reported the five- to 18-year follow-up of a group of patients randomized to trapeziectomy alone, trapeziectomy with tendon interposition, or trapeziectomy with LRTI. Outcomes measured in strength reached 100% or more compared with the contralateral side with maintenance of thumb range of motion (opposition) and decreased pain. The outcomes of the three groups were similar at a minimum of five-year follow-up. In our study, strength measurements similarly reached more

than 100% compared with the contralateral hand after correction for hand dominance. Our results presented range of motion measures with a median Kapandji score of 10 and only six degrees less palmar abduction than the contralateral hand. This range of motion after treatment may be considered as good without compromising function. The data on hand measurements in the current study are similar to those presented using other common techniques for CMC thumb joint arthritis.^{38,39}

To the authors' knowledge, thumb height measurements on radiographs after pyrocarbon disc interposition have not been previously reported. To analyze thumb height, we used ratios of the different heights with the PP as a comparative standard. This was modified from the previous report by Downing and Davis.²⁹ The total thumb height ratio in our study showed a statistically significant loss in time, but with a mean loss of 2.2 mm (SD 5.0 mm), it was less than what was reported by other studies on thumb height loss after different techniques.^{40,41} Those previous studies indicated that thumb height was not related to clinical outcome, but no comparison was made with techniques with almost full maintenance of thumb height, such as with pyrocarbon disc interposition.

A commonly described disadvantage of the pyrocarbon disc interposition arthroplasty is the risk for dislocation of the disc. However, in our study, the dislocation rate was low (2%), and in most cases, it followed isolated traumatic events early after the operation. Patients with radiological signs of subluxation at follow-up were asymptomatic and did not need revision. Also, a small amount of subluxation is inherent in the gliding concept of the disc, to enable movement of the thumb CMC joint. Another disadvantage is the risk of subsequent painful STT arthritis after hemi-trapeziectomy. Although STT arthritis does not always follow CMC thumb joint arthritis and is not always painful⁴², this is a possible risk after a hemi-trapeziectomy with interposition is performed. In this study, seven patients (4.6%) developed painful STT arthritis and underwent revision surgery. An accurate clinical and radiological examination is important to exclude STT arthritis before surgery. Another important consideration is the relatively high cost of the implant. Despite comparable results with other less expensive techniques on all measurements and PROMs, faster return to work and shorter rehabilitation time could justify the costs for an implant. Unfortunately, we did not have enough data for a cost-effectiveness analysis. Future studies are needed to address this.

Our study was limited by the absence of preoperative PROMs and clinical measurements; therefore, we cannot make conclusions based on the PROMs. Furthermore, the retrospective design may have underestimated the complication rate. To overcome lack of preoperative strength measurements, we compared data with those of the contralateral hand after correction for dominance

In conclusion, we believe that pyrocarbon disc interposition arthroplasty is a viable option for CMC thumb joint arthritis. Our findings show good implant survival rate with high patient satisfaction, good power, acceptable range of motion, preserved thumb height and positive outcomes based on different PROMs.

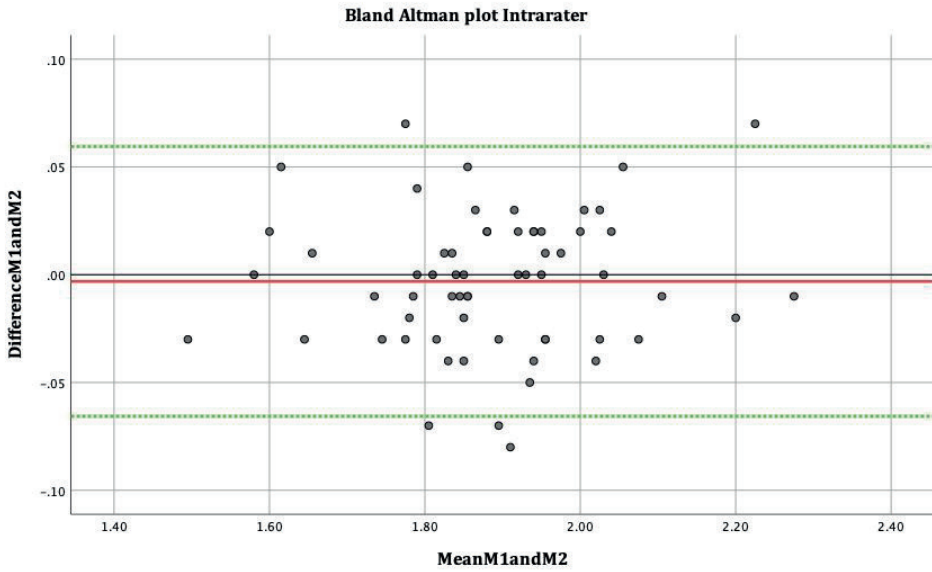
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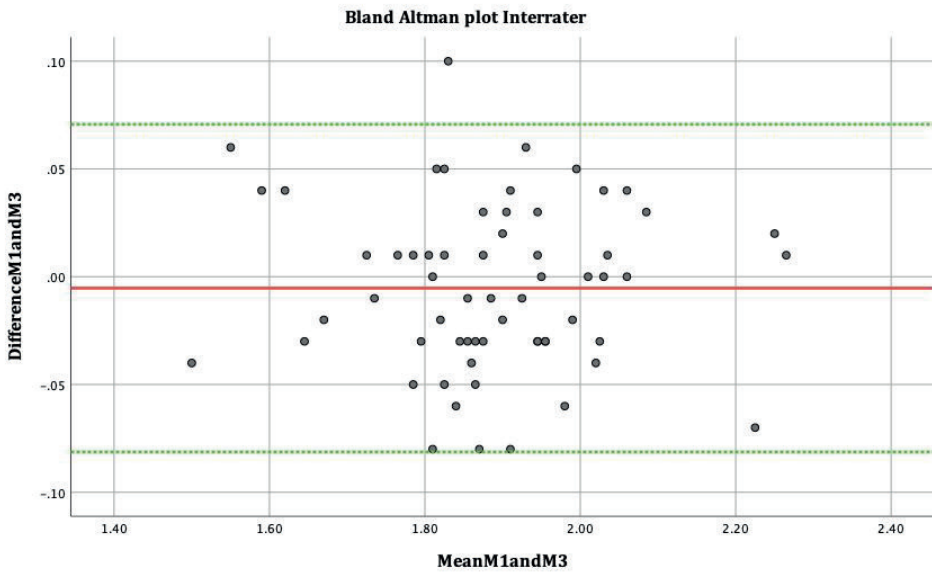
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A

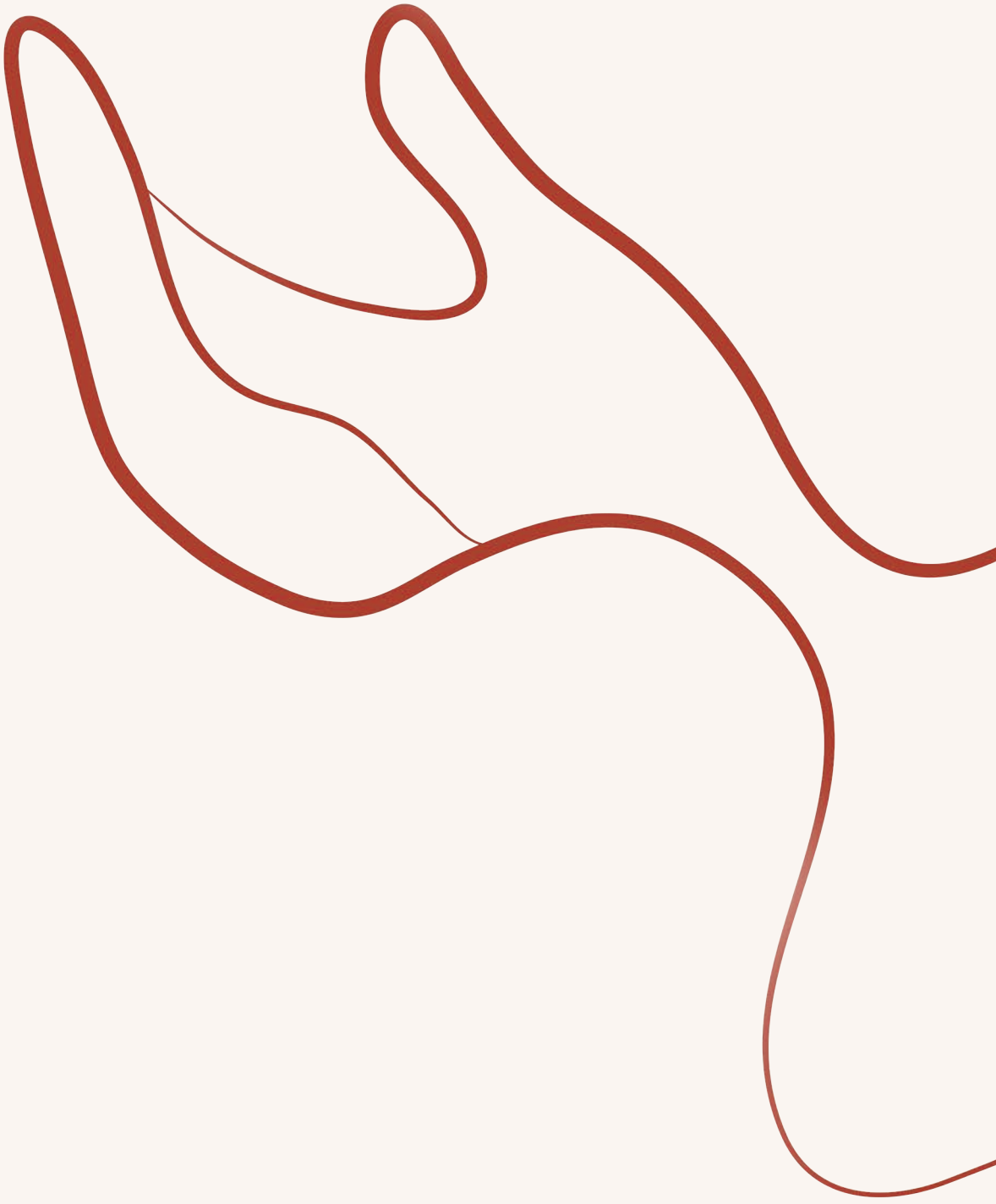


B



Appendix 1. Bland-Altman plots for agreement.

The red line in the middle represents the mean difference of the volume between observers; green dotted lines represent the upper and lower limits of agreement (mean difference $1.96 \times \text{SD}$). **A)** Bland-Altman plot for intra-rater agreement (91.9%). **B)** Bland-Altman plots for inter-rater agreement (98.4%).



Chapter 7

LONG-TERM FOLLOW-UP OF PATIENTS
TREATED WITH PYROCARBON DISC
IMPLANT FOR THUMB CARPOMETACARPAL
OSTEOARTHRITIS: THE EFFECT OF DISC
POSITION ON OUTCOME MEASURES

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ABSTRACT

Background: Pyrocarbon disc interposition arthroplasty is an effective treatment for thumb base osteoarthritis. However, as with all implant techniques, the disc can (sub) luxate over time. The relationship between disc position, the experienced pain, and the necessity for revision surgery is not known.

Objectives: This study evaluated the effect of radiographic pyrocarbon disc position on the Michigan Hand Questionnaire (MHQ) outcome measures. In addition, the correlation between disc position and other factors, including pain intensity, thumb strength, and occupation, was assessed.

Methods: In this retrospective study, we included 136 patients (161 thumbs) with a median follow-up of 6.7 years (range 3.3 to 11). Radiographs were scored on disc position and classified as 'well aligned' (grade 1) up to 'luxated' (grade 4). A database used for outcome measures included MHQ scores, pain intensity, satisfaction, thumb strength, range of motion, occupation, and hand dominance.

Participants: A total of 136 thumbs (in 136 patients) were eligible for further analysis. Most of the patients were woman (n = 92; 68%) with a median age at operation of 58 years (range 30 to 82).

Results: In bivariate analyses, we assessed any association between disc position and outcome measures. Eighty of the 136 implants (59%) were well-positioned (not displaced), 41% were (slightly) displaced (grade II-III). No relationship existed between the degree of disc displacement and MHQ scores. Manual labor occupation was the only factor that correlated with more severe disc displacement. We could not detect any association between disc position and other outcome variables including pain intensity, thumb strength, or hand dominance.

Conclusion: Our study suggests that radiographic disc displacement has little clinical consequences. Future studies must assess if there is a causality between heavy mechanical stress to the CMC1 joint and luxation of the pyrocarbon disc over time.

INTRODUCTION

Several surgical techniques, with or without implants, are effective in reducing pain in patients with thumb carpometacarpal osteoarthritis (CMC1 OA), not responding well to nonoperative therapy. Likewise, the PyroDisk CMC1 arthroplasty (Integra LifeSciences Corporation, Plainsboro, NJ, USA) can lead to improved hand function and less pain up to eight years after surgery.¹⁻⁵ Patients have reported high satisfaction rates with a good prevalence of thumb strength and range of motion.⁶ In a previous paper from our research group, a survival rate of 91% was found with a minimum of five-year follow-up.⁶

As with any joint implant surgery, one of the main disadvantages is the risk of disc luxation and implant failure over time. The failure rate for the pyrocarbon disc is relative low (1.0 per 100 procedure years) compared to other CMC1 joint implant arthroplasties as reported in a recent systematic review.⁷ Two case-series of 19 and 20 patients, respectively, reported disc displacement in 21% (4/19) and 15% (3/20) after a mean follow-up of at least two years.^{2,3} Only two of those seven patients with radiographic disc displacement required revision surgery.^{2,3}

These findings raise the question of whether the position of the disc affects treatment outcomes in patients who underwent pyrocarbon interposition arthroplasty for CMC1 OA. The primary aim of this study was to evaluate the effect of disc position on the patient reported hand health status measured by the Michigan Hand Questionnaire (MHQ). Secondary, we evaluated if radiological disc position correlated with (1) pain intensity, (2) patient satisfaction, (3) Patient Rated Wrist/Hand Evaluation questionnaire (PRWHE), (4) thumb strength, (5) range of motion, (6) hand dominance, and (7) manual labor occupation.

PATIENTS & METHODS

Study design and clinical setting

This study concerns a case series and describes retrospectively gathered data. It is part of a multicentre study by van Laarhoven *et al.*⁶ on outcomes after pyrocarbon disc interposition arthroplasty for the treatment of CMC1 OA. The focus of this study is on radiographic outcomes of the disc arthroplasty and therefore differs essentially from our previous paper. The local institutional review board approved our study and written informed consent was obtained from all participants. Surgery was performed by one of four surgeons in two different urban centres, who are all hand fellowship trained and most are certified by the Federation of the European Societies for Surgery of the Hand.⁸ Their experience ranges from level four to level five according to the classification by Jin Bo Tang.⁹

Surgical technique

The surgical technique of disc implantation has been described in detail previously by van Laarhoven *et al.*⁶ In short, a distal hemi-trapeziectomy is performed and the pyrocarbon disc placed. After drilling a tunnel through the base of the first metacarpal and hemi-trapezium, the implant is fixated with a tendon strip (of either the flexor carpi radialis or abductor pollicis longus) by looping the tendon through the tunnel in the hemi-trapezium, the central hole in the disc and the metacarpal base tunnel. For proper alignment, the tunnels should be centered to prevent early (sub)luxation. The residual tendon is then folded back and fixed on itself. The position of the implant is checked with radiography. After four weeks of immobilization, hand therapy is commenced for eight weeks thereafter.

Patients

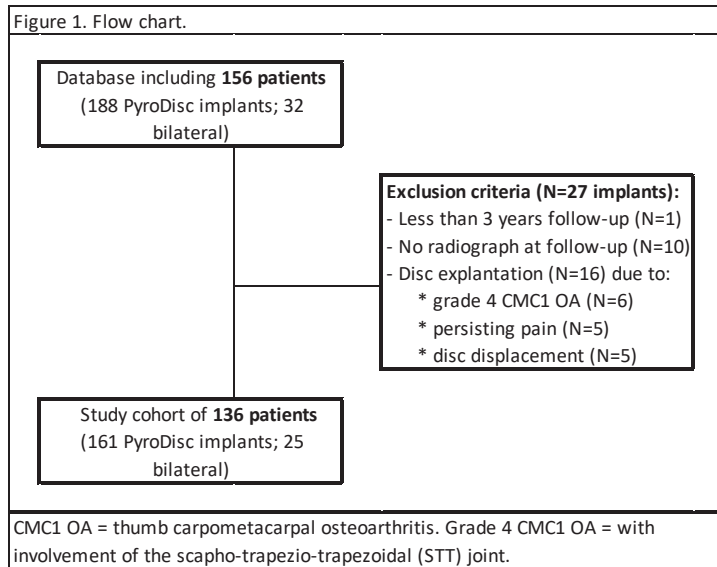
Patients included in this study underwent a pyrocarbon disc interposition arthroplasty between 2006 and 2014. Patients had ongoing symptoms of CMC1 OA despite nonoperative care for at least three months and Eaton-Glickel classification II or III on radiographs.¹⁰ Exclusion criteria were the existence of scapho-trapezio-trapezoidal (STT) in addition to CMC1 OA on radiographs (Eaton-Glickel grade IV), a past medical history of inflammatory or rheumatic arthritis, or hyperlaxity syndromes.

Data collection

Between July 2017 and April 2018, 156 patients (188 thumbs) were enrolled in the primary study.⁶ Patients were invited at the outpatient clinic to complete several questionnaires about demographic characteristics and PROMs. Radiographs of

the operated hand were obtained (thumb posteroanterior (PA) and thumb lateral views); strength and motion measurements of both hands were performed (see 'clinical outcome measures').

In the present study, we focused on the radiographic outcomes of the disc implant. Our primary goal was to evaluate the effect of disc position on MHQ scores. Only thumbs with the disc still *in situ* and with a follow-up duration of at least three years were included. For this reason, 27 of the 188 thumbs were excluded from further analysis resulting in 136 eligible patients and 161 thumbs (Figure 1). Reasons for exclusion of these 27 thumbs were: no radiograph obtained at follow-up ($n = 10$), less than three years of follow-up ($n = 1$), or prior removal of the disc ($n = 16$; details are described in the next paragraph).



Prior disc removal

Sixteen patients underwent disc removal prior to the start of this present study. Patient characteristics and reasons for disc removal are described in Appendix 1. Only patients with a trauma of the operated hand (3/16) had severe disc displacement or luxation on radiographs (grade III or IV) and all underwent re-operation within two years of initial surgery (Appendix 1). In most patients (13/16) however, the reason for disc removal was not disc dislocation, but the progression of CMC1 OA to grade IV OA, including the STT joint (7/16) or persisting unexplainable pain (6/16) (Appendix 1). Radiographs of these patients

taken at time of removal showed that most discs (12/13; removed because of STT OA or persisting pain) were well aligned or slightly displaced at time of removal (grade I or II). Furthermore, of the patients with the disc still *in situ*, only a small number of patients (3%) developed STT OA without causing pain, as shown in one of our previous studies.⁶ Patients with prior disc removal could not be included in this present study because there were no outcome measurements available at the moment of disc removal.

Clinical outcome measures

The following outcome measures were obtained at follow-up: [1] the MHQ (Dutch language version)¹¹ measures hand health status with scores between 0 and 100, higher scores indicate a better hand health status; [2] the Patient Rated Wrist/Hand Evaluation questionnaire (PRWHE, Dutch language version)¹² addresses pain and disability related to the hand and wrist. Scores range from 0 to 100; 50 points are based on reported hand/wrist function and 50 points on pain with higher scores indicating poorer status for both items. We used the subscale for pain in the PRWHE questionnaire, existing of five dimensions, as an independent variable. This score ranges from 0 to 50 points with 50 points presenting more pain; [3] patient satisfaction was gauged on a 10-point Likert scale with '1' indicating not satisfied at all and '10' excellent satisfaction; [4] operated on dominant hand (yes/no); [5] a history of mechanical stress to the CMC1 joint (yes/no) was based on patient's prior or present self-reported occupation.^{13,14} Two authors independently (CvL and JO) classified patient's occupation as manual labor occupation (e.g. construction worker, carpenter, chef) or not (e.g. office worker, accountant).¹⁵ Disagreements were resolved by discussion or consensus involving a third reviewer (BvdH).

Grip strength was assessed with a Jamar dynamometer with the shoulder adducted and in neutral rotation, elbow at 90 degree flexion, and the forearm and wrist in neutral position (E-link H500 Hand Kit, Biometrics Ltd, Gwent, UK).¹⁵ Key pinch and tip pinch strength of both hands were measured using a baseline pinch gauge (E-link H500 Hand Kit, Biometrics Ltd, Gwent, UK). Strength measurements were recorded as the average of three attempts. Range of motion measurements included palmar thumb abduction by Pollexograph¹⁴ and thumb opposition using Kapandji scores.^{16,17}

Radiographic outcome measurements

Radiographs of the operated thumb were obtained at follow-up in lateral and PA views. Radiographs taken directly postoperative were compared with radiographs obtained at the follow-up and scored on disc position and bone stock resorption. The radiographic disc position was assessed in relation to the longitudinal axis of the CMC1 joint on PA and lateral views separately – according to a scoring system described by Barrera-Ochoa *et al.*² and previously used in other studies on pyrocarbon disc position.³ The

base of the first metacarpal bone was divided into equal quarters and perpendicular lines were drawn parallel to the long axis (Appendix 2). Potential ulnar or radial (sub)luxation of the disc was captured on a PA view; on a lateral view, any potential volar or dorsal displacement was assessed. Implant positioning was classified in one of four categories: centered (grade I = no displacement), less than one-fourth displaced (grade II = slight displacement) more than one-fourth but less than one-half displaced (grade III = moderate displacement), or greater than one-half of the first metacarpal base (grade IV = severe displacement/luxation). The highest grade of implant displacement – either on PA or lateral view – was used for further analysis.

Intra-observer and inter-observer reliability of radiographic scoring for implant position were assessed. For intra-observer reliability, disc position was scored twice on 40 radiographs by a single rater with two weeks in between evaluations. For inter-observer reliability, a second reviewer rated a subset of 40 patients on disc position.

Statistical analysis

Continuous variables are reported as median and interquartile range (IQR) and discrete variables as absolute numbers with percentages. Since only one disc was classified as a grade IV luxation, grade III and IV were merged for further analysis. We excluded one of the bilateral thumbs blinded and at random in all 25 bilateral patients to avoid statistical violence, resulting in 136 thumbs (136 patients) for further analysis. This is based on the principle that statistical independence is violated if left- and right-sided measures within one patient are considered to be independent, as stated by Park *et al.*¹⁸ Missing values were imputed with the median of the specific measurement at follow-up. Median imputation was used for two missing MHQ questionnaires, six missing pain subscales, eight PRWHE scores and five satisfaction scores. Based on the nonnormal distributed and unpaired characteristics of our data, we used the Spearman's rank correlation coefficient to determine any association between disc luxation and continuous variables, including MHQ scores. We used Mann-Whitney test for the variables hand dominance and manual labor occupation. Additionally, we dichotomized the variable 'disc displacement' into two groups: not displaced/centred (grade I) or displaced/luxated (grade II, III and IV merged). We used the Mann-Whitney test to assess any relationship between disc luxation (dichotomized) and other outcome measures; and Fisher exact test for the variables hand dominance and occupation. *P* values < 0.05 were considered statistically significant.

Power analysis

A *post hoc* power analysis demonstrated that 84 patients provided 80% statistical power to detect a significant difference, with two-tailed alpha set at 0.05, in MHQ scores with a medium effect size of 0.3. This means we had enough patients to detect a difference in MHQ scores between the different groups of disc positioning with our study size of 136 patients.

Table 1. Patient characteristics.

Variables	N (%)
Patients	136 (100)
Woman	92 (68)
Age at operation (y, (range))	58 (30 to 82)
Median follow-up (y, (range))	6.7 (3.3 to 11)
Dominant hand operated	57 (43)
Bilateral operated	25 (16)
Manual labor occupation	31 (23)
Radiographic disc position	
Grade I. Centered / Not displaced	80 (59)
Grade II. Less than ¼ displaced	38 (28)
Grade III. ¼ to ½ displaced	17 (13)
Grade IV. More than ½ luxated	1 (0.74)

Discrete variables as number (percentage), unless otherwise specified.

RESULTS

Reliability

The intra-observer reliability for scoring disc position on radiographs, determined by weighted kappa, was 0.97 for PA view (standard error [SE] 0.17) and 0.93 (SE 0.17) for lateral view (Appendix 3). The inter-observer reliability measured by weighted kappa for PA view was 0.91 (SE 0.17) and 0.92 (SE 0.17) for lateral view (Appendix 3).

Patient characteristics and radiographic findings

Most of the 136 patients were woman ($n = 92$; 68%) with a median age at operation of 58 years (range 30 to 82) and a median follow-up time of 6.7 years (range 3.3 to 11) (Table 1). Thirty-one patients (23%) reported a present or prior manual labor occupation. Median scores of the assessed PROMs, thumb strength and range of motion are shown in Appendix 4. Of the 136 implants, 80 (59%) were well aligned at follow-up and rated as grade I (Table 1; Appendix 2). Thirty-eight (28%) discs were slightly displaced (grade II), 13% was moderate displaced and one disc was luxated (grade IV) (Table 1; Appendix 2). There were no signs of bone stock resorption or osteolysis of the disc implant.

Primary outcome: effect of disc position on MHQ score

In bivariate analysis, we found no relationship between the severity of disc displacement and MHQ scores [Spearman's rank (ρ) = 0.088; $P = 0.31$] (Table 2). Similarly, when treated as a dichotomous variable (centered *versus* displaced), disc position did not correlate with MHQ scores either [$Z = -0.99$; $P = 0.32$] (Table 3).

Secondary outcomes

Manual labor occupation was the only factor that correlated with more severe disc displacement ($P < 0.001$; Table 2 and 3). We could not detect any relationship between severity of disc displacement and other outcome variables including patient reported function by PRWHE scores, pain intensity, patient satisfaction, thumb strength, range of motion or hand dominance (Table 2 and 3). Of the 28 patients with a manual occupation, 68% ($n = 21$) had radiographic displacement of the implant (grade \geq II) compared to 33% ($n = 33$) of those with another occupation (Table 3).

Table 2. Correlation between disc displacement and outcome measures (disc position as ordinal variable).

Variables	Disc displacement	<i>P</i> value
MHQ	0.088	0.31
PRWHE	-0.094	0.28
Pain	-0.044	0.61
Satisfaction	-0.10	0.23
Jamar	0.036	0.68
Key pinch	0.033	0.70
Tip pinch	0.083	0.33
Palmar thumb abduction	-0.12	0.16
Kapandji (0-10)	0.12	0.16
Dominant hand operated	0.60	0.55
Manual labor occupation	-3.3	<0.001

Spearman's rank correlation coefficient for all interval variables; Mann-Whitney test for occupation and hand dominance with Z-score. **Bold** indicates statistically significant difference.

Table 3. Correlation between disc displacement and outcome measures (disc position as dichotomous variable).

Variables	Disc displacement		Z	P value
	Yes (n = 56)	No (n = 80)		
MHQ	78.0 (64 - 89)	71.1 (62 - 89)	-0.99	0.32
PRWHE	15.0 (3.5 - 40)	20.5 (4.5 - 48)	0.94	0.35
Pain	10.0 (2.0 - 18)	11.8 (0.0 - 26)	0.49	0.62
Satisfaction	9.0 (7.0 - 10)	10.0 (7.5 - 10)	1.31	0.19
Jamar	24.0 (16 - 32)	22.9 (16 - 34)	-0.38	0.70
Key pinch	4.8 (3.7 - 5.9)	4.5 (3.2 - 6.5)	-0.30	0.77
Tip pinch	3.4 (2.7 - 4.4)	3.3 (2.3 - 4.3)	-0.90	0.37
Palmar thumb abduction	45 (40 - 50)	48 (42 - 56)	1.72	0.086
Kapandji (0-10)	10 (9.0 - 10)	9.0 (8.5 - 10)	-1.32	0.19
Dominant hand operated, n (%)				
Yes	65 (58)	48 (43)	N/A	0.33
No	14 (70)	6 (30)		
Manual labor occupation, n (%)				
Yes	21 (68)	10 (32)	N/A	0.001
No	35 (33)	70 (67)		

Disc position was dichotomized to 'displaced' (grade II, III, IV) or "centered/not displaced" (grade I). Continuous variables shown as median scores (IQR), discrete variables as number (%). Fisher exact test for occupation and hand dominance; Mann-Whitney test for all other variables. N/A = not applicable. **Bold** indicates statistical significance.

DISCUSSION

In an earlier study, pyrocarbon disc interposition arthroplasty for CMC1 OA was shown to improve patient-reported hand function and pain, up to eight years postoperative, with a survival rate of 91%.^{1-4,6} This present study primarily evaluated the effect of radiographic disc position on MHQ scores. Secondary, we studied if disc position correlated with other factors, including pain intensity, thumb strength and manual labor occupation.

Our results show that patients did not experience more pain, less grip strength or worse hand function when disc displacement was found on radiographs. This is in line with previous literature, although these studies were underpowered to evaluate the effect of disc position on patient reported outcomes and hand function.¹⁻³ Other factors than perfect disc alignment seem to be more important in treatment of CMC1 OA. For example, a positive attitude has been associated with better outcomes after CMC1 surgery.¹⁹ In addition, there is mounting evidence that pain intensity and dissatisfaction with treatment are related to symptoms of depression and less effective coping strategies.²⁰⁻²² This underlines that during postoperative follow-up, the main focus should be on PROMs and adaptive coping strategies instead of radiographic findings.

We doubt the routine utility of radiographs during postoperative follow-up, especially if there is no clinical concern. A study on the hemisphere pyrocarbon implant for CMC1 OA reports low sensitivity (65%) and specificity (63%) of radiography in predicting clinical outcome.²³ Besides, a study on pyrolytic implants for small hand joints found that radiographic survival rate is worse than clinical survival.²⁴ A symmetrical lucency around the pyrocarbon disc of 1 mm can be attributed to the radiolucent coating and a small amount of displacement may be explained by the gliding concept of the disc that allows joint movement. Bone stock resorption is uncommon and was not found in our series, as expected based on findings of a previous study.²

Our data suggests that (a history of) manual labor occupation is associated with implant displacement over time. To prove causality, future prospective studies are needed. Nevertheless, it is an interesting finding that heavy occupational tasks may be associated with disc displacement over time since this technique is preferred when there is a need to maintain adequate thumb strength and stability, especially in people with demanding occupational tasks. Importantly, the clinical relevance of this potential association, however, remains questionable because disc displacement seemed to have limited clinical impact.

The disc displacement prevalence of 41% we found is much higher than the 2.2% to 31% prevalence reported in previous studies.^{1-3,5,25} This may be explained by the fact that some studies did not use a clear scoring system to assess radiographic disc position.^{1,4,5} We used a very strict scoring method in which even a small displacement of the disc was scored as 'displaced'. Another explanation may be the relatively long follow-up of our study (mean of 6.9 years), presenting a more accurate percentage of disc displacement over time. Despite the relatively high percentages of (slightly) displaced discs in our study, the clinical results are good and in correspondence with those of others.^{2,3,25} If displacement becomes symptomatic, revision surgery mostly occurs within the first two years after surgery as reported in our and in similar studies.^{1-3,5}

Our study results must be interpreted in the context of some study limitations. First, preoperative measurements of the different patient-reported outcomes, thumb strength, and motion were not available. Therefore, we could not assess any differences in outcome measures over time. However, in the light of our study aim, we believe that it is possible to make a statement about the association between the disc position and the clinical outcomes postoperatively. Second, even a small displacement was judged as 'displaced', which may have led to an overestimation of displaced discs and an underestimation of the possible correlation between outcome and disc position. Third, we were unable to include 16 patients because of disc removal prior to the start of this study. These patients were not included in the study because of missing outcome data. This may have contributed to a lack of correlation, although it seems unlikely since it concerns a very small amount of our total study cohort. Besides, this study aimed to investigate the clinical outcome related to implant position for those patients with the disc still *in situ*. Fourth, the subgroup of patients with STT OA in our study cohort was too small ($n = 5$) for statistical analysis to detect any relationship with disc position. However, there appears to be no indication for the development of STT OA and implant dislocation. Fifth, we gauged patient's prior and present occupation in a general questionnaire, as performed in previous studies¹³, but more specific data on duration of occupational tasks, work postures, and other physical activities was not available. Sixth, this study was conducted in two urban centres in the Netherlands and results may not generalize to other settings.

In conclusion, we could not detect any relationship between the position of pyrocarbon disc on radiographs and a broad variety of clinical outcomes, including patient-reported pain and hand function. Our data suggests that heavy occupational tasks are associated with increased severity of radiographic disc displacement but future studies are needed to study this in better detail and to reveal any causative factors. A variable amount of displacement of the disc occurred in 41% of the patients but this had little clinical consequences. Therefore, follow-up radiographs should not be taken routinely if there are no complaints.

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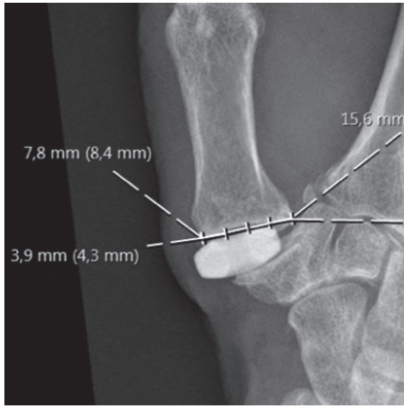
APPENDICES

Appendix 1. Reasons for disc removal.

Patient	Gender	Age at operation*	Reason for disc removal	Time (mo) implementation and removal	Grade of disc luxation
1	W	71	STT OA	11	2
2	W	80	STT OA	60	1
3	W	61	STT OA	32	1
4	W	55	STT OA	20	1
5	W	62	STT OA	6	2
6	W	57	STT OA	84	1
7	W	68	STT OA	22	3
8	W	56	traumatic tendon rupture	1	4
9	M	55	traumatic tendon rupture	16	3
10	W	48	traumatic tendon rupture	23	3
11	M	56	persisting pain	19	2
12	W	48	persisting pain	14	1
13	W	47	persisting pain	10	1
14	W	54	persisting pain	12	1
15	W	61	persisting pain	18	2
16	W	48	persisting pain	3	2

W = woman, M = man, STT OA = scapho-trapezio-trapezoidal osteoarthritis. Main reasons for disc removal: (1) STT OA, (2) traumatic tendon rupture leading disc luxation, (3) persisting pain without clear underlying cause. *Age at initial operation (disc placement) in years. Disc luxation scored according to scoring system described in Appendix 2.

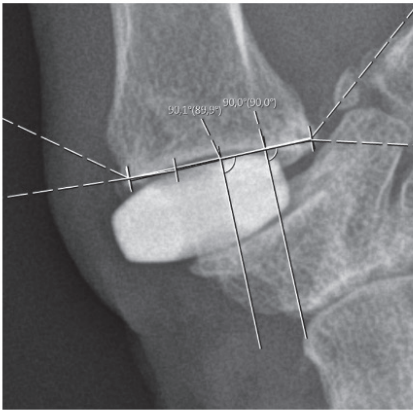
Appendix 2. Classification of disc position.



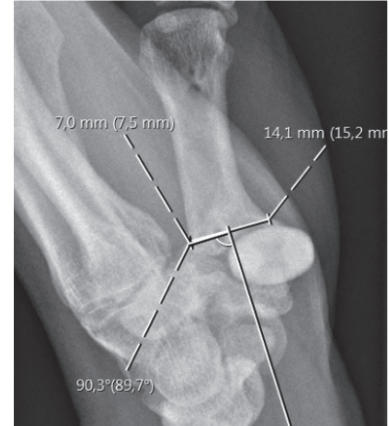
[A] The base of MC1 was divided in 4 quarters.



[B] No luxation (Grade 1).



[C] Less than 1/4 displacement (Grade 2).



[D] Between 1/4 - 1/2 luxation (Grade 3).

Appendix 3. Reliability scores.

	Kappa (SE)*	P value
<i>Intra-observer reliability</i>		
Disc position PA	0.97 (0.17)	<0.001
Disc position lateral	0.93 (0.17)	<0.001
<i>Inter-observer reliability</i>		
Disc position PA	0.91 (0.17)	<0.001
Disc position lateral	0.92 (0.17)	<0.001

*Weighted kappa for inter- and intra-observer reliability with standard errors (SE). PA = posteroanterior view.

Appendix 4. Median scores at follow-up.

Variables	N = 136
MHQ	74 (62 to 89)
PRWHE	19 (3.5 to 45)
Pain	12 (0 to 25)
Satisfaction	9 (7 to 10)
Jamar	24 (16 to 33)
Key pinch	4.7 (3.4 to 6.2)
Tip pinch	3.3 (2.6 to 4.3)
Palmar thumb abduction	46 (42 to 54)
Kapandji (0-10)	9 (9 to 10)

All continuous variables as median (IQR). Median imputation for missing values: MHQ 2, PRWHE 8, pain 6, and satisfaction 5.



Chapter 8

JOINT DISTRACTION FOR THUMB CARPOMETACARPAL OSTEOARTHRITIS: TWO-YEAR FOLLOW-UP RESULTS OF TWENTY PATIENTS

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ABSTRACT

Background: Joint distraction is a fairly new treatment for patients with symptomatic thumb carpometacarpal osteoarthritis (CMC1 OA). A previous pilot study of five patients showed that CMC1 joint distraction is technically feasible. The current study presents the results of CMC1 joint distraction in 20 patients with a two-year follow-up period.

Objectives: The primary study aim was to assess if patients with CMC1 OA have better physical function and less pain two years after CMC1 joint distraction. Second, we assessed the number of patients that achieved a minimal clinically important difference (MCID) in patient reported outcome measures (PROMs) at each time point. Furthermore, this study sought differences on magnetic resonance imaging (MRI) of the CMC1 joint before and after distraction. Adverse events were noted and reported.

Participants: Twenty patients with a median age of 54 years (range 41 to 64) with symptomatic CMC1 OA and an established indication for a trapeziectomy.

Methods: This was a prospective cohort study. An external distractor device was placed over the CMC1 joint and left *in situ* for eight weeks. Disabilities of the Arm, Shoulder, and Hand (DASH) score, Michigan Hand Outcome Questionnaire (MHQ), Visual Analogue Scale (VAS), and grip strength were recorded preoperatively and three, six, 12 and 24 months postoperatively.

Results: Two years after joint distraction, physical function and pain scores had improved significantly compared to baseline: DASH from 48 to 17, MHQ from 56 to 83, and VAS for pain from 50 to 18 mm. Fourteen of 19 patients (74%) reached a MCID in DASH and MHQ scores. One patient was not satisfied with treatment outcome and chose to proceed with a trapeziectomy 14 months after initial distraction therapy.

Conclusion: This study demonstrates that CMC1 joint distraction can postpone more invasive surgical interventions (e.g. trapeziectomy) for at least two years. Larger comparative studies are needed to assess the value of CMC1 joint distraction in the treatment of CMC1 OA.

INTRODUCTION

Carpometacarpal osteoarthritis of the thumb (CMC1 OA) affects approximately one-third of the population aged 55 years and older.^{1,2} The radiographic prevalence increases to 90% in people over 80 years of age.^{1,2} Initial treatment of patients with symptomatic CMC1 OA routinely involves nonoperative options first, including splints, oral analgesia and hand therapy.³ If nonoperative management does not offer sufficient relief, surgical treatment can be considered.^{4,5} Surgical treatment options of CMC1 OA vary greatly. Also, there is no evidence for the superiority of each technique regarding pain and functional outcome.^{4,5} Trapeziectomy with or without ligament reconstruction and tendon interposition (LRTI) or suspension arthroplasty is effective but carries the long-term risk of metacarpal subsidence, persistence, or recurrence of symptoms.^{4,6,7} Prostheses are associated with loosening, subluxation, fracture, and synovitis, potentially requiring revision surgery.^{4,6,7} With respect to patients requiring surgical intervention for CMC1 OA at a relatively young age, other less invasive techniques that preserve the joint may be considered more desirable.

Joint distraction is an innovative joint sparing treatment for patients (< 65 years) with ankle or knee OA. It aims to postpone or prevent an invasive surgical intervention.^{8,9} Previous evidence reports that joint distraction can reduce pain, improve physical function, and increase joint cartilage thickness measured on magnetic resonance imaging (MRI).^{8,10,11} Van der Woude *et al.*¹¹ showed persisting pain reduction and greater physical function compared with baseline at five-year follow-up in patients who underwent knee distraction for painful OA. A paper published in 2018 reported a nine year knee joint survival rate of nearly 50% after joint distraction with long-lasting clinical and structural improvements.⁸ Our previous pilot study of five patients with a one-year follow-up period demonstrated that CMC1 joint distraction is technically feasible and provides pain reduction and improved physical function.¹²

We aimed to assess the effect of CMC1 joint distraction in a larger cohort including 20 patients with a two-year follow-up period. The purposes of this study were: (1) to assess surgical outcomes of joint distraction – in terms of physical function and pain – for patients at a relatively young age (< 65 years) with CMC1 OA; (2) to analyze the number of patients who achieved a minimal clinically important difference (MCID) in patient-reported outcome measures (PROMs) at each time point; (3) to assess MRI findings of the CMC1 joint before and after the surgery; and (4) to report the adverse events.

PATIENTS & METHODS

Study design

This prospective cohort study was approved by our local institutional review board. We enrolled 20 patients from a single outpatient center and obtained written informed consent. The first five patients were enrolled between October and September 2014 to assess technical feasibility of the surgical technique. The following 15 patients were enrolled between September 2016 and November 2017. All patients were aged < 65 years, had symptomatic CMC1 OA (Eaton-Glickel classification II or III on radiographs), and failed to obtain acceptable results with nonoperative treatment efforts (e.g. hand therapy or three-month splint use). In all patients, the indication for invasive surgical treatment (e.g. trapeziectomy) was made.¹⁵ Patients were excluded for the following reasons: severe radiographic CMC1 OA (Eaton-Glickel grade IV), previous surgical treatment of the affected CMC1 joint, a past medical history of inflammatory or rheumatoid arthritis, or use of immunosuppressive or chemotherapeutic drugs. Details of the inclusion and exclusion criteria are further described in the prior pilot study by Spaans *et al.*¹²

Surgical technique

All procedures took place in our day care surgery center and were performed by one of two hand surgeons (A.B. or A.M.v.d.M.). General anesthesia was performed in five of 20 patients who specifically preferred this over locoregional anesthesia. All patients received two grams of intravenous cefazoline preoperatively. Under fluoroscopic guidance, the distractor device (Osteo-x, Osteotec, Dorset, UK) was placed over the CMC1 joint. The device is anchored percutaneously with two proximal K-wires into the trapezium bone and two distal K-wires in the first metacarpal by using the distractor as a drill guide (Figure 1). Subsequently, the device distracted 3 mm intraoperatively and the K-wires shortened to 1 cm above the distractor device. The average procedure time was 15 to 30 minutes, depending on surgeon experience and individual cases (e.g. height of trapezium bone for placement of K-wires). A custom-made thermoplastic splint was applied to cover and protect the distractor. The distractor was left *in situ* for the following eight weeks, after which it was removed in our outpatient clinic. Hand therapy commenced thereafter.

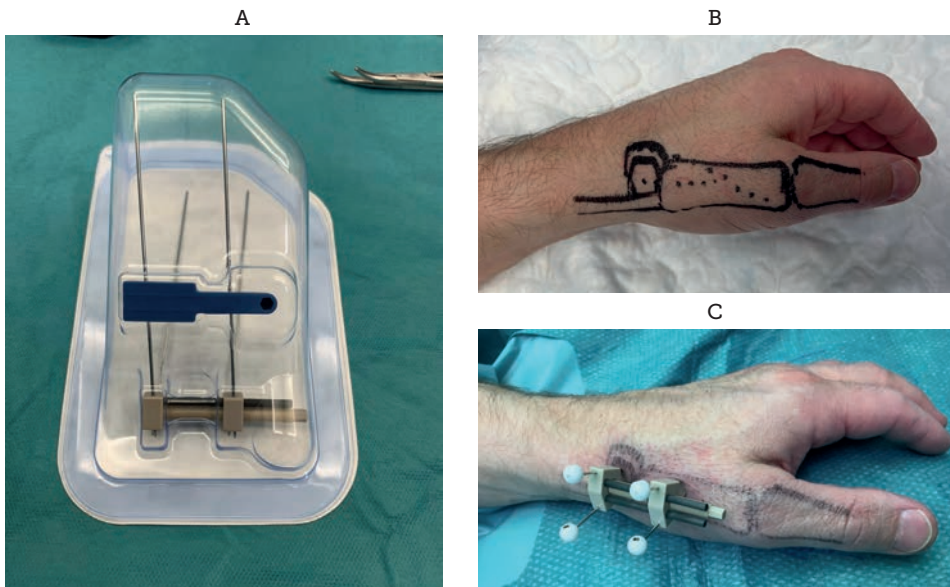


Figure 1. (A) The distractor device. (B) Drawing of the trapezium bone and metacarpal bone. (C) Distractor device *in situ* with two K-wires in the trapezium bone and two in the first metacarpal.

Patient evaluation

Upper extremity-specific disability was measured with the Disabilities of Arm, Shoulder, and Hand (DASH) questionnaire (Dutch language version), which produces scores from 0 to 100, with higher scores indicating more disability.¹⁴ Hand health status was assessed using the Michigan Hand Outcome Questionnaire (MHQ) (Dutch language version), which produces scores between 0 and 100, with higher scores indicating greater hand health.¹⁵ The applied minimal clinically important differences (MCID), the smallest difference that patients perceive as beneficial, was based on those of previous studies: 10 points for DASH and nine points for MHQ.^{16,17} Thumb pain, thumb function, and overall patient satisfaction were scored on a 0 to 100 mm visual analogue scale (VAS). A score of 0 mm represented no pain, perfect thumb function, or perfect satisfaction. A score of 100 mm represented the worst imaginable pain, poorest satisfaction, or worst possible thumb function.¹⁸ Patients were asked to complete these questionnaires preoperatively and at three, six, 12 and 24 months after the procedure. During the distraction period, only VAS scores were assessed every two weeks. The reported two-year follow-up period is in accordance with the suggested guidelines of required minimal follow-up in hand surgery studies.¹⁹

An independent certified hand therapist measured active range of thumb motion: [1] radial abduction (degrees), [2] extension (cm) with a DeVore goniometer, [3] palmar abduction with the Pollexograph (degrees), [4] abduction by intermetacarpal distance (cm), and [5] opposition by Kapandji measurements (0-10).²⁰ Grip strength was measured using a hand dynamometer with the shoulder adducted and in neutral rotation, elbow at 90 degree flexion, and the forearm and wrist in neutral position. Key, tip and three-point pinch strength were measured by baseline pinch gauge (P100 Hand Kit, Biometrics Ltd, Gwent, UK). Strength measurements were recorded as the average of three attempts.

Diagnostic imaging

Radiographs (anteroposterior, lateral, and Bett's view) were obtained at all visits to evaluate the joint space. MR imaging of the CMC1 joint was obtained in the first five patients preoperatively and 12 months postoperatively using a dedicated wrist coil (Siemens 3T Skyra, Erlangen, Germany). The Outcome Measures in Rheumatology Clinical Trials (OMERACT) thumb base osteoarthritis MRI scoring system (TOMS) was used to assess subchondral bone defects, cartilage, osteophytes, synovitis, and bone marrow lesions on a scale from 0 to 3 (normal to severe) of the CMC1 and scapho-trapezio-trapezoidal joint.²¹ Subluxation of the CMC1 joint was assessed and scored as absent ("0") or present ("1").²¹ MR images were reviewed by two experienced independent researchers, blinded for patient treatment details, using the OMERACT TOMS tool. Previous reports define the average-measure intraclass correlation coefficients of the OMERACT TOMS tool for the CMC1 joint as good to excellent for most features (> 0.70), except for cartilage assessment (0.39) and osteophytes (0.47).²²

Adverse events

Adverse events were scored according to the Clavien-Dindo classification of surgical complications ranging from grade I (minor complication) to grade V (death) (Appendix 1).²³

Sample size calculation

The aim of this proof-of-principle study was to give more insight in the effects of CMC1 distraction. An *a priori* power analysis was not performed. Results obtained in this study will be used for a *a priori* power analysis of future studies.

Statistical analysis

Continuous variables are reported as median with interquartile range (IQR) and discrete variables as absolute numbers with percentages. The Wilcoxon signed-rank test was used to compare the differences between DASH, MHQ, VAS scores, range of motion and strength measurements. All *P* values < 0.05 were considered statistically significant.

RESULTS

Participants

The median age of 20 patients was 54 years (range 41 to 64). Nineteen (95%) were women (Table 1). Fourteen patients (70%) underwent distraction on their dominant hand (Table 1). For one patient, the preoperative measurements of VAS, strength and range of motion were not available for analysis. One patient proceeded with a trapeziectomy 14 months after initial distraction treatment because of ongoing pain. Results of this patient are not included in the two-year follow-up results.

Table 1. Patient characteristics.

Variables	N = 20
Age, median (range) (y)	54 (41 to 64)
Gender	
Man	1 (5)
Woman	19 (95)
Dominant hand	
Left	3 (15)
Right	17 (85)
Operated on dominant hand	14 (70)

Discrete variables as number (percentage), unless otherwise specified.

Difference in pain and physical function

At one-year follow-up, all PROMs improved after CMC1 joint distraction compared with baseline. These improvements remained at two-year follow-up (Table 2). DASH scores improved by 28 points at one year and by 31 points (from 48 to 17; $P < 0.001$) at two years; MHQ increased by 21 points at one year and by 27 points at two years (56 to 83; $P < 0.001$).

VAS scores for pain intensity improved from 50 mm to 18 mm ($P < 0.001$) at two years, thumb function from 59 mm to 26 mm ($P = 0.001$), and overall patient satisfaction from 75 mm at baseline to 24 mm two years post-distraction ($P = 0.002$) (Table 2).

Some range of motion measures decreased one year post-distraction but improved back to baseline levels at two-year follow-up. There was no difference in motion and strength measurements after two years compared with baseline, except for an increase of thumb palmar abduction (Table 2).

Table 2. Baseline, one-year and two-year follow-up results of all patients.

Variables	Baseline N = 19*
DASH	48 (34 to 57)
MHQ	56 (41 to 62)
VAS pain	50 (37 to 72)
VAS function	59 (40 to 75)
VAS satisfaction	75 (61 to 86)
Range of motion	
Radial thumb abduction in degrees	60 (55 to 65)
Palmar thumb abduction, pollexograph in degrees	40 (40 to 46)
Palmar thumb abduction, imd in cm	5.3 (5.0 to 5.8)
Extension in cm	4.0 (3.5 to 5.0)
Kapandji score	10 (9 to 10)
Strength measurements (kg/m ²)	
Grip	20 (13 to 26)
Key pinch	4.5 (3.5 to 5.6)
Three point pinch	3.6 (2.8 to 4.7)
Tip pinch	3.2 (2.1 to 3.3)

DASH = Disabilities of Arm, Shoulder, and Hand; MHQ = Michigan Hand Outcome Questionnaire; VAS = Visual Analogue Scale; imd = intermetacarpal distance. All continuous variables as median (IQR).

Minimal clinically important differences

Twelve patients (n = 12/20; 60%) reached the MCID for DASH score at one year and 14 patients (n = 14/19; 74%) did so at two years (Appendix 2). For the MHQ these numbers were 15 (n = 15/20; 75%) at one year and 14 (n = 14/19; 74%) at two years (Appendix 2).

Diagnostic imaging

Figure 2 shows radiographs before, during, and 12 and 24 months after distraction therapy. Analysis of MRI scored by OMERACT TOMS showed no difference in osteophytes, cartilage loss, or subluxation (Table 3). There was a small increase of synovitis, subchondral bone defects and bone marrow lesions in the CMC1 joint one year after distraction (Table 3; Figure 3).

1-year N = 20	P value	2-year N = 19†	P value (2-years vs. baseline)
20 (4 to 49)	<0.001	17 (3.3 to 28)	<0.001
77 (62 to 95)	<0.001	83 (64 to 95)	<0.001
15 (0 to 37)	0.003	18 (7 to 28)	<0.001
30 (5 to 56)	0.007	26 (13 to 32)	0.001
13 (0 to 34)	0.002	24 (1 to 47)	0.002
57 (54 to 60)	0.020	58 (55 to 62)	0.601
44 (39 to 51)	0.115	44 (40 to 54)	0.091
6.0 (5.5 to 6.5)	0.032	6.2 (5.5 to 6.7)	0.004
3.0 (2.5 to 4.0)	0.033	3.5 (3.0 to 5.0)	0.554
9 (9 to 10)	0.816	10 (9 to 10)	0.741
21 (17 to 28)	0.040	23 (21 to 26)	0.053
5.4 (4.0 to 6.2)	0.067	5.0 (4.5 to 6.7)	0.074
4.6 (3.3 to 5.0)	0.409	4.6 (3.3 to 5.0)	0.089
2.9 (2.2 to 4.3)	0.334	3.3 (2.4 to 3.9)	0.223

Bold indicates statistically significance, $P < 0.05$. *One missing value at baseline for all measures except DASH and MHQ. †One patient excluded after trapeziectomy.

Adverse events

Adverse events were scored according to the Clavien-Dindo classification (Appendix 1).²³ In one patient, a single K-wire tip broke while putting on socks; in three other patients, a broken K-wire was noticed during removal of the distractor device and a small piece of K-wire was left *in situ* in the trapezium bone in these four patients. To avoid further K-wire breakage, we changed to using unthreaded K-wires and released tension of the distraction device before its removal. Thereafter, no further K-wire complications were noted. Six patients experienced a superficial pin tract infection, which was managed successfully with oral antibiotics in five patients. In one patient, the distractor device had to be removed at six weeks to control the infection. After removal, the infection resolved. One patient developed De Quervain's tenosynovitis on the operated side six months after distraction therapy and was treated successfully with surgical release of the affected compartment.

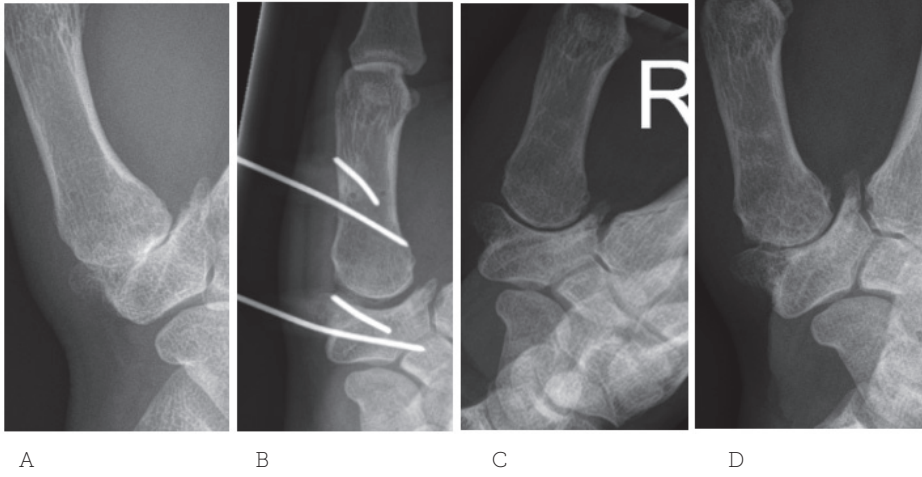


Figure 2. Radiographs (A) before, (B) during distraction therapy, and (C) at one-year and (D) at two-years of follow-up. Image courtesy: Spaans *et al.*¹²

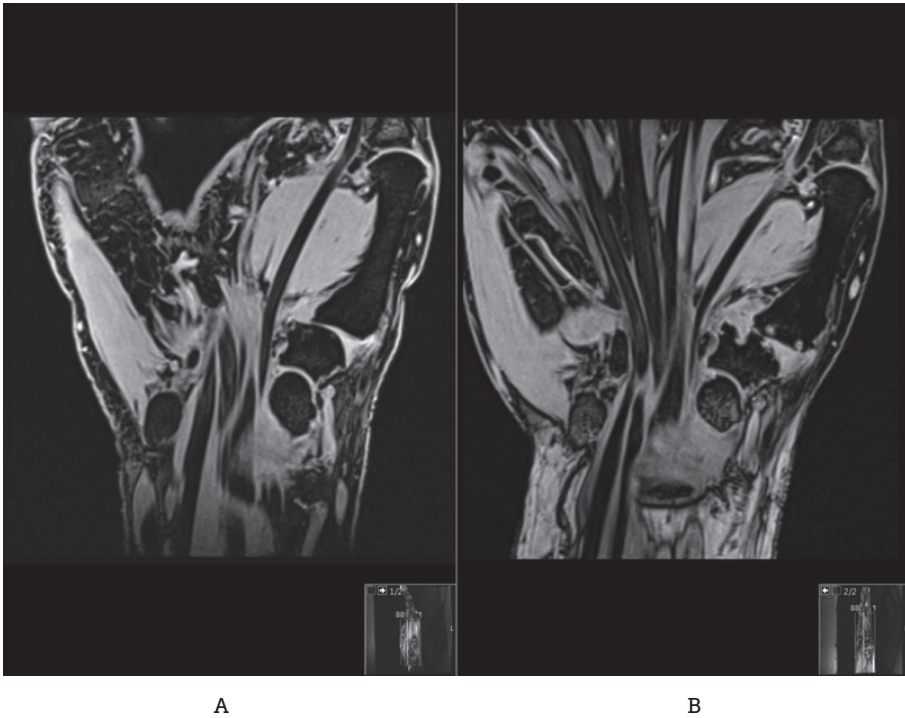


Figure 3. MRI (A) before and (B) 12 months after distraction therapy with slight increase of bone marrow lesions and subchondral bone defects.

Table 3. OMERACT TOMS scores on MRI.

Variables	Preoperative	One-year postoperative
Synovitis	0.25 (0.0 to 0.25)	0.50 (0.0 to 0.75)
Subchondral bone defects	0.30 (0.30 to 0.50)	0.75 (0.70 to 0.90)
Osteophytes	0.70 (0.60 to 0.90)	0.70 (0.60 to 0.90)
Cartilage loss	0.50 (0.25 to 0.75)	0.50 (0.25 to 0.75)
Bone marrow laesions	0.40 (0.10 to 0.50)	0.65 (0.60 to 0.75)
Subluxation (number (%))	0.0 (0.0)	0.0 (0.0)

All continuous variables as median (IQR), unless otherwise specified. OMERACT TOMS = Outcome Measures in Rheumatology Clinical Trials thumb base osteoarthritis MRI scoring system. Scores range from 0 to 3, except for the subluxation variable which has scores of 0 or 1.

DISCUSSION

Distraction is an innovative and joint preserving technique. It has the potential to delay or prevent more invasive surgical procedures for patients with CMC1 OA seeking care.^{8,11,12} This study shows a significant improvement in PROMs at two years after distraction therapy.

We acknowledge some limitations of the present study. First, this is a noncomparative trial. The contribution of a possible placebo effect and regression to the mean of the outcome measures could not be assessed. There is evidence that many people with CMC1 OA adjust over time and do not seek medical care.^{5,24,25} Future studies comparing distraction with other operative and nonoperative treatments are required to address such effects. Second, this study describes a small number of patients, mainly women, who were enrolled in a single urban center. Our results might not generalize to other populations, regions or practice settings.

This proof-of-principle study demonstrates the ability of CMC1 joint distraction to improve physical function and reduce pain at one and two years after the procedure. The median improvements in DASH, MHQ and VAS pain scores of 28, 21, and 35 at one year respectively and 31, 27, and 32 at two years are comparable to prior published outcomes after trapeziectomy (with or without interposition).²⁶⁻²⁹ Wang *et al.*²⁹ retrospectively reviewed 20 patients who received trapeziectomy with LRTI and reported improvements of 30 points in DASH (from 52 to 22) and 54 in pain intensity (68 to 14) at two-year follow-up. No MHQ scores were assessed. Although pain intensity improved more in their study, this can be related to the higher baseline intensity reported, since the results at two years are nearly the same (14 *versus* 18). The improvement in MHQ of 22 points at one year is comparable to the results of a recent

prospective cohort study among 233 Dutch patients who underwent trapeziectomy with interposition tendinoplasty: MHQ scores increased with 21 points to 69 points after one year.²⁸ A randomized prospective trial by Davis and Pace comparing simple trapeziectomy *versus* trapeziectomy with LRTI and K-wire insertion among 128 patients showed 31 points improvement of DASH scores at one year after simple trapeziectomy and 28 points improvement after trapeziectomy with LRTI and K-wire insertion.²⁷ These results are comparable to the 28 points improvement in DASH we noted at one-year follow-up. Both studies did not report results at two years, which is the suggested minimum length of follow-up in hand surgery reports.¹⁹ The finding that joint distraction results in improved patient-reported outcomes that are comparable to outcomes in other procedures for CMC1 OA supports the use of CMC1 joint distraction in selected patients.

Out of 19 patients, 14 (74%) reached a MCID in both DASH and MHQ scores two years after joint distraction. To our knowledge, there are no other studies describing the MCID of individual patients with CMC1 OA. Some studies mention the average MCID of all patients after treatment of CMC1 OA.^{28,30} Our findings show that CMC1 joint distraction leads to improvements that most patients experience as beneficial.

The finding that no differences in cartilage quality were detectable on additional imaging deviates from previous distraction studies.^{8,11} This is possibly related to the differences in shape and type of joints studied. The CMC1 joint has a smaller joint space compared with knee joints and is a non-weight-bearing joint with a unique saddle shape.⁵ Additionally, the complexity of the shape and the oblique orientation of the trapezium makes assessment of the CMC1 joint challenging on both radiographs and MRI. For these reasons, radiographic classification systems lack reliability.³¹ Studies on knee distraction showed increased cartilage thickness and joint space width after treatment.^{10,11} These findings, however, were not correlated with better patient outcomes.^{10,11} Improved imaging techniques or invasive arthroscopic sampling of articular cartilage are needed to reliably assess CMC1 cartilage quality. Alternatively, biochemical analysis of synovial fluids can be a promising avenue for future research of the CMC1 joint.

One of the 20 patients experienced ongoing pain after joint distraction and proceeded with a trapeziectomy 14 months after the initial surgery. We defined this re-operation in one patient as treatment failure. A previous study on ankle OA reported that 17% (18/105) underwent arthrodesis or osteotomy within two years of distraction, defined as treatment failure.³² In a cohort of knee OA patients, 17% (3/18) converted to knee arthroplasty between three and five years after distraction.¹¹ The failure rate of 1/20

patients in this study illustrates that joint distraction can postpone invasive surgical interventions in the majority of patients. Future studies can assess factors associated with treatment failure, for example patient characteristics, to better select patients who will likely benefit from joint distraction.

In nine of 20 patients (45%), 11 adverse events occurred of which 10 events were classified as a grade I complication (Appendix 1). This rate is comparable to a study by Davis *et al.*³³ after trapeziectomy and K-wire stabilization for four weeks: in 101 of 183 patients (55%), an adverse event occurred, mainly nerve- or tendon-related problems. Other studies on CMC1 OA seems to have fewer adverse events: in 14 of 65 patients (22%) after trapeziectomy with or without LRTI, as reported by Field and Buchanan.³⁴ A comparative trial by Davis and Pace showed complication rates of 31% after single trapeziectomy and 46% after trapeziectomy with LRTI and K-wire stabilization.²⁷ For arthrodesis of the CMC1 joint nonunion rates up to 26% have been reported in a previous review.⁵ Adverse event rates of 15% were reported for Swanson implants.⁴ In knee distraction series, 17 of 20 patients (85%) suffered from pin tract infections and two patients (10%) from a pulmonary embolus.¹⁰ The present small cohort distraction study had a relatively high number of adverse events compared to other CMC1 OA procedures but the severity of the events was classified as the lowest category of complications (grade I; Appendix 1). One-third of the adverse events in our study was related to the use of threaded K-wires. After changing to unthreaded wires, no more device-related complications were noted. A more reliable adverse event rate and treatment failure rate can be established by studying a larger cohort with longer follow-up.

In conclusion, this study demonstrates that eight weeks of CMC1 distraction in patients younger than 65 years of age with symptomatic CMC1 OA can reduce pain and improve physical function after one year, which is sustained at two years. These findings suggest that joint distraction could postpone more invasive procedures, such as trapeziectomy, for most patients. To better determine the value of joint distraction in the treatment of CMC1 OA, future studies are required with a larger cohort of patients, a comparison group, and longer follow-up.

Acknowledgements

The authors thank Ilona Overduin and Laura Broekman for their work as hand therapists. We thank Féline Kroon and Sjoerd van Beest for scoring the MR images.

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APPENDICES

Appendix 1. The Clavien-Dindo classification of surgical complications.*

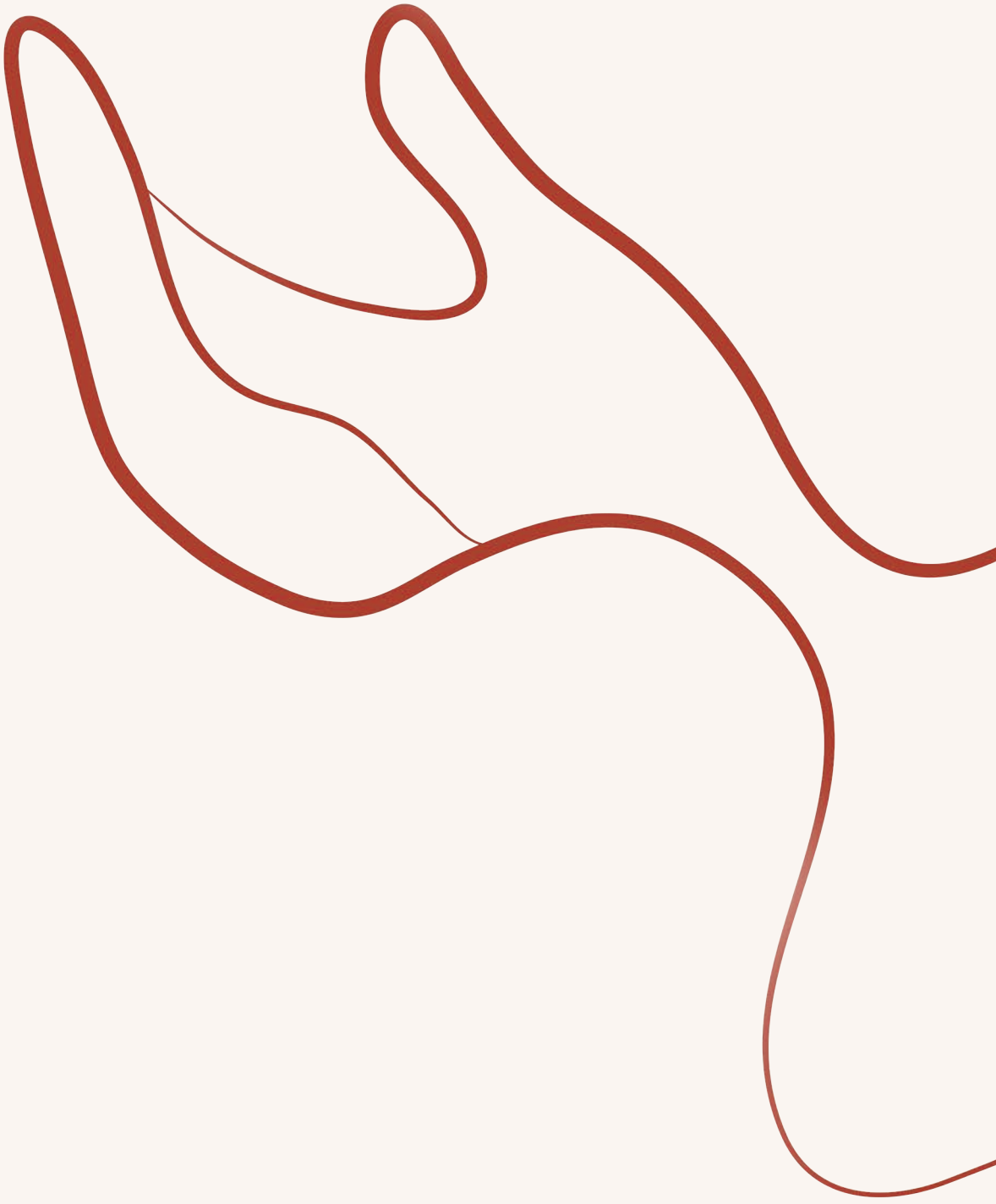
Grades	Definition	Adverse events in study cohort [†]
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	- Superficial pin tract infection (n = 5) - Pin infection and early device removal (n = 1) - Broken K-wire (n = 4)
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	
Grade III	Requiring surgical, endoscopic or radiological intervention.	- De Quervain release (n = 1)
- IIIa	Intervention not under general anesthesia.	
- IIIb	Intervention under general anesthesia.	
Grade IV	Life-threatening complication (including central nervous system complications) requiring IC(U)-management.	
- IVa	Single organ dysfunction (including dialysis).	
- IVb	Multi organ dysfunction.	
Grade V	Death of a patient.	

IC = intermediate care; ICU = intensive care unit. *Presented with permission as the description from Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg.* 2004;240(2):205–213. [†]Added column, not part of the Clavien-Dindo classification.

Appendix 2. MCID of MHQ and DASH scores.

Patient	DASH			MHQ		
	Baseline N = 20	1-year N = 20	2-years N = 19	Baseline N = 20	1-year N = 20	2-years N = 19
1	36.7	1.7	10.0	54.7	96.1	95.1
2	59.2	24.2	27.5	33.4	64.1	64.0
3	56.7	50.0	24.0	61.3	71.8	67.7
4	62.5	42.5	13.8	48.5	65.3	85.9
5	50.8	18.3	19.2	41.0	81.7	89.8
6	35.0	17.5	10.8	56.3	77.5	83.4
7	70.0	65.8	71.7	36.9	31.6	31.5
8	55.0	50.8	45.0	53.5	54.4	46.1
9	44.8	60.0	X	56.5	43.0	X
10	51.8	0.83	2.5	41.0	100	98.3
11	27.5	6.7	3.3	62.6	79.8	86.3
12	33.3	0.83	0.0	65.4	100	89.3
13	39.8	0.83	0.0	60.6	93.9	98.0
14	62.5	18.3	17.5	32.7	76.9	58.4
15	33.3	24.2	26.7	60.2	81.6	79.8
16	25.0	4.2	4.2	66.2	98.8	98.9
17	44.0	4.2	0.0	52.2	96.9	95.0
18	24.2	22.5	16.7	68.3	69.9	81.8
19	57.5	48.3	59.2	37.4	47.0	30.2
20	51.7	65.8	55.8	64.8	60.4	64.7
MCID reached		12 (60%)	14 (74%)		15 (75%)	14 (74%)

MCID = minimal clinically important differences; DASH = Disabilities of Arm, Shoulder, and Hand; MHQ = Michigan Hand Outcome Questionnaire. **Bold** indicates measures that surpassed the MCID of 10 points for DASH and 9 points for MHQ. "X" = excluded.



Chapter 9

CAN WE DECREASE THE DURATION OF BASAL THUMB JOINT DISTRACTION FOR EARLY OSTEOARTHRITIS FROM EIGHT TO SIX WEEKS? STUDY PROTOCOL FOR A NON-INFERIORITY RANDOMIZED CONTROLLED TRIAL

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Trials

2021;22(1):316

ABSTRACT

Background: To our knowledge, to date, 52 patients with thumb carpometacarpal osteoarthritis (CMC1 OA) were treated with joint distraction. So far, most patients experienced improved physical function and less pain. After two years, only one patient proceeded to trapeziectomy.

Objectives: To determine if we can safely lower the distraction duration from eight to six weeks for CMC1 joint distraction, maintaining the improvement in physical function and pain.

Methods: This is a monocenter randomized controlled non-inferiority trial. All patients will be treated with CMC1 joint distraction. The primary outcome is to assess whether six weeks of joint distraction is not inferior to eight weeks in terms of physical function at one year after surgery. Secondary outcomes will identify differences between groups at one year in pain intensity, patient satisfaction, hand health status, adverse event rates, treatment failure, differences in thumb strength and range of motion, and radiographic changes.

Participants: 68 patients with ongoing symptoms of CMC1 OA despite nonoperative treatment. All patients have an established indication for an invasive surgical intervention (such as a trapeziectomy) at a relatively young age (< 65 years).

Conclusion: If safe, the duration of basal thumb joint distraction can be reduced to six weeks, reducing patient burden. Because this is a relatively new treatment, this trial will provide greater knowledge of potential adverse events. This knowledge allows for more informed decision making for patients considering CMC1 distraction treatment. Future studies can directly compare joint distraction to other treatments of CMC1 joint arthritis like splinting and trapeziectomy.

INTRODUCTION

One out of three people aged 55 years and older has radiographic signs of carpometacarpal osteoarthritis of the thumb joint (CMC1 OA).¹⁻³ The prevalence increases with aging to 90% for adults aged 80 years and older.¹⁻³ Patients with symptoms of CMC1 OA are initially offered nonoperative treatment including splints, analgesics and hand therapy to reduce pain.⁴ If these interventions do not offer sufficient relief, surgical treatment can be considered.⁴⁻⁶ There are numerous variations in surgical treatment for CMC1 OA. There is, however, no evidence for the superiority of individual techniques regarding pain and functional outcome.⁵⁻⁷ Trapeziectomy alone, or combined with ligament reconstruction and tendon interposition or suspension arthroplasty, carries the long-term risk of metacarpal subsidence with or without persisting symptoms.⁵⁻⁹ Prostheses are associated with loosening, subluxation, fracture and synovitis, potentially requiring revision surgery.⁵⁻¹⁰ Arthrodesis of the CMC1 joint reduces range of motion and has the associated risk of nonunion resulting in revision surgery.¹¹ For patients with persisting symptoms of CMC1 OA requiring surgical intervention at a relatively young age, other techniques that preserve the joint and are less invasive may be more desirable.

Joint distraction is a joint sparing treatment for relatively young patients (< 65 years of age) with symptoms of OA and aims to postpone or prevent an invasive surgical intervention.¹²⁻¹⁵ Previous evidence on ankle and knee OA shows that joint distraction can result in sustained clinical improvement with actual repair of joint cartilage after treatment.^{12,14-18} Van der Woude *et al.*¹⁵ showed persisting pain reduction and greater physical function compared to baseline at five-year follow-up among patients who underwent knee distraction. Another study demonstrated an almost 50% (8/17) joint survival rate after nine years.¹⁴

Joint distraction is also feasible for the osteoarthritic CMC1 joint.¹⁹ Nowadays, to our knowledge, more than 50 patients with persisting symptoms of CMC1 OA despite nonoperative therapy were treated with CMC1 joint distraction. Recent follow-up results of 20 patients who underwent CMC1 joint distraction shows that in 19 of 20 patients an invasive surgical intervention was postponed for at least two years (unpublished data). On average, all patients experienced less pain and better physical function after two years. Unpublished data of the first five patients shows that all patients were still satisfied five years post-distraction without further surgical interventions.

Distraction of the CMC1 joint is currently applied for eight weeks. However, the duration of knee joint distraction has been decreased from eight to six weeks.¹⁷ This is based on results of two previous studies that report similar clinical results

at one year and less pin tract infections among patients in the six-week group.^{17,18} Pin tract infections occurred in 85% of patients in the eight-week group versus 55% in the six-week group.¹⁷ During CMC1 joint distraction, pin tract infections occur in approximately one of three patients and are usually adequately treated with oral antibiotics (unpublished data of 40 patients). It is unknown if shortening of the CMC1 joint distraction duration from eight to six weeks will also result in less adverse events and still achieve sufficient clinical benefits for patients. Therefore, we designed this study protocol for a randomized controlled non-inferiority trial to compare six weeks with eight weeks of CMC1 joint distraction.

Study objectives

The primary objective is to assess if six weeks of CMC1 joint distraction is not inferior to a duration of eight weeks. Our primary outcome is physical function measured with the Patient-Reported Outcomes Measurement Information System Physical Function for the Upper Extremity (PROMIS UE) at one year after distraction.

Our secondary objectives are:

- We hypothesize that there is no difference between groups in terms of pain intensity, patient satisfaction, joint stiffness, thumb function, range of motion, and strength at one year.
- We hypothesize that there is no difference in hand health status measured with the Michigan Hand Outcome Questionnaire (MHQ) between the six-week and eight-week group at one year.
- We will investigate if there is a difference in adverse event rate and treatment failure at one year.
- We will measure minimal joint space width on radiographs at one year and test if there is a difference between the two groups.
- We will assess symptoms of depression and catastrophic thinking (captured by two short questionnaires) since there is mounting evidence that psychosocial factors influence symptom intensity and magnitude of physical limitations among patients with CMC1 OA.²⁰⁻²² We will test if these, and other factors, are independently associated with physical function and hand health status.
- To study the long-term effects of joint distraction in the treatment of CMC1 OA, we will test all hypotheses mentioned above at two years and five years post-distraction.

PATIENTS & METHODS

Study design

This is a monocenter randomized controlled non-inferiority trial conducted at the St. Antonius Hospital in the Netherlands: a peripheral teaching hospital in a large urban area. Patients will be randomly assigned to group A or B using a secured computer program (Research Electronic Data Capture (REDCap)). All patients are treated with continuous CMC1 joint distraction by placing an external distractor device over the affected joint. The distractor device will be removed after six weeks among patients in group A; for patients randomized to group B, the device is removed after eight weeks.

Participants

The study population consists of 68 patients with ongoing symptoms of CMC1 OA despite nonoperative treatment. All patients have an established indication for an invasive surgical intervention (such as a trapeziectomy) at a relatively young age (< 65 years).

Inclusion criteria

In order to be eligible to participate in this study, patients must meet all of the following criteria:

- Age < 65 years
- Eaton-Glickel classification II or III on radiographs²³
- Failed nonoperative treatment (e.g. splint for at least three months)
- Established indication for invasive surgical treatment for CMC1 OA according to standard clinical practice
- Willingness to participate in the study and able to understand distractor maintenance and hygiene instructions

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participation in this study:

- Severe CMC1 OA with Eaton-Glickel grade IV on radiographs²³
- Joint subluxation of >30%
- Surgical treatment of the CMC1 joint in the past
- Inflammatory or rheumatoid arthritis present or in past medical history
- Use of immunosuppressive or chemotherapeutic drugs
- Previous corticosteroid injection in the CMC1 joint
- Hypermobility syndrome or syndromic diseases
- Unable or unwilling to attend follow-up appointments

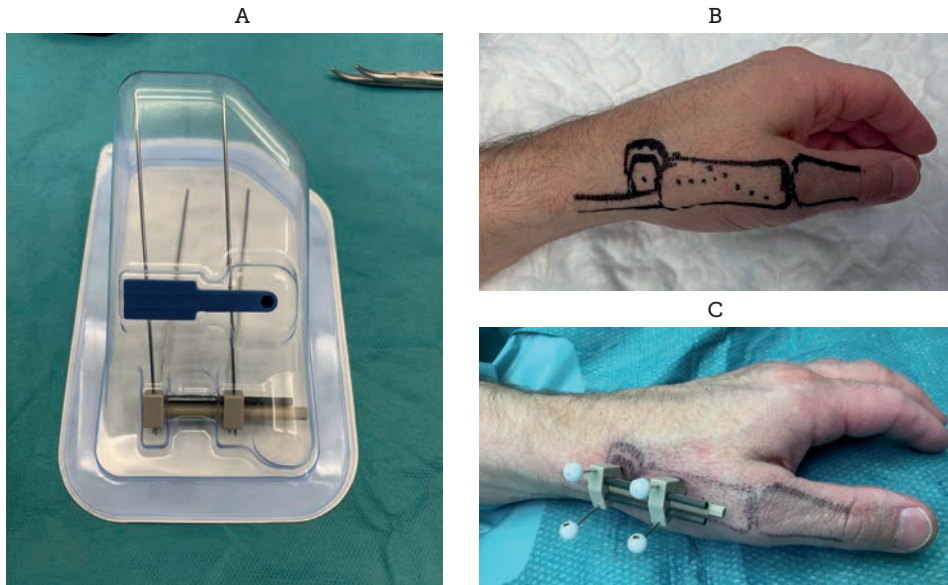


Figure 1. (A) The distractor device. (B) Drawing of the trapezium bone and first metacarpal. (C) Distractor device *in situ* with two K-wires in the trapezium and two in the metacarpal.

Surgical procedure

CMC1 joint distraction will be performed by one of two hand surgeons with experience in this procedure. Both surgeons are hand fellowship trained and certified by the Federation of the European Societies for Surgery of the Hand. They have developed and performed all CMC1 joint distractions ($n \geq 60$) since the start of this treatment in 2014. Their level of experience is a category five – according to the classification by Jin Bo Tang – based on the pioneering contribution both surgeons made in developing this technique.²⁴ Patients will be operated under regional anesthesia, unless patients prefer general anesthesia. All patients receive systematic antibiotics perioperative (two grams cefazoline intravenous). An external distractor device (Osteo-x, Osteotec, Dorset, UK) is placed over the affected CMC1 joint (Figure 1A). The device is anchored transcutaneous with two proximal K-wires in the trapezium bone and two distal K-wires in the first metacarpal bone (Figure 1B). Subsequently, the distractor device is distracted 3 mm intraoperative. The K-wires are cut 1.0 to 1.5 cm above the device (Figure 1C). Adequate positioning of the distractor and proper placement of the K-wires in the trapezium and metacarpal bone is checked with video-fluoroscopy during the procedure. The position of the device is checked with standard radiographs at set postoperative intervals (Figure 2 and 3). Patients are given a custom-made thermoplastic splint to cover and protect the distractor device. Hygiene instructions regarding pin entry point maintenance

will be given. Patients are discharged after surgery (daycare), unless the unlikely event occurs that a hospital admission is needed. During the period of distraction, patients will be seen at the outpatient clinic at set post-operative intervals.

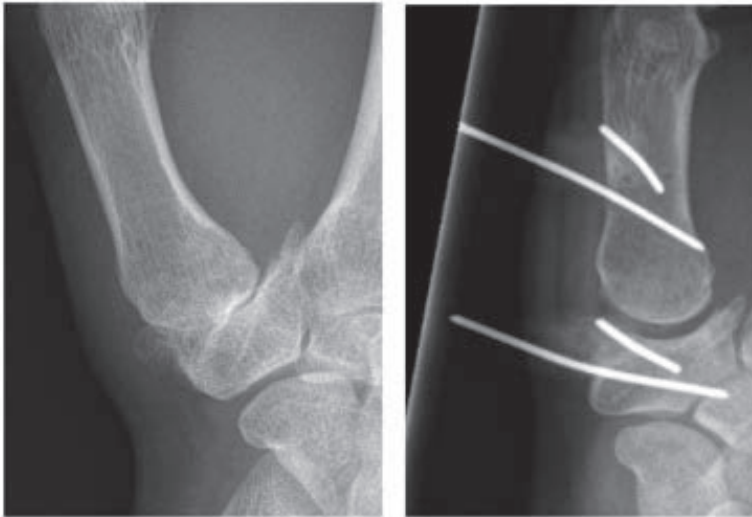


Figure 2. Radiograph of the CMC1 joint before (left) and during distraction (right). Published with permission of the original authors (Spaans *et al.*¹⁹) and the Journal of Plastic Surgery and Hand Surgery.

STUDY PARAMETERS

Primary parameter

The primary parameter is physical function at one year measured with the Patient-Reported Outcomes Measurement Information System Physical Function for the Upper Extremity (PROMIS UE).²⁵ This is a validated 16-item questionnaire answered on a five-point Likert scale. The PROMIS UE has T-scores with a mean of 50; higher scores indicate better physical function.

Secondary study parameters

- Patient characteristics: gender, age at operation, work status, marital status, and level of highest education.
- Michigan Hand Outcome Questionnaire (MHQ - Dutch language version): a validated 57-item questionnaire that gauges hand health status on a scale from 0 to 100 with higher scores indicating better hand health status.²⁶

- Patient Health Questionnaire (PHQ-2): two-item questionnaire with scores from 0 representing 'lowest level of depression' to six 'highest level of depression'.²⁷
- Pain Catastrophizing Scale (PCS-4): four-item questionnaire rated on a five-point Likert scale with scores ranging from 0 indicating 'no catastrophic thinking' to 16 'worst possible catastrophic thinking'.²⁸
- Visual analogue scale (VAS) scores for pain, patient satisfaction, thumb stiffness and function: with scores from 0 representing 'no pain at all' or 'fully satisfied' or 'no stiffness at all' or 'optimal function' to 100 'worst pain possible' or 'not at all satisfied' or 'worst stiffness possible' or 'worst possible function'.
- Range of motion obtained by an independent certified hand therapist:
 - Thumb opposition by Kapandji scores (range 0 to 10)
 - Palmar thumb abduction (degrees) by Pollexograph²⁹
- Strength measures* (in kg) obtained by an independent certified hand therapist:
 - Grip strength measured with a Jamar hand dynamometer
 - Key and tip pinch strength measured with baseline pinch gauge *

Strength measures are recorded as the average of three attempts
- Radiographs will be obtained in three different views (posteroanterior, lateral and Bett's view). Joint space (in mm) will be scored by an independent blinded radiologist.
- Adverse events: classified according to the Clavien-Dindo classification of surgical complications ranging from grade I (minor complication) to grade V (death).³⁰ Any adverse event that occurs during the distraction period or at follow-up will be administered and classified. For example, pin tract infections that are adequately treated with oral antibiotics will be classified as grade I (minor complication). In the unlikely event that intravenous antibiotics and a hospital admission is needed, this will be rated as a grade II complication.
- Treatment failure: defined as conversion to an invasive surgical procedure (e.g. trapeziectomy) after distraction therapy due to ongoing symptoms of CMC1 OA.

STUDY PHASES

Recruitment and consent

Patients visiting the plastic surgery outpatient clinic of the St. Antonius Hospital in the Netherlands due to symptoms of CMC1 OA will be screened for eligibility. A radiograph is taken at initial visit as standard of care. The hand surgeon will assess eligible patients for enrolment based on the set inclusion and exclusion criteria. Patients who fulfil the inclusion criteria will be invited to participate in the study. Written informed consent will be obtained by the coordinating investigator from all participants.

Preoperative measurements

Patients will be asked to complete a series of questionnaires on REDCap, a secured web-application for clinical research, including patient demographics (gender, age, marital status etc.), physical function, pain scores and symptoms of depression. All questionnaires are described in detail under 'study parameters'. Thereafter, patients will visit the hand therapist for strength and range of motion measures of both hands. Next, placement of the distraction device is scheduled and patients will be seen by the anesthesiologist for screening and approval of the surgical procedure.

Postoperative appointments and measurements

The study phases and data collection time points are shown in Figure 3. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist is provided as supplementary online material. In case of any problems or concerns regarding the distraction device, extra visits will be scheduled if needed. After placement of the distractor device, a thermoplastic splint is applied and hygiene instructions are given. Patients can go home on the same day of surgery. It is not allowed to drive a car, lift objects or bear weight with the operated hand during the duration of distraction therapy. Three weeks (for group A) or four weeks (for group B) after placement of the distractor device, patients are seen at the outpatient clinic. Only VAS pain scores will be collected at this time point and no other questionnaires or measurements are assessed. Any adverse events will be registered if needed.

The distractor device will be removed at the outpatient clinic after six weeks for patients in group A and after eight weeks for patients in group B. After removal, a radiograph is obtained and hand therapy commences according to a standard protocol for rehabilitation after surgical intervention. Patients are informed not to perform heavy weight bearing exercises of the thumb and index finger up to 12 weeks after removal of the distractor device. There is no other relevant concomitant care permitted or prohibited during the trial. A short overview of the exercises and timeline is provided

in Appendix 1. At three months, six months and one year after placement of the distractor device (regardless of group), patients will be seen for follow-up measures at the outpatient clinic. At these visits, several questionnaires will be completed, radiographs of the thumb will be obtained, and any adverse events that may have occurred will be evaluated and registered. The same measurements are collected at two years and five years after initial surgery to evaluate the long-term effects of joint distraction. If patients underwent other surgical interventions for ongoing symptoms of CMC1 OA, despite joint distraction of the affected hand, this will be registered as treatment failure.

action point TIMEPOINT	STUDY PERIOD									
	Enrolment	Operation	Post-operative					Follow-up		Close-out
	-t ₁	distractor placement t = 0	3wk (A) 4wk (B)	removal of distractor 6wk (A)	removal of distractor 8wk (B)	3mo	6mo	1 year	2 years	5 years
ENROLMENT:										
Eligibility screen	X									
Informed consent	X									
Randomization and allocation	X									
INTERVENTIONS:										
Group A 6 weeks		←————→								
Group B 8 weeks		←————→								
ASSESSMENTS:										
Baseline variables	X									
Surveys*	X		X**			X	X	X	X	X
Thumb strength and motion	X					X	X	X	X	X
Radiographs	X		X	X	X	X	X	X	X	X
Adverse events		X	X	X	X	X	X	X		
Treatment failure								X	X	X
Statistical analysis								X	X	X

Figure 3. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure showing the phases of the trial and data collection time points. *PROMIS UE, MHQ, VAS scores, PCS-4 and PHQ-2. **Only VAS scores for pain.

Potential benefits and risks assessment

Joint distraction is a fairly new treatment for CMC1 OA. Patients will be informed that this treatment is not offered in regular clinical practice yet, only in the context of a formal clinical study. By participating in the study, patients contribute to better understanding in the place of CMC1 joint distraction therapy compared to the

presently available surgical alternatives, which may be beneficial to patients in the future. Rehabilitation is not expected to be longer than that of the currently available invasive operative interventions.

Potential risks or complications

- Radiation burden. A total of eight radiographs will be obtained during the study period. The radiation burden will be 0.02 mSv per radiograph, resulting in a total amount 0.16 mSv. In our opinion, this is an acceptable small amount.
- Pin tract infections. Based on data from the previous cohort, pin tract infections occur in approximately one out of three patients. It can usually be adequately treated with oral antibiotics. In case of persisting infection, the distractor device may need to be removed at an earlier time point. In case of severe infection, hospital admission and intravenous antibiotics may be needed, but the estimated risk is minimal.
- Loosening of the device due to direct external forces. A customized thermoplastic splint is fashioned directly after placement of the device to provide cover and protection. If, for any reason, the device is loosened or dislodged, re-fixation or removal will follow varying per case.
- Disappointing outcome. In case distraction therapy yields insufficient improvement, the established options of invasive surgical treatment will still be possible, albeit with delay caused by study participation.

Potential benefits

- Patients may experience significant clinical benefits (less pain, better physical function) after this minimal invasive procedure.
- Patients in the six-week group may experience less pin tract infections. A distraction period of six weeks has not been studied for CMC1 OA specifically, but based on knee distraction studies, six weeks of continuous joint distraction seems to result in less pin-tract infections compared with an eight-week distraction duration (85% versus 55% respectively).^{17,18} However, it must be mentioned that pin tract infections occur more often during knee distraction than CMC1 joint distraction treatment.¹⁹

Randomization and blinding

Patients will be randomized to one of two groups at a 1:1 allocation ratio. We will use Research Electronic Data Capture (REDCap)³¹, a secured web-application and electronic platform for managing clinical research data, for randomization and allocation concealment. A fixed block size design will be generated in this secure web-application by the coordinating investigator who is not involved in patient care

or in the assessment of the postoperative outcomes. Details about the randomization method or block sizes will not be available to or shared with those who enroll participants, assign interventions, or assess outcomes. Once a patient has been enrolled, the research assistant will log into the secured computer system (REDCap) and assign patients to group A or B. During placement of the distractor, the hand surgeon, operating room-assistant, and nurses will not know to which group the patient is randomized. Patients cannot be blinded. Radiographs will be scored by a blinded radiologist.

Sample size calculation

We aim to assess non-inferiority of six weeks distraction compared to eight weeks measured by PROMIS UE scores. We performed a sample size calculation based on the minimal clinically important difference (MCID) of the PROMIS UE questionnaire. The MCID is the smallest difference that patients perceive as beneficial. Previous studies report a MCID of 9.0 points for PROMIS UE with a standard deviation of 11.³² Non-inferiority will be considered if the mean difference with 95% confidence interval (95% CI) is no more than 9.0 points lower in the six-week group compared with the eight-week group. To detect non-inferiority with 90% power, and a one-sided confidence level set at 97.5%, and 5% estimated loss to follow-up, we aim to include 68 patients. Each month, it is estimated that four patients will be eligible and willing to participate, resulting in an inclusion time of two years.

Statistical analysis

The following characteristics will be reported in the baseline characteristics table: age, gender, work status, marital status, level of education, PROMIS UE scores, MHQ, PHQ-2, PCS-4, VAS for pain, satisfaction, thumb stiffness, thumb function, range of motion, strength, and joint space width on radiographs. Testing for differences in baseline characteristics among groups will only be done if visual inspection of the results indicates possible significant differences.

The primary outcome will be the difference in PROMIS UE score between the six-week group (A) and eight-week group (B) at one-year follow-up. We will report the mean with SD and 95% CI and the mean difference with 95% CI. If the mean difference with 95% CI falls within the predefined non-inferiority margin of 9.0 points of PROMIS UE scores, we will conclude non-inferiority.

Regarding the secondary hypotheses, we will test for superiority between the six-week and eight-week group:

- We will assess any differences between groups in MHQ scores, VAS pain, VAS satisfaction, VAS function, VAS stiffness, range of motion, and strength at one-year follow-up compared to baseline. We will test for superiority between groups by comparing the mean differences at one year.
- Treatment failure is scored when a patient proceeds with an invasive surgical procedure (e.g. trapeziectomy) after distraction therapy due to ongoing symptoms of CMC1 OA. We will analyze the difference between groups in the proportion of participants who are classed as treatment failure at one year.
- Adverse event rates will be reported and classified according to the Clavien-Dindo classification of surgical complications.³⁰ We will analyze the difference between groups in the proportion of participants who are classed as adverse event at one year.
- Joint space width at one-year follow-up is compared to baseline measures in both groups. Mean difference in mm between groups is assessed at one-year follow-up.

This will be intention-to-treat analyses. In case of nonadherence, to test the robustness of our results, we will also report the results of per-protocol analyses.³³ We will create two multivariable linear regression models to assess factors independently associated with PROMIS UE and MHQ scores at one year. In these models, we will include all mentioned study parameters (except PROMIS UE and MHQ scores) with $P < 0.10$ in bivariate analysis. P values < 0.05 are considered statistically significant.

We will perform the same statistical tests and analysis as mentioned above at two years and five years post-distraction to study the long-term results. Incomplete data will be adequately described. We will use multiple imputation for any missing data or means for missing values.

Withdrawal

Participants can leave the study at any time for any reason if they wish to do so, without any consequences. If a patient wishes to withdraw during the distractor period, the distractor can be removed in the outpatient clinic and standard treatment will continue. After removal of the distractor, a patient is also free to discontinue participation by refusing to complete questionnaires or follow-up imaging. We do not anticipate any circumstance in which the investigator would recommend the patient withdraws from the study since the potential risks and complications expected are limited and not life-threatening or harmful (see section 'Potential benefits and risks assessment').

Data management, monitoring, and publication

Data will be handled confidentially. Data will be administered on an encrypted computer in REDCap: a secured electronic data capture tool for clinical research.⁵¹ Patient data will be anonymized. All included patients are identified by a patient identification number. A list of these numbers with name combinations will be securely stored by the coordinating investigator. The handling of personal data will be performed in compliance with the Dutch Personal Data Protection Act and in compliance with Good Clinical Practice guidelines. Data will be kept for 15 years after the end of the study. Written informed consent from study participants will securely locked away within the hospital.

This study will be monitored by a certified monitor according to the St. Antonius Hospital and Medical Research Ethics Committees United (MEC-U) monitoring policy. Insurance is provided for all participants in accordance with Dutch legislation. The results of this study will be published in peer-reviewed journals and presented at (inter) national conferences. Any protocol amendments will be submitted at the MEC-U for approval and relevant parties, including participants, will be informed if needed.

DISCUSSION

Joint distraction is a fairly new treatment for patients with CMC1 OA.¹⁹ To our knowledge, to date, 52 patients have been treated with joint distraction. In contrast to other joint distraction treatments, CMC1 distraction is not offered in regular clinical practice yet, only in study context. Distraction therapy can result in less pain and better physical function and can therefore postpone an invasive surgical intervention.^{12-16,18} In a previous study about CMC1 joint distraction, a surgical intervention was postponed for at least two years in most (19 of 20) patients (unpublished data).

This trial will test if we can decrease the current distraction duration from eight to six weeks and still achieve sufficient clinical benefits for patients. For knee distraction, a decreased treatment duration of six weeks (instead of eight weeks) resulted in less pin tract infections while good clinical results were still achieved.^{17,18} Therefore, knee distraction is nowadays applied for six weeks. It is unknown if six weeks of continuous CMC1 joint distraction, compared with eight weeks, leads to similar results: less adverse events and sufficient clinical benefits (e.g. less pain and better physical function). The outcomes of this study will give a more decisive answer to this question. If safe, the duration of basal thumb joint distraction can be reduced to six weeks, reducing patient burden.

This study will also enable to assess the short-term and long-term effects of joint distraction in 68 patients. We expect that joint distraction will lead to less pain and better physical function in patients on average, regardless of group. Because this is a relatively new treatment, this trial will provide greater knowledge of potential adverse events. This knowledge allows for more informed decision making for patients considering CMC1 distraction treatment and will help to better define the place of joint distraction in treatment of CMC1 OA.

It is not feasible to blind participants to wearing a distractor for six or eight weeks. Due to logistical constraints, we are also unable to blind surgeons and hand therapists. The lack of blinding might influence our results, but is common in trials assessing a surgical intervention. Besides, we realize the need for additional studies to compare joint distraction with other operative and nonoperative techniques. However, we first designed this study to explore the possibilities to decrease distraction duration and bring CMC1 joint distraction, in this regard, in line with other joint distraction techniques. Based on the results of this current study, we will conduct a next comparative study to achieve a better understanding of the effects and benefits of joint distraction directly compared to other techniques (like splinting or trapeziectomy) in the treatment of CMC1 OA.

This study will mainly focus on clinical and patient-reported outcomes. We realize that there is also a need to gain more knowledge about the working mechanism of joint distraction. Future studies can contribute to a better understanding of this mechanism by – for example – focusing on arthroscopic sampling of articular cartilage, detailed imaging techniques, or biochemical analysis of synovial fluids.

There is major evidence that psychosocial factors – such as catastrophic thinking and symptoms of depression and anxiety – account for more of the variation in CMC1 OA symptom intensity than measure of pathophysiology.^{20,21,34} To study differences in the magnitude of psychosocial factors before and after CMC1 joint distraction, this study, we will measure symptoms of pain catastrophizing and of depression with two short questionnaires (PHQ-2 and PCS-4).^{27,28} This could lead to a better understanding of the impact of psychosocial factors on physical function and other outcomes after CMC1 joint distraction therapy. Future studies can focus on exploring other/additional treatment opportunities for patients with CMC1 OA to optimize care (e.g. more effective coping strategies). This could result in a more multidisciplinary approach in treatment of CMC1 OA.

Trial Status

This study was registered at the CCMO (Central Committee on Research Involving Human Subjects) in the Netherlands on 9 August 2019 (NL68225.100.18), at the Medical Research Ethics Committees United (MEC-U) on 9 August 2019 (R19.003), and registered with the Netherlands Trial Register (registration number NL8016) on 15 September 2019. This manuscript is based on research protocol version number 3.0, dated 24 July 2019. Recruitment started at the St. Antonius Hospital, the Netherlands on 5 December 2019. The approximate date on which recruitment will be completed, is 31 December 2021.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-021-05283-9>.

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APPENDICES

Appendix 1. Hand therapy protocol after CMC1 joint distraction.

After distractor removal (six (group A) or eight (group B) weeks after surgery):

- Start with motion exercises:
 - Active thumb opposition
 - Active thumb palmar abduction
 - Active thumb extension
 - No weight bearing exercises with thumb and index finger yet.
- Advice for daily activities:
 - Only use thumb for light activities, no heavy lifting yet.
 - Driving a car is allowed if a patient feels safe to do so.
- Follow-up appointments are scheduled depending on thumb stiffness, pain and patient preference.
 - If the thumb is very stiff and painful: weekly visits are scheduled.
 - Otherwise the next visit is scheduled after two weeks and every other week thereafter.

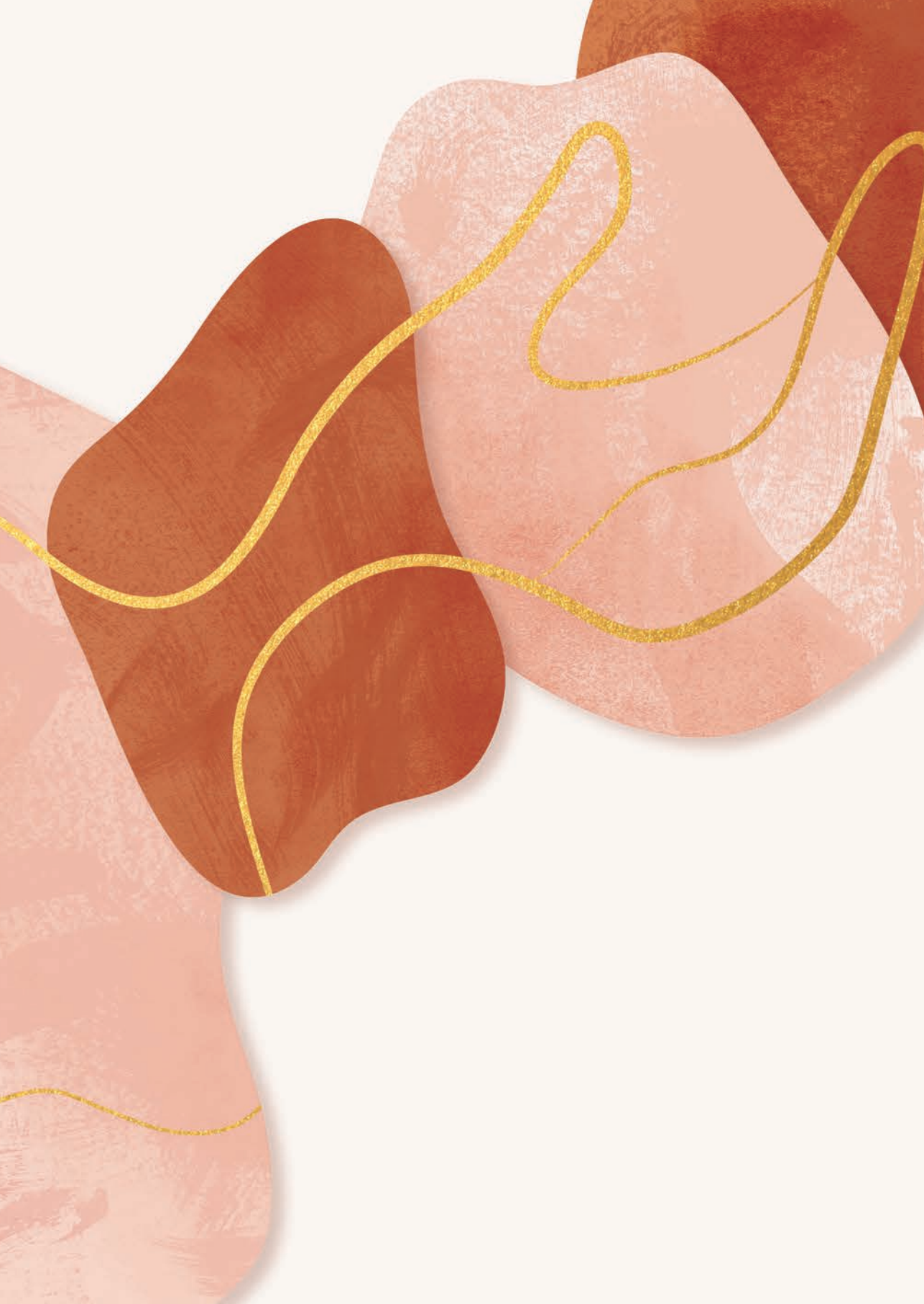
Two weeks after removal of distractor (eight (group A) or ten (group B) weeks after surgery):

- Continue motion exercises, expand if possible.
- Advice for daily activities:
 - Use thumb for moderate activities, no heavy lifting yet.
 - Riding a bike is allowed if a patient feels safe to do so.

Three months after placement of distractor:

- Advice for daily activities:
 - All activities are allowed, including lifting.









Discussion



The practice of medicine is shifting from a paternalistic model towards an active collaboration between patients and physicians. The doctor no longer decides on treatment alone. Instead, the doctor offers, and the patient chooses the preferred treatment. Together they decide on the best course of action. In order to come to a shared decision, patients and doctors need to understand each other's biases, considerations, expectations and preferences. The first and second part of this thesis explores these themes regarding thumb base osteoarthritis. In the third part we focus on the outcomes of surgical treatment of thumb base osteoarthritis by pyrocarbon disc and joint distraction.

PART ONE | PATIENT'S PERSPECTIVE

Thumb base osteoarthritis can be perceived as part of normal human aging.^{1,2} The evidence is compelling that everyone will get osteoarthritis at the thumb base if we live long enough; it is not something some of us get and some of us do not.^{1,2} Studies to date emphasize the beneficial effects of engaging people in maintaining their health.^{3,4} Engagement, or self-management capability, emphasizes an active role in gathering information and making decisions about treatment options.⁵ Self-management can become counterproductive when the required knowledge comes from unreliable sources. The World Wide Web is a common source for people to obtain information about their diagnosis, treatment options and prognosis. To date the majority of people (about 70%) seeks information online about their condition before visiting a doctor.⁶ There is concern that most medical websites, including those on osteoarthritis, are non-peer reviewed personal opinions and of poor quality.⁷⁻¹⁰ Still, nine out of ten people perceive health care related websites as a reliable source.¹¹ This biased information consciously or subconsciously influences people's treatment decisions. Chen *et al.* showed that if people seek more advice online about their medical condition, their treatment preference is more often based on the online information obtained.¹²

In the first study of this thesis (**Chapter 1**), we determined the quality of website information on thumb base osteoarthritis. We assessed the quality and readability of the top 67 websites available via Google, Yahoo!, and Bing on thumb base osteoarthritis and assessed factors associated with greater quality. We found that quality on average was 'fair' but the information was often hard to read: all but one website exceeded the recommended sixth-grade reading level. It is important to keep in mind that around 15% of the people is at or below this particular level.^{13,14} Not-for-profit websites, those with Health On the Net (HON) certification, and websites without a clear preference for one type of treatment were associated with better quality. This is in line with other studies that report poor readability and low quality of online information on osteoarthritis.⁷⁻¹⁰

Asking people to notice HON certification before they read a website is probably not feasible. Most website users do not pay any attention to the origin or reliability of health information they obtain this way.^{15,16} Instead of turning people away from the internet, it may be more effective to pro-actively direct people to available, reliable, peer-reviewed material about their health condition. This should be done preferably before their visit, as this can help people to feel more knowledgeable and at ease to discuss treatment options with their physician. These materials – for example a web application or short video with reliable information about a health condition – can be combined with decision aids (tools to enhance shared decision making).¹⁷ This combination could establish a more realistic mindset about the etiology of thumb base osteoarthritis (it is part of human aging) and optimally enhance one's self-management skills (how to adapt to this condition). A Cochrane review encourages the use of decision aids as it increases peoples knowledge about a medical condition, awareness of their personal values, and participation in the decision-making process.¹⁸ Further implementation of decision aids in surgical health care can contribute to shared and well-considered treatment decisions.¹⁹ While we develop reliable digital information for patients, surgeons should be ready to gently correct known misconceptions caused, in part, by material found on the internet. For example, by asking which information people derived online and how this changed their preferences.¹²

In **Chapter 2** of this thesis, we further explored people's implicit and explicit preferences. One of medicine's main goals is the relief of suffering.²⁰ Sometimes the desired path of physicians and patients to obtain this goal do not align. For example, when a clinician encounters a patient who seem to prefer more testing or invasive treatments than expertise support.^{21,22} Satisfying the patient could actually go against the golden rule of medicine to "do no harm", as unnecessary testing risks false positive and false negative findings and unnecessary surgery can result in a long recovery and potential complications. However, not assenting a patient's preference for more testing or invasive treatment, may risk a dissatisfied patient. Patient satisfaction has become an important metric in health care. Some insurance programs are even considering tying satisfaction to reimbursement, making satisfaction ratings part of the pay-for-performance health care system.²³ Additionally, online satisfaction ratings of physicians have become readily accessible.^{23,24} Because of this, clinicians may feel pressured towards treating patients according to a patient's expectation or preference. It can be challenging not to agree with surgery or an injection if that is the intervention a patient explicitly desires, whether this is an appropriate treatment or not.

We aimed to determine if patients unconsciously associate suggestions for invasive treatments with better care. We created an Implicit Association Test (IAT) to evaluate implicit preferences toward invasive treatment (surgery, injection) or expertise support (reassurance, education). This test was specifically developed for this study using free software from Maede AW. Other IATs have been validated in numerous studies.^{25,26} Interestingly, we found that patients had a slight implicit (not expressed) association of good care with supportive care but an explicit (expressed) preference for physical treatment. Men had a greater expressed preference for physical treatment than women. Our data suggests that many patients with upper or lower extremity symptoms explicitly prefer surgery over a nonsurgical approach. This could be problematic because many upper extremity conditions are managed - at least initially - nonoperatively. For thumb base osteoarthritis the usual first step is a splint and a quick "surgical fix" unfortunately does not exist. More invasive treatments are debatable as corticosteroid injections do not outperform placebo and there is little consensus about which surgical technique to perform.²⁷⁻²⁹

Our results also show that patients implicitly associate supportive treatment with good care. This indicates that people are likely receptive to supportive treatment (education, self-management, reassurance). If physicians would be able to tap into these implicit associations, they can provide good care while limiting testing and treatment and without dissatisfying the patient. This requires effective communication strategies and a comfortable trusting patient-physician relationship to discuss other aspects of care than physical treatment alone. A decision aid can help patients to select a treatment that aligns with their implicit preferences – in other words making their implicit preferences explicit.^{17,19} Probably because decision aids provide understandable, balanced information about the expected outcomes that patients can work through at their own pace. When patients are fully informed about the available treatment options and potential outcome, the choice for nonoperative and less invasive techniques increases.¹⁹ Moreover, the discrepancy between what patients prefer and what doctors think they prefer is reduced, decreasing the risk of misinterpreting patient's preferences and values.^{19,30} This better ensures that a choice for surgery is in line with a person's values and not driven by the expectation of a surgical "quick fix" for a long-term condition like thumb base osteoarthritis.

In conclusion, information found on the World Wide Web for thumb base osteoarthritis is often biased and is likely to increase misconceptions about the nature, etiology and a surgical "quick fix" for something that seems part of normal human aging. Instead of wrongly suggesting that thumb base osteoarthritis is something that some of us get and some of us do not, it is probably better to emphasize that we will all get it one way

or the other if we live long enough.^{1,2} In other words, education is a core treatment and first step in the management of thumb base osteoarthritis. Clinicians should prepare to address existing misconceptions established by prior information obtained. This helps making implicit preference for supportive care explicit. We expect this will increase patient satisfaction with splinting and watchful waiting, the initial and most common treatment for people with thumb base osteoarthritis.

PART TWO | SURGEON'S PERSPECTIVE

There is substantial surgeon-to-surgeon variation in treatment of CMC1 osteoarthritis.^{28,31,32} Studies suggest that treatment type depends as much on a person's zip code as on his or her medical problem.³³ This treatment variation is unwarranted as it implies that many people are either overtreated or undertreated. Reducing practice variation may reduce unnecessary health care spending and improve treatment quality in the case of over- or undertreatment.

In **Chapter 3** we aimed to gain more insight into treatment variation by assessing the prevalence of, and factors associated with radiographs and intra-articular injections for CMC1 osteoarthritis. Among the 2961 patients identified in a national insurance claims database covering the entire United States and with codes of a new visit, we found a high prevalence of radiographs obtained (52%) and intra-articular injections performed (26%). Women were more likely than men to receive an injection and patients from the southern parts of the United States had higher rates of radiographs. This variation emphasizes the idea that testing and treatment decision may depend on the surgical office that people visit.

Before we expand on practice variation, we question the use of radiographs and intra-articular injections in the management of CMC1 osteoarthritis. Radiographs seem not particularly helpful in the treatment-decision making process or during follow-up. Current best evidence shows no correlation between symptoms and radiographic severity of thumb base osteoarthritis.² The high prevalence of CMC1 osteoarthritis, characteristic symptoms (pain at the thumb-base) and signs (positive grind and shear test) makes diagnosis reliable and accurate without radiographs.^{34,35} Injections cannot cure the problem as there is still no disease modifying treatment for CMC1 osteoarthritis.²⁷ Two systematic reviews show that both glucocorticoids and hyaluronic acids injections do not surpass placebo injections with respect to improvement in pain intensity and physical incapability.^{36,37} Some studies suggest that corticosteroid injections can even be detrimental to articular cartilage and have the potential harm of skin-related

adverse events.³⁸⁻⁴⁰ Taking this into account, the high prevalence of radiographs and injections we found in **Chapter 3** suggests that surgeons overemphasize radiographic findings and the efficacy of injections. In order to reduce practice variation, we need to understand why clinicians persist in these non-evidence-based practices. It perhaps relates to the, in **Part 1** identified, explicit patient preference for physical care. Surgeons may consider they fulfill the patient's wish for physical treatment when they offer an injection. It is important to keep in mind that this could actually be harmful: injections for CMC1 osteoarthritis do not add any value but can lead to complications.

In order to reduce unwarranted practice variation, we need to have a better understanding of what is actually driving it. In **Chapter 4** we therefore created 16 unique vignettes of people with CMC1 osteoarthritis and varying characteristics. A total of 126 hand surgeons were asked to decide if they would recommend surgery for each person or not. We found that substantial pain (a subjective measure), a previous injection that did not relieve pain (injection might not surpass placebo), radiographs of severe CMC1 osteoarthritis (radiographic severity does not correlate with symptoms), and fewer symptoms of depression were associated with a greater likelihood of recommending surgery. In other words, at least in clinical vignettes, surgeons seem to base their recommendation for surgery mainly on subjective and unreliable measures. This is something both physicians and patients need to be aware of. As a result, most of the times surgeons do not agree on the indication for surgery, reflected by a kappa of 0.22 (95%CI 0.11 to 0.33) in our study. Moreover, it is notable that trapeziectomy with LRTI was the most commonly recommended treatment ($n = 89$; 72%), although systematic reviews from 2005 and onwards show that adding LRTI to simple trapeziectomy adds complications and delays recovery.^{28,41} It remains unclear, and future studies should assess this trend, why most surgeons prefer some form of a suspensionplasty even though the current evidence does not support this. Surgeons seem to have the perception that adding a stabilization or interposition technique provides advantages over trapeziectomy alone. These advantages may include less subsidence of the first metacarpal on the scaphoid, preservation of thumb height, increased stability and better outcomes on the long-term. However, there seems no relationship between ligament reconstruction and limitation of radiographic subsidence.⁴² Moreover, most (but not all⁴³) studies, found no association between metacarpal subsidence and symptoms.⁴⁴⁻⁴⁶

In case of inconclusive evidence, as it is for CMC1 osteoarthritis, surgeons base their treatment decision mainly on their own perspective and beliefs.⁴⁷ As a result, surgeons often do not agree with each other on the indication for surgery and preferred surgical techniques. Instead of incorporating our own surgical biases, we might be able to

reduce practice variation through shared decision making and decision aids.^{17,18} Both help to elicit people's preferences, which ensures that the treatment choice reflects personal values and is not based on misconceptions.

Chapter 5 focused on surgeons' attitude towards the psychosocial aspects of CMC1 osteoarthritis. There is notable evidence that symptoms of anxiety and depression increase the intensity of symptoms among people.⁴⁸⁻⁵⁰ Resiliency, self-efficacy and effective coping strategies are one of the most effective alleviants for pain and disability but not all surgeons may be familiar with this line of evidence and it may be unpopular topics to discuss for surgeons. It may seem easier to offer a surgical solution to people seeking specialty care than to discuss emotional aspects of illness. To test these assumptions, we assessed surgeon willingness to offer psychological interventions for CMC1 osteoarthritis as presented in **Chapter 5**. Interestingly, most surgeons were willing to offer a workbook (92%) or psychologist referral (84%). Among the few surgeons declining to refer, their reasoning was 'it would not be of any help' and 'stigmatization'. Surgeons seem aware of the importance of psychological influence and, in contrast with other studies⁵¹⁻⁵³, willing to refer if someone is interested and if psychological care is readily available in their office. This suggests it could be worth the effort to increase the availability of mental health support in surgeon's offices. This in turn could help people to better adapt, instead of depending on a surgical quick fix that may or may not work.

We have shown that people actually implicitly associate good care with supportive care, and that surgeons are biased to offer surgical care based on personal preference and subjective factors – and that they disagree about who to offer surgery. Offering injections and radiographs does not add much value in treatment of CMC1 osteoarthritis and may inhibit people from building resilience in the face of common age-related changes. Many surgeons are nowadays aware of this too, and are also willing to make use of mental health support if this is available and people are interested. We hope this information may help to shift the biomedical paradigm of CMC1 osteoarthritis treatment (consisting of radiographs, injections and surgery) to a biopsychosocial paradigm that also includes addressing mental health opportunities related to CMC1 osteoarthritis.

PART THREE | SURGICAL INTERVENTIONS FOR THUMB CARPOMETACARPAL OSTEOARTHRITIS

In the third part of the thesis, we focus on outcomes of surgical treatment for thumb base osteoarthritis. There are numerous surgical procedures for the CMC1 joint including partial or total trapeziectomy, multiple suspension and interposition techniques, joint replacement, or arthrodesis. First, it is important to mention that only a small number of people with CMC1 osteoarthritis are asking for surgery.^{17,48,54} Based on the high prevalence of CMC1 osteoarthritis, it seems likely that most people (up to 96%) with radiographic CMC1 osteoarthritis are asymptomatic and eventually will never seek medical care.^{1,55} Only a subset of people brings their problem to the attention of a doctor. Of those seeking care, the majority (up to 85%) is satisfied with supportive treatment including hand therapy, splint or medication to relieve pain.^{54,56} However, if one cannot adapt to this condition and is unsatisfied with the offered nonoperative care, surgical treatment can be considered.^{57,58}

Pyrocarbon disc arthroplasty

In **Chapter 6** we analyzed a retrospective cohort of 164 thumbs in 137 people with CMC1 osteoarthritis who had a pyrocarbon disc interposition arthroplasty. People were assessed at a minimum of five years after surgery (median 7.2 years, range 5 to 11). Sixteen of 164 discs (10%) were removed, mostly due to ongoing pain ($n = 6$) or newly developed STT osteoarthritis ($n = 7$). Kaplan-Meier curve showed an implant survival rate of 91%. Implant survival in our study is comparable to others who report implant survival rates of 94% at five years and 90% at eight years after placement.^{59,60} Median satisfaction score after disc interposition was nine points on a 0 to 10 scale (IQR 7 to 10). Key, tip and pinch strength were comparable to the contralateral hand with excellent thumb opposition.

A prospective study on pyrocarbon discs among 43 people shows that hand function, pain intensity and thumb opposition all improved at one year after surgery.⁵⁹ Over the next nine years this improvement was maintained. Three of 43 patients (7%) had revision surgery: this is similar to our results. It is important to keep in mind that no study so far had included a control group, and improvement after surgery could be explained by non-specific effects, such as regression to the mean, self-limiting course, and the placebo effect.^{61,62} There are only a few studies comparing pyrocarbon interposition arthroplasty with the more popular alternatives such as trapeziectomy with or without suspensionplasty. Oh *et al.* retrospectively compared 20 patients after pyrocarbon disc arthroplasty with 19 patients having trapeziectomy and LRTI at a minimum of two years after surgery.⁶³ There was no difference between groups

regarding hand function, pain intensity, range of motion or complications. Patients with a pyrocarbon disc had greater improvement of pinch strength (mean 6.6 kg (SD 2.6) to 10.7 kg (SD 1.7)) compared to those after trapeziectomy with LRTI (mean 6.7 kg (SD 1.7) to 8.9kg (SD 1.1)) – but it is unclear if this mean difference of 1.8 kg is clinically relevant and this was a trial without randomization.

A potential advantage of the pyrocarbon disc interposition is the preservation of thumb height. Thumb height is often determined by relating the height of the trapezial space to the length of the first metacarpal or proximal phalanx height.⁶⁴ There is some recent evidence that preservation of thumb height after pyrocarbon disc arthroplasty may lead to better key pinch strength.⁶⁵ This is in line with a previous study that showed a relationship between thumb height loss and less key pinch strength.⁶⁶ Other higher quality studies have shown that thumb height maintenance has no correlation with clinical outcome including pain intensity or thumb pinch strength.^{45,46,64,67} The exact correlation between thumb height maintenance, better strength and improved patient reported outcomes remains therefore unclear and is something future studies should assess.

A potential disadvantage of pyrocarbon disc interposition is the risk of subluxation. Previous studies report rates of disc displacement between 11% and 21% but only two of 39 people in these series requested revision surgery, which suggests that subluxation does not need to be addressed in all cases.^{60,63} In **Chapter 7** we evaluated the effect of radiographic disc displacement on hand health status (MHQ scores) and other factors including pain intensity and thumb strength. We found that radiographic disc displacement occurred in 41% (n = 56) of the 136 people. Manual labor was the only factor associated with more severe disc displacement. It remains up for debate if increased pressure due to heavy occupational tasks causes severe displacement: this needs verification in future studies. However, it is an interesting finding since proponents claim that the pyrocarbon disc maintains adequate thumb strength and stability, especially in people with demanding occupational tasks. No relationship was found between disc position and other outcome variables including hand health status and pain intensity. It is remarkable that if implant dislocation occurs, most people do not experience pain or limitation in their daily activities. Some people might argue that the initial surgery denervates the joint⁶⁸, so implant dislocation does not cause pain. However, there is a growing body of evidence that symptom intensity is mostly related to mental and social health.^{49,57,69-71} In this light, one might consider that surgery for CMC1 osteoarthritis offers a rite of passage, more than a substantial change to pathophysiology, and allows people to come to terms and adapt to the aging of their hands.

Some proponents of the pyrocarbon disc arthroplasty suggest that it does not 'burn any bridges' because other surgical interventions, including a trapeziectomy, are still possible. There is little experimental evidence on the outcomes after revision surgery to support this statement. There are also no head-to-head randomized controlled trials supporting clinically relevant stronger key pinch after pyrocarbon disc arthroplasty compared to trapeziectomy, nor any randomized controlled studies that show improved patient reported outcome. The failure rate of 10% (16 of 164 thumbs) in our study seems higher than what can be expected. Unplanned re-operation rates for CMC1 arthroplasties, in general, vary between 1.5 to 4.0% and are usually performed within the first year after initial surgery because of ongoing pain.^{72,73} Revision rates of non-implant techniques for CMC1 osteoarthritis are overall lower than those of implant arthroplasties.⁷⁴ In light of higher costs and a higher failure rate, it is currently hard to justify the use of pyrocarbon interposition arthroplasty on a wide scale. Future studies of higher quality comparing pyrocarbon disc arthroplasty directly with trapeziectomy are needed to show the potential advantages of the pyrocarbon disc including thumb height preservation, better strength and faster return to work to defend the higher costs.

The future of CMC1 osteoarthritis management

The multitude of available surgeries to address CMC1 osteoarthritis suggests some dissatisfaction with the results and their predictability. About 15% of the people choosing surgery do not experience sufficient pain relief and some of them request a second operation.^{31,45,75} One out of five surgeons have changed their preferred procedure for CMC1 osteoarthritis over the last five years,³² which suggests that surgeons may not be completely satisfied with the results of operative treatment. Generally speaking, we can define two ways to approach this problem. Some explore new avenues of invasive treatment, such as intra-articular injection of autologous fat (liparthroplasty),^{76,77} arthroscopic debridement or synovectomy only,^{78,79} or joint distraction. Others move away from invasive procedures and focus on adaptation and resilience, while waiting for the natural history and regression to the mean to reduce symptoms.^{22,80} This notion is supported by the substantial variation in offers of operative treatment as found in **Chapter 4** and by another study that showed a seven-fold variation in the rate of surgery between seven hand surgeons.⁸¹

Innovative and joint preserving surgery

One of the innovative treatments is distraction of the CMC1 joint: a joint preserving technique with the promise to delay or prevent more invasive surgical procedures for patients with CMC1 osteoarthritis seeking care. The concept of joint preservation is appealing. A recent study on knee joint distraction reports structural long-term benefits

with cartilage repair and increased cartilage thickness on MRI, up to ten years post-treatment.⁸² There is more experience with, and data available on knee joint distraction but it is important to realize that the CMC1 joint differs significantly from the knee. The basal thumb joint has a smaller joint space, is non-weight-bearing and has a unique saddle shape. We cannot extrapolate the beneficial results from knee joint distraction directly to the CMC1 joint. However, the first preliminary results of CMC1 joint distraction are promising. In **Chapter 8** we describe a cohort of 20 people in which one person elected trapeziectomy in the first two years after CMC1 joint distraction.

In joint distraction surgery, the two sides of a that joint are temporarily pulled apart over a short distance by an external fixator (Chapter 8 and 9). Theoretically it is expected to reduce mechanical stress on the cartilage and allows chondrocytes to initiate repair.⁸⁵ However, the real effects remain speculative. An animal study demonstrated that joint distraction reduces the level of secondary inflammation and cartilage degeneration by decreasing serum levels of interleukin-1b⁸⁴, which is associated with osteoarthritis.⁸⁵ Another study on knee joint distraction supports this molecular change in synovial fluids as a strategy for slowing down the progression of osteoarthritis.⁸⁶ They report increased levels of several biomarkers including interleukin-8, which they associated with greater improvement in patient reported outcomes after 12 months. On the other hand, there is evidence that *collagen type-II* is one of the components that can explain repair of cartilage over time.^{82,87} After distraction of the osteoarthritic knee joint, synovial fluid analysis showed an increased ratio of *collagen type-II* synthesis over breakdown, which suggests formation of hyaline cartilage.⁸⁸

To determine the clinical value of joint distraction for the treatment of CMC1 osteoarthritis, we need to study its effects on patient reported outcomes, adverse events, revision rates, and cost effectiveness. Improved imaging techniques will help to reliably assess CMC1 cartilage quality after joint distraction. We aim to assess this in our next study as presented in **Chapter 9**. We will determine if six weeks of continuous joint distraction is sufficient to maintain the improvement in physical function and pain. If proven to be safe, the duration of CMC1 distraction can be reduced to six weeks, thereby reducing the burden to patients. This trial will also provide greater knowledge of potential adverse events. This allows for more informed decision making for patients considering experimental CMC1 distraction treatment.

Adaptation and resilience instead of surgery

The main symptom of CMC1 osteoarthritis is pain at the base of the thumb. Subjective outcomes are always improved by non-specific effects (regression to the mean⁶¹, self-limiting course⁸⁹, and the placebo effect⁶²). To our knowledge there are no placebo

studies available showing that CMC1 surgery alleviates symptoms better than surgery that simulates treatment of pathology. For other musculoskeletal conditions, including knee osteoarthritis^{90,91}, high quality evidence demonstrated that sham surgery was just as effective as actual surgery in all six included trials to reduce pain intensity and physical capability.⁹² Another review comparing actual surgery with sham surgery among variable diagnoses found that 51% of the trials showed better or similar results in the sham surgery group.⁶² Most people eventually will adapt and do not seek medical care for their CMC1 osteoarthritis. Symptom intensity is mostly related to mental and social health, not pathophysiology.^{48-50,93,94} This suggests that strategies to address unhelpful thoughts and distress might be effective at reducing symptom intensity and offer an alternative to surgical treatment. There is growing evidence that psychosocial interventions are efficacious for several musculoskeletal changes, like low back pain and knee osteoarthritis.⁹⁵⁻⁹⁸ Perhaps interventions like cognitive behavioral therapy, or even just addressing general mental health can play a role in future multidisciplinary care strategies for management of CMC1 osteoarthritis.⁹⁹

CONCLUSION

The best treatment for CMC1 osteoarthritis is still open for debate but unbiased education and understandable information seems to be a crucial first step. People need to be informed about the natural history of CMC1 osteoarthritis, the available treatment options and expected outcomes. We encourage further study and implementation of decision aids - or other informative web applications - in surgical health care to stimulate the shared decision making process. This may contribute to treatment decisions that are based on a person's values and not driven by surgeon's preferences or the misconception of a surgical "quick fix". Surgeons often disagree about the indication for CMC1 osteoarthritis surgery and mainly base their treatment decision on subjective factors. However, most surgeons seem willing to discuss psychological opportunities if mental health expertise is available. We hope this information helps shift CMC1 osteoarthritis treatment consisting of radiographs, injections and surgery to a more biopsychosocial paradigm that also includes addressing mental health opportunities related to CMC1 osteoarthritis. We envision two future strategies to address CMC1 osteoarthritis. At first, novel surgical techniques, such as joint distraction, might outperform regression to the mean, the natural history and the placebo effect, although this remains to be seen. Alternatively, empathy, gentle reorientation of negative thoughts and awareness of distress and anxiety may build resilience and offer a valid alternative to surgery.

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Summary



The first carpometacarpal (CMC1) joint is formed by the articulation of two bones: the first metacarpal bone and the trapezium (Figure 1). It is a unique joint because of its saddle shapes that provide a wide range of motion while being able to sustain heavy forces during pinch and grip strength. Current evidence shows that osteoarthritis of the CMC1 joint is an expected part of human aging: everyone gets it if we live long enough. Symptoms vary greatly among people and most people adapt to it without seeking medical help. Pain at the base of the thumb from CMC1 osteoarthritis is a common reason for people to consult their doctor. Thumb pain can cause reduced pinch strength and impaired hand capability such as difficulty opening jars or turning a key. Symptom intensity does not correlate with the severity of CMC1 osteoarthritis on radiographs. This supports adaptation as the primary aim of care with the help of splinting and analgesics. Notwithstanding, numerous surgical options are available but there is no consensus about which surgical treatment is most effective. The aim of this thesis was to explore patients' and surgeons' perspectives on CMC1 osteoarthritis, and discuss outcomes of surgical treatment by pyrocarbon disc and joint distraction.

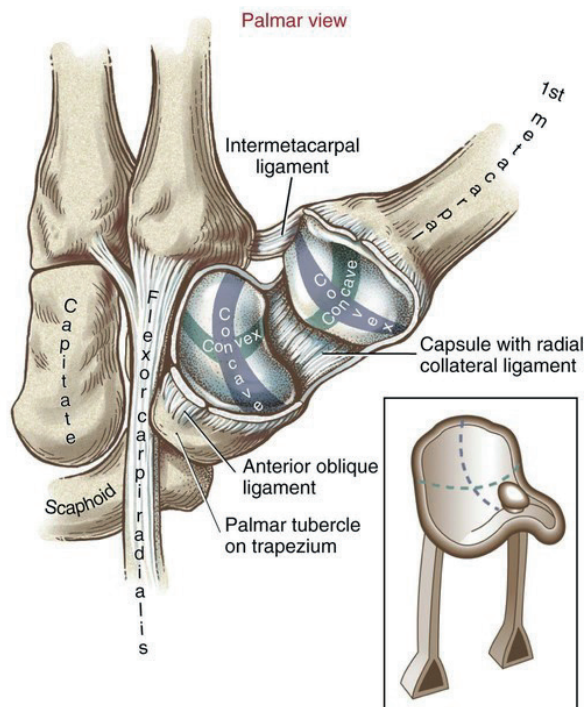


Figure 1. The carpometacarpal of the right thumb is opened to expose the saddle shape of the joint. Reprinted from *Essentials of Kinesiology for the Physical Therapist Assistant*, Third Edition, P.J. Mansfield and D.A. Neumann, Chapter 7: Structure and Function of the Hand, 2019, with permission from Elsevier.

PART ONE | PATIENT'S PERSPECTIVE

Many people misperceive symptomatic CMC1 osteoarthritis as an acute problem or injury. These misconceptions may – in part – be established by information that people read online before visiting a doctor. There is concern that medical websites are biased and of poor quality. Still nine out of ten people believe the online medical information they read, is reliable. We determined factors associated with the quality and content of 67 websites on CMC1 osteoarthritis. We found that online information is often difficult to read and biased in favor of a particular treatment. Taking into account that 70% of all people search for information online before visiting a doctor, it is likely that the lack of high quality and reliable information can contribute to misconceptions about the nature, etiology and treatment options for CMC1 osteoarthritis. This suggests that it will help clinicians to be prepared to gently reorient any misconceptions about the etiology of CMC1 osteoarthritis (it is part of human aging) and that a surgical quick fix does not exist.

The initial and most common treatment for CMC1 osteoarthritis is adaptation assisted by splinting and analgesics. Some people may be disappointed if advice and reassurance alone are offered by the doctor instead of surgical or physical treatment. In other words, people may implicitly associate more invasive care (surgery or injection) with better quality care. We aimed to determine whether people unconsciously associate suggestions for invasive treatments (injection, surgery) with better care compared to expertise support (reassurance, self-management, education). We used a specifically developed Implicit Association Test to explore people's implicit (non-expressed) and explicit (expressed) preferences. We found that patients had a slight implicit (not expressed) association of good care with supportive care but an explicit (expressed) preference for physical treatment.

Our data suggest that many patients with upper or lower extremity symptoms explicitly prefer surgery over a nonsurgical approach. But our data also indicates that people are likely to be receptive to supportive treatment. If physicians would be able to tap into these implicit associations, they can provide good care while limiting testing and treatment and without dissatisfying the patient. A decision aid (a tool to enhance shared decision making) may help patients to select a treatment that aligns with their implicit preferences – in other words making their implicit preferences explicit.

PART TWO | SURGEON'S PERSPECTIVE

There is substantial surgeon-to-surgeon variation in treatment of CMC1 osteoarthritis. This treatment variation is unwarranted as it implies that many people are either overtreated or undertreated. We aimed to gain more insight into treatment variation by assessing the prevalence of, and factors associated with radiographs and intra-articular injections for CMC1 osteoarthritis. Among 2961 patients identified in an insurance claims database covering the United States, we found a high prevalence of radiographs obtained (52%) and intra-articular injections performed (26%). Women were more likely than men to receive an injection and people from the southern parts of the United States had higher rates of radiographs. This variation emphasizes the idea that testing and treatment decision may depend on the surgical office that people visit.

In order to reduce unwarranted practice variation, we aimed to better understand what is actually driving it. We created 16 unique vignettes of people with CMC1 osteoarthritis and asked 126 hand surgeons if they would recommend surgery for each person or not. We found that substantial pain (a subjective measure), a previous injection that did not relieve pain (injection might not surpass placebo), radiographs of severe CMC1 osteoarthritis (radiographic severity does not correlate with symptoms), and fewer symptoms of depression were associated with a greater likelihood of recommending surgery. This suggests that, at least in clinical vignettes, surgeons base their recommendation for surgery mainly on subjective and unreliable measures. As a result, surgeons do not agree on the indication for surgery most of the times. This is something both physicians and patients need to be aware of. We might be able to reduce practice variation through shared decision making and decision aids. Both help to elicit people's preferences, which ensures that the treatment choice reflects personal values and is not based on misconceptions.

Most people with CMC1 osteoarthritis do not seek care. Some people experience pain and others, with the same pathophysiology, do not to the same extent. This is best explained through the bio-psycho-social model in which variation in symptom intensity is largely accounted for by variation in mental and social health. In this light, we assessed surgeons' willingness to offer psychological interventions for people with CMC1 osteoarthritis seeking specialty care. Surgeons seemed aware of the importance of psychological influence and willing to refer if someone is interested and if psychological care is readily available in their office. Among the few surgeons declining to refer, their reasoning was 'it would not be of any help' and 'stigmatization'. It could be worth the effort to increase the availability of mental health support in surgeon's offices. This could help people to better adapt to the situation, instead of placing their hope on having no pain by solving the problem with a surgical "fix".

PART THREE | SURGICAL INTERVENTIONS FOR THUMB CARPOMETACARPAL OSTEOARTHRITIS

There are numerous surgical procedures for CMC1 osteoarthritis including partial or total trapeziectomy, multiple suspension and interposition techniques, joint replacement, or arthrodesis. One of the options is a pyrocarbon disc interposition arthroplasty which is placed after partial trapeziectomy and fixated with a tendon strip. We assessed a total of 136 people (164 thumbs) after a median of 7.2 years (range 5 to 11) after pyrocarbon disc placement. Thirty-one of 136 people (23%) reported a present or prior manual labor occupation. Our data showed high patient satisfaction (score 9 out of 10). Thumb strength and motion were comparable to the contralateral hand. Sixteen of 164 discs (10%) were removed, mostly due to ongoing pain or progression of osteoarthritis involving the STT joint. Proponents argue that pyrocarbon disc interposition arthroplasty results in excellent patient satisfaction, good thumb strength and motion, and potential thumb height preservation. Although the ability to maintain the space between the base of the first metacarpal and the trapezium remnant, the relationship of this space to pain intensity and hand capability, is debated. Others emphasize the higher costs and a reoperation rate of 10%. Another potential disadvantage is the risk of disc subluxation. We evaluated the effect of radiographic disc displacement on hand health status (MHQ scores) and other factors including pain intensity and thumb strength. We found that radiographic disc displacement occurred in 56 of 136 people (41%). Manual labor was the only factor associated with more severe disc displacement. Future study can assess if increased pressure due to heavy occupational tasks causes severe displacement. No relationship was found between disc position and other outcome variables including hand health status and pain intensity. It is remarkable that if implant dislocation occurs, most people do not experience pain or limitation in their daily activities. It may in part be explained by the growing body of evidence that symptom intensity is mostly related to mental and social health rather than pathophysiology severity.

For people with CMC1 osteoarthritis who are dissatisfied with symptoms and desire a surgical intervention, techniques that preserve the joint may be an option. CMC1 distraction is a joint preserving technique with the aim to delay or prevent more invasive surgical procedures for people (generally before 65 years of age) with CMC1 osteoarthritis seeking care. The rationale for joint distraction is to temporarily unload the joint cartilage by eliminating contact between the joint surfaces. It can allow people to maintain their native joint which may hold appeal. A previous pilot study showed that distraction is technically feasible for the CMC1 joint. We determined if, two years after eight weeks of distraction, patients experienced better physical function and

less pain. Twenty patients with a median age of 54 years (range 41 to 64 years) and an established indication for invasive surgical intervention (e.g. trapeziectomy) were included. An external distractor device was placed over the CMC1 joint and left *in situ* for eight weeks. After two years, physical function and pain scores had improved significantly compared to baseline. Besides, 14 of 19 patients (74%) reached a minimal clinically important difference in hand health status (MHQ and DASH scores). One patient was not satisfied with treatment outcome and chose trapeziectomy 14 months after initial distraction therapy. In other words, application of CMC1 joint distraction was associated with a second surgery for arthroplasty among one of 20 people within two years. Larger comparative studies are needed to assess the value of joint distraction in the treatment of CMC1 osteoarthritis.

We will investigate whether we can decrease the duration of basal thumb joint distraction in a randomized controlled non-inferiority trial. Sixty-eight patients will be included and randomized to group A (six weeks) or group B (eight weeks of distraction). All patients are younger than 65 years and have an established indication for invasive surgery (e.g. trapeziectomy) because of ongoing symptoms of CMC1 osteoarthritis despite nonoperative care. The primary outcome is to assess whether six weeks is not inferior to eight weeks of joint distraction in terms of physical function at one year after surgery. Secondary outcomes will identify differences between groups at one year in pain intensity, patient satisfaction, hand health status, adverse event rates, treatment failure, differences in thumb strength and range of motion, and radiographic changes. If safe, the duration of basal thumb joint distraction can be reduced to six weeks, reducing patient burden. Because this is a relatively new treatment, this trial will provide greater knowledge of potential adverse events. This knowledge allows for more informed decision making for patients considering CMC1 distraction treatment.

CONCLUSIONS

1. Online information on CMC1 osteoarthritis is often difficult to read and biased in favor of a particular treatment. Clinicians should be prepared to gently reorient any misconceptions about the etiology (it is not an acute injury but part of human aging) and on the effectiveness of treatment options (adaptation is the foundation of healthcare, a surgical "quick fix" does not exist).
2. There is surgeon-to-surgeon variation in testing (obtaining radiographs) and treatment (injection and surgery) for CMC1 osteoarthritis. Surgeons seem to base their recommendations for operative treatment largely on subjective factors. Shared decision making and decision aids may help ensure that a treatment choice is not based on misconceptions or surgeon preferences, and instead reflects the personal values of the patient.
3. If implant displacement occurs after pyrocarbon disc interposition arthroplasty for CMC1 osteoarthritis, most people do not experience pain or limitation in their daily activities. Revision surgery is performed in about 1 out of 10 people mainly because of dissatisfaction with pain alleviation (which does not correspond with radiographic findings). Given this lack of correspondence, the role of the pyrocarbon interposition is open to debate, and revision surgery is not needed based on the radiographic findings alone.
4. Temporary joint distraction is a technically feasible treatment for people with CMC1 osteoarthritis. Application of this technique was associated with a second surgery for arthroplasty among one of 20 patients within two years. Larger, randomized, comparative studies are needed to be sure that this distraction alleviates symptoms better than simulated distraction and to assess the exact place of joint distraction in treatment of CMC1 osteoarthritis.



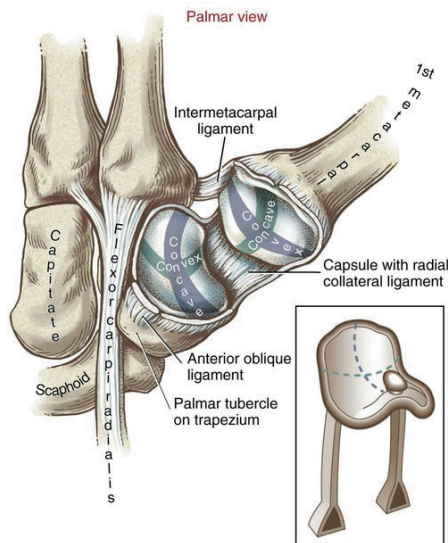
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Summary in Dutch

SAMENVATTING IN HET NEDERLANDS

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Het duimbasisgewricht wordt gevormd door het eerste middenhandsbeentje en het trapezium (Figuur 1). Het is een uniek zadelvormig gewricht wat naast een grote beweeglijkheid ook grote knijp- en grijpkrachten kan weerstaan. De huidige literatuur laat zien dat slijtage van het duimbasisgewricht hoort bij het normale verouderingsproces van de mens: iedereen krijgt duimbasisartrose als we maar lang genoeg leven. Klachten en beperkingen variëren erg per persoon: de meeste mensen passen zich aan en zoeken geen medische hulp. Anderzijds zien huisartsen geregeld mensen in verband met pijn aan de basis van de duim. Mensen met pijn aan hun duimbasis kunnen moeite ervaren met fijne motoriek en kracht zetten: het openen van potten of het omdraaien van een sleutel kan lastig zijn. De intensiteit van klachten en mate van beperking in het dagelijks leven door duimbasisartrose komen echter niet overeen met de mate van radiologische vastgestelde duimbasislijtage. Acceptatie en aanpassingen in het dagelijks leven zijn de belangrijkste behandeldoelen. Vaak is een operatie hiervoor niet nodig en kan dit met een spalk en pijnstilling worden bereikt. Desalniettemin zijn er tal van chirurgische opties beschikbaar, maar er is tot op heden geen consensus over welke chirurgische behandeling het meest effectief is. Het doel van dit proefschrift was om het perspectief van patiënten en chirurgen op duimbasisartrose te onderzoeken en de resultaten van huidige en nieuwe chirurgische behandelingen door middel van pyrocarbon disc en duimbasisdistractie te beschrijven.



Figuur 1. Het duimbasisgewricht van de rechter duim is geopend om de zadelvormen te laten zien. Met toestemming van Elsevier overgenomen uit: Essentials of Kinesiology for the Physical Therapist Assistant, Third Edition, P.J. Mansfield and D.A. Neumann, Chapter 7: Structure and Function of the Hand, 2019.

DEEL ÉÉN | HET PERSPECTIEF VAN DE PATIËNT

Veel mensen denken ten onrechte dat duimbasisartrose een acute aandoening is. Deze misvatting kan – voor een deel – ontstaan zijn door informatie die mensen op internet lezen voordat ze naar de dokter gaan. Er zijn zorgen over de matige kwaliteit en onbetrouwbaarheid van huidige medische websites. Negen op de tien mensen zijn er echter van overtuigd dat de online informatie die zij lezen betrouwbaar is. Wij onderzochten factoren die verband houden met de kwaliteit en inhoud van 67 websites over duimbasisartrose. We ontdekten dat medische websites over duimbasisartrose vaak moeilijk leesbaar zijn en een duidelijke voorkeur hebben voor één bepaalde behandeling. Aangezien 70% van alle mensen online naar informatie zoekt voordat ze naar de dokter gaan, is het aannemelijk dat onbetrouwbare online informatie kan bijdragen aan misvattingen over duimbasisartrose. Het zou kunnen helpen als artsen deze misvattingen bespreken, onwaarheden corrigeren (duimbasisartrose is geen acute aandoening maar hoort bij het ouder worden van de mens), en uitleggen dat er geen snelle chirurgische oplossing bestaat.

De eerste en meest gebruikelijke behandeling voor duimbasisartrose is aanpassing aan het verouderingsproces, eventueel met behulp van spalken en pijnstilling. Sommige mensen kunnen teleurgesteld zijn als de arts alleen advies en uitleg geeft en geen operatie of andere fysieke behandeling aanbiedt. Met andere woorden, mensen kunnen meer invasieve zorg (een operatie of injectie) impliciet associëren met kwalitatief betere zorg. Wij wilden toetsen of mensen suggesties voor invasieve behandelingen (een injectie of operatie) onbewust associëren met betere zorg in vergelijking met uitleg en geruststelling. We gebruikten een speciaal ontwikkelde test om de impliciete (niet-uitgesproken) en expliciete (uitgesproken) voorkeuren van mensen te toetsen. Onze resultaten toonden dat mensen een ondersteunende behandeling (geruststelling en advies) over het algemeen impliciet associëren met goede kwaliteit van zorg, maar dat zij een expliciete (uitgedrukte) voorkeur hebben voor een fysieke behandeling (injectie of operatie). Dit suggereert dat veel patiënten met symptomen van de bovenste extremiteit expliciet de voorkeur geven aan een operatie boven een niet-chirurgische behandeling. Maar onze gegevens geven ook aan dat mensen waarschijnlijk ontvankelijk zijn voor ondersteunende behandeling (geruststelling en advies). Als artsen in staat zijn om in te spelen op deze impliciete associaties en andere behandelingen dan een operatie of injectie bespreekbaar kunnen maken, zouden ze goede zorg kunnen bieden zonder onvrede te wekken bij patiënten. Een keuzehulp (interactief online hulpmiddel om gedeelde besluitvorming te bevorderen) kan patiënten helpen om een behandeling te kiezen die aansluit bij hun eigen (impliciete) voorkeur.

DEEL TWEE | HET PERSPECTIEF VAN DE CHIRURG

De behandeling van duimbasisartrose varieert aanzienlijk van chirurg tot chirurg. Deze variatie is onwenselijk omdat het impliceert dat veel mensen waarschijnlijk overbehandeld of onderbehandeld worden. Om meer inzicht te krijgen in de behandelvariatie van duimbasisartrose voerden we een database studie uit. Er werden 2961 patiënten geïnccludeerd vanuit een verzekeringsdatabase uit de Verenigde Staten. We vonden een hoge prevalentie van röntgenfoto's (52%) en intra-articulaire injecties (26%), uitgevoerd tijdens het eerste bezoek. Vrouwen kregen vaker een injectie dan mannen en mensen uit de zuidelijke Staten kregen vaker een röntgenfoto. Deze variatie bevestigt dat de diagnostiek en behandeling van duimbasisartrose wisselt per chirurg en met name afhangt van de voorkeur van de chirurg zelf.

Om onwenselijke behandelvariatie te verminderen, wilden we eerst meer inzicht krijgen in de factoren die deze variatie veroorzaken. We creëerden daarvoor 16 unieke vignettes van mensen met duimbasisartrose en vroegen 126 handchirurgen of ze een operatie voor elk persoon zouden aanbevelen of niet. Substantiële pijn (een subjectieve maatstaf), een eerdere injectie die de pijn niet verlichtte (injectie is niet beter dan placebo), röntgenfoto's van ernstige duimbasisartrose (radiologische ernst correleert niet met symptomen) en weinig symptomen van depressie, waren geassocieerd met een grotere kans op een operatie. Dit suggereert dat chirurgen hun aanbeveling voor een operatieve behandeling voornamelijk baseren op subjectieve factoren, in ieder geval in deze klinische vignettes. Als gevolg hiervan zijn chirurgen het meestal niet eens met elkaar over de indicatie voor een operatie. Dit is iets waar zowel artsen als patiënten zich bewust van moeten zijn. Mogelijk kunnen we praktijkvariatie verminderen door de patiënt actief te betrekken in de keuze voor behandeling, bijvoorbeeld door gedeelde besluitvorming of door het aanbieden van een interactieve keuzehulp. Dit kan ervoor zorgen dat de behandelkeuze beter gebaseerd is op de wens van de patiënt zelf, en niet op de voorkeuren van de chirurg of op misvattingen.

De meeste mensen met duimbasisartrose gaan hiervoor niet naar de dokter. Sommige mensen ervaren veel pijn, terwijl anderen met dezelfde gewrichtsslijtage deze klachten niet ervaren. Dit verschil kan het best worden verklaard vanuit het bio-psycho-sociale model waarin variatie in klachten grotendeels wordt toegeschreven aan variatie in mentale en sociale gezondheid. Vanuit dit oogpunt hebben we onderzoek gedaan naar de bereidheid van chirurgen om psychologische interventies aan te bieden aan mensen met duimbasisartrose. Wij ontdekten dat chirurgen zich bewust lijken te zijn van de belangrijke invloed van psychologische factoren op de klachten van duimbasisartrose. Chirurgen lijken ook bereid te zijn om iemand

door te verwijzen voor psychosociale ondersteuning, als iemand hier interesse in toont en deze psychosociale zorg direct beschikbaar is in de kliniek. Slechts een paar chirurgen wilden niemand verwijzen, meestal vanwege de reden dat 'het niets zou helpen' of vanwege 'stigmatisering'. Het zou de moeite waard kunnen zijn om de beschikbaarheid van psychosociale zorg in chirurgische klinieken uit te breiden. Dit zou mensen kunnen helpen om zich aan te passen aan hun duimbasisartrose in plaats van te hopen op een snelle chirurgische oplossing.

DEEL DRIE | CHIRURGISCHE INTERVENTIES VOOR DUIMBASISARTROSE

Er zijn talloze chirurgische ingrepen beschikbaar voor duimbasisartrose waaronder het gedeeltelijk of totaal verwijderen van het trapezium, meerdere peesinterposities en/of ophangplastieken, gewrichtsvervanging of gewrichtsartrodese. Eén van de opties is een interpositie met een pyrocarbon disc. Deze disc wordt geplaatst na een hemi-trapeziëctomie en vervolgens vastgezet met een peesstrip. We beoordeelden in totaal 136 mensen (164 duimen), gemiddeld 7.2 jaar (mediaan; variërend van 5 tot 11 jaar) na plaatsing van een pyrocarbon disc. Eén-en-dertig van de 136 mensen (23%) rapporteerden dat zij een fysiek belastend beroep voor de handen hadden. Onze data lieten een hoge patiënttevredenheid zien (score van 9 uit 10). De kracht en beweeglijkheid van de geopereerde duim waren vergelijkbaar met die van de contralaterale hand. Zestien van de 164 implantaten (10%) waren verwijderd, meestal vanwege aanhoudende pijnklachten of uitbreiding van de artrose. Enkele voordelen van de pyrocarbon disc interpositie zijn de uitstekende patiënt tevredenheid, de goede kracht en beweeglijkheid van de duim, en het potentiële voordeel van behoud van duimhoogte (alhoewel er controversie bestaat over de klinische relevantie van het behoud van duimhoogte in relatie tot minder pijn en een betere handfunctie). Nadelen van de pyrocarbon disc zijn met name de kosten en het re-operatie percentage van 10%. Een ander nadeel is het risico op (sub)luxatie van de disc. We beoordeelden de mate van dislocatie op röntgenfoto's en evalueerden het effect hiervan op onder andere handfunctie (MHQ scores), pijnintensiteit en kracht. Radiologische dislocatie van de pyrocarbon disc trad op in 56 van de 136 mensen (41%). Zware handarbeid was de enige factor die verband hield met de ernst van de dislocatie. Verder onderzoek kan uitwijzen of zware handarbeid inderdaad luxatie kan veroorzaken. Er werd geen verband gevonden tussen de positie van de disc en andere uitkomstmaten, waaronder de handfunctie en pijnintensiteit. Het is opmerkelijk dat de meeste mensen geen pijn of beperking ervaren in hun dagelijkse activiteiten als er (sub)luxatie van de pyrocarbon disc optreedt. Dit ondersteunt het

bio-psycho-sociale verklaringsmodel dat de intensiteit van klachten niet zozeer verband houden met de technische aspecten van een operatie of de ernst van de pathofysiologie, maar meer met de psychosociale gezondheid van mensen.

Voor mensen die aanhoudende klachten ervaren van hun duimbasisartrose en een voorkeur hebben voor operatieve behandeling, kunnen minimaal invasieve technieken die het gewricht intact houden een aantrekkelijke optie zijn. Duimbasisdistractie is een gewricht sparende behandeling en heeft als doel om een meer invasieve operatie uit te stellen of te voorkómen. Het streven van gewrichtsdistractie is om het gewrichtskraakbeen tijdelijk te ontlasten door contact tussen de gewrichtsoppervlakken te vermijden. De oorspronkelijke anatomie van het gewricht wordt behouden. Het betreft meestal mensen jonger dan 65 jaar die een medisch specialist bezoeken vanwege aanhoudende klachten. Een eerdere pilotstudie toonde aan dat distractie van het duimbasisgewricht technisch haalbaar is. In een vervolgstudie onderzochten wij of patiënten twee jaar na distractie een betere handfunctie en minder pijn ervaarden. Twintig patiënten met een mediane leeftijd van 54 jaar (variërend van 41 tot 64 jaar) en een reeds vastgestelde indicatie voor een invasieve chirurgische ingreep (bijv. trapeziectomie) werden geïncludeerd. Een externe distractor werd over het duimbasisgewricht geplaatst en acht weken later poliklinisch weer verwijderd. Na twee jaar waren de handfunctie- en pijnscores aanzienlijk verbeterd ten opzichte van vóór gewrichtsdistractie. Bovendien bereikten 14 van de 19 patiënten (74%) een verbetering in handfunctie scores (MHQ en DASH) wat wordt gezien als een 'klinisch belangrijk verschil'. Eén patiënt was niet tevreden en koos 14 maanden na de initiële distractiebehandeling alsnog voor een trapeziëctomie. Met andere woorden, slechts één op de 20 mensen behandeld met duimbasisdistractie onderging binnen twee jaar alsnog een invasieve gewrichtsoperatie. Grotere vergelijkende studies zijn nodig om de exacte waarde van gewrichtsdistractie in de behandeling van duimbasisartrose vast te stellen.

In een toekomstige gerandomiseerde gecontroleerde studie zullen we non-inferioriteit toetsen bij vermindering van de duur van duimbasisdistractie van acht naar zes weken. Er zullen 68 patiënten worden geïncludeerd en gerandomiseerd naar groep A (zes weken) of groep B (acht weken) distractie. Inclusiecriteria zijn onder andere een leeftijd jonger dan 65 jaar en een vastgestelde indicatie voor operatieve behandeling (bijv. trapeziectomie) vanwege aanhoudende klachten van duimbasisartrose ondanks niet-operatieve zorg. Het primaire doel van deze studie is om te beoordelen of zes weken niet slechter is dan acht weken gewrichtsdistractie. Dit meten we primair door middel van handfunctie en gezondheidsscores (MHQ scores) één jaar na de initiële distractie behandeling. Secundaire uitkomsten na één jaar zijn de verschillen tussen

beide groepen (A en B) in pijnintensiteit, patiënttevredenheid, handgezondheidsstatus, complicaties, falende behandeling (conversie naar bijvoorbeeld trapeziectomie), verschil in kracht en beweeglijkheid van de duim, en radiologische veranderingen van het duimbasisgewricht. Als de resultaten gunstig zijn, kan de duur van duimbasisdistractie worden teruggebracht van acht naar zes weken. Hiermee verminderen we de belasting voor de patiënt. Omdat duimbasisdistractie een relatief nieuwe behandeling is, zal deze studie ook meer kennis verschaffen over potentiële bijwerkingen of nadelige gevolgen. Deze kennis zorgt voor een beter geïnformeerde besluitvorming voor patiënten die duimbasisdistractie overwegen.

CONCLUSIES

1. Online informatie over duimbasisartrose is moeilijk leesbaar en bevat vaak een uitgesproken voorkeur voor één bepaalde behandeling. Artsen moeten bereid zijn om mogelijke misvattingen over de oorzaak van duimbasisartrose (het is namelijk geen acute aandoening maar hoort bij het verouderingsproces van de mens) en over de effectiviteit van behandelingen bespreekbaar te maken (acceptatie is de sleutel van de behandeling, een snelle chirurgische oplossing bestaat niet).
2. Chirurgen verschillen aanzienlijk in de mate waarin ze diagnostiek (röntgenfoto's) aanvragen en een behandeling (intra-articulaire injectie) uitvoeren bij mensen met duimbasisartrose. Chirurgen lijken hun aanbevelingen voor een operatieve behandeling vooral te baseren op subjectieve factoren. Gedeelde besluitvorming en een interactieve keuzehulp zouden ervoor kunnen zorgen dat de behandelkeuze niet gebaseerd is op misvattingen of voorkeuren van de chirurg; idealiter komt de behandelkeuze overeen met de waarden en voorkeuren van de patiënt.
3. Als er dislocatie van de pyrocarbon disc optreedt, ervaren de meeste mensen geen pijn of beperkingen hiervan in hun dagelijkse activiteiten. Een revisie operatie wordt uitgevoerd in ongeveer 1 op de 10 mensen meestal vanwege aanhoudende pijnklachten. Pijn intensiteit komt echter niet overeen met de mate van (sub)luxatie zoals vastgesteld op röntgenfoto's. De rol van pyrocarbon disc interpositie voor duimbasisartrose staat nog onder discussie; een revisie operatie kan worden overwogen bij aanhoudende klachten, maar is niet nodig op basis van radiologische bevindingen alleen.
4. Duimbasisdistractie is een technisch haalbare behandeling voor mensen met duimbasisartrose. Binnen twee jaar koos slechts één van de 20 patiënten alsnog voor een trapeziectomie na eerdere duimbasisdistractie. Er zijn grotere, gerandomiseerde en vergelijkende onderzoeken nodig om de exacte plaats van gewrichtsdistractie in de behandeling van duimbasisartrose te bepalen.



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List of Publications

1. C.M.C.A. van Laarhoven, **J.S.E. Ottenhoff**, E. Heeg, J.H. Coert, B.E.P.A. van der Heijden. Novel method to measure thumb height for carpometacarpal thumb joint arthroplasties; the thumb height ratio. *Plast Reconstr Surg*. 2023;151(4):697e-698e.
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About the Author

Janna Sophie Eugenia Ottenhoff was born in 1992 in Bethesda, Maryland, United States. She grew up in Leiden, the Netherlands, with her brother Max and sister Matthije. After graduating cum laude from gymnasium at the Visser 't Hooft Lyceum, she took an interim year in which she went travelling and worked for six months in Phnom Penh, Cambodia as a volunteer. In 2011, Janna decided to choose medicine over economics and enrolled in the Utrecht University Medical School. Her internship in gynaecology took place at the University Malaya Medical Centre in Kuala Lumpur and her social medicine internship at Parera: the Royal Dutch Naval Base on Curaçao.



Janna developed a special interest in plastic, reconstructive and hand surgery. From 2017 on, she became involved in various research projects with a special focus on basal thumb osteoarthritis. In the Netherlands she worked with research teams from the St. Antonius Hospital in Nieuwegein and the Jeroen Bosch Hospital in Den Bosch. Later that year, Janna joined the research team of Prof. Dr. Ring at the University of Texas in Austin for a seven-month research internship focusing on psychosocial aspects of upper extremity illness. Under supervision of Prof. dr. Mink van der Molen, Prof. dr. Coert, and Dr. Teunis, she started her PhD thesis work.

Back home in the Netherlands, Janna obtained her medical degree in 2018 and worked at the Department of General Surgery (St. Antonius Hospital, Nieuwegein) and Department of Plastic, Reconstructive and Hand Surgery (University Medical Center, Utrecht), while continuing her scientific work. Over the last years, Janna visited hospitals in Zambia, Bangladesh and Peru and worked with national and international staff on a voluntary basis. In 2020, she started her plastic surgery residency program in Utrecht.

