

'Thumbs Up'

Surgical Management and Outcome of Primary Osteoarthritis at the Base of the Thumb

Guus M. Vermeulen

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Surgical Management and Outcome of Primary Osteoarthritis at the Base of the Thumb

Chirurgische Behandeling en
Resultaten van Primaire Artrose van de Duimbasis

Proefschrift

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LIST OF ABBREVIATIONS

CMC	carpometacarpal
CRPS I	complex regional pain syndrome type I
TI	tendon interposition
LR	ligament reconstruction
LRTI	ligament reconstruction and tendon interposition
ST	scaphotrapezial
STT	scaphotrapeziotrapezoid
RCT	randomized clinical trial
TMC	trapeziometacarpal
FCR	flexor carpi radialis
APL	abductor pollicis longus
DASH	disabilities of arm shoulder and hand
PRWHE	patient-rated wrist/hand evaluation
ROM	range of motion



Introduction and outline of this thesis



‘One does never operate on a bone you can swallow’, said Sir John Charnley (1911–1982) a pioneer in orthopaedic surgery. For many years this was probably the best thing to do, because surgical treatment of wrist and hand problems was not yet common knowledge. Nowadays, due to research and innovation, surgery on small bones can be the right treatment in wrist and hand problems.

Hand osteoarthritis (OA) is one of the most common OA phenotypes, after knee OA and hip OA. OA at the base of the thumb is, after distal interphalangeal joint OA, the most common affected joint in the hand and can cause severe pain, weakness and deformity, which can result in significant disabilities. It typically affects postmenopausal women in their fifth to sixth decade of life.⁽¹⁾ Dahaghin et al. showed in a population-based cohort (n = 3906; 54.8% female) aged 55 and older that the prevalence of radiographic OA of the first carpometacarpal (CMC) joint and scaphotrapezial (ST) joint is rather high (35.8%). Furthermore, they confirmed a modest association between hand pain and radiographic OA, the strongest relationship being with the first CMC and ST joint compared to the other joints in the hand (OR; 1.9, CI 1.5–2.4). Hand disability, however, showed a rather weak association with radiographic OA, of which the first CMC and ST joint were not statistically significant (OR; 1.3 CI 1.0–1.9).⁽²⁾

The exact pathogenesis of hand OA is largely unknown but could be the result of multifactorial etiologies. Higher age, obesity, female gender, and family history are recognized risk factors.⁽³⁾ An additional cause of OA at the base of the thumb is thought to be weakening of the palmar beak ligament, resulting in increased metacarpal translation on the trapezium bone. In areas of high contact, shear stress forces can damage the articular cartilage, which can progress to degenerative OA.^(4, 5)

In 1987 Eaton and Glickel⁽⁶⁾ described a radiological classification, which is nowadays most often used and is based on the classification of Eaton and Littler from 1973.⁽⁷⁾ The modified classification of Eaton and Glickel includes arthritic changes in the scaphotrapezial joint and is used throughout this thesis:

- Stage 1 The articular contours are normal with slight widening of the joint space.
- Stage 2 Slight narrowing of the joint space with minimal sclerotic changes. Joint debris <2 mm diameter.
- Stage 3 Joint space markedly narrowed or obliterated. Cystic changes, sclerotic bone, varying degrees of dorsal subluxation. Joint debris >2 mm in diameter. The scaphotrapezial joint appears normal.
- Stage 4 Complete destruction of the first CMC joint, as in Stage 3. The scaphotrapezial joint is narrowed with sclerotic and cystic changes apparent.

Additional findings in literature showed that the interobserver reliability of the radiological classification of Eaton and Glickel is poor and that radiological classifications do not correlate well with clinical symptoms. Therefore, the radiological classification of Eaton and Glickel does not have direct treatment implications. The interobserver reliability of this classification can be improved when a combination of posterior-anterior, lateral, and Bett's view X-rays are used. The Bett's view, also called Gedda view, has additional value because all four articular surfaces of the os trapezium are projected without overlap of adjacent bones (Figure 1.1).⁽⁸⁻¹⁰⁾

Surgical treatment of OA at the base of the thumb is reserved for symptomatic patients not responding to conservative treatment and suffering from interference with occupational or recreational activities. Conservative treatment consists of splinting, exercises, physical therapy, NSAIDs, or intra-articular injections with steroids or hyaluronacid. During the last decades, a variety of surgical techniques has been described to restore function of the thumb, with pain relief, stability, mobility, and strength as the main goals of treatment.⁽¹¹⁾

The 8 most commonly used surgical procedures presented in literature to treat OA at the base of the thumb are: 1. volar ligament reconstruction, 2. metacarpal osteotomy, 3. CMC arthrodesis, 4. joint replacement, 5. trapeziectomy, 6. trapeziectomy with TI, 7. trapeziectomy with LR, and 8. trapeziectomy with LRTI. Findings in the systematic reviews published before 2010, reviewing literature up to 2007, showed no evidence of superiority of any of these surgical



Figure 1.1 Bett's view X-ray, also called Gedda view, has additional value because all four articular surfaces of the os trapezium are projected without overlap of adjacent bones.

procedures.⁽¹²⁻¹⁴⁾ We postulated at the start of this research, however, that differences between these 8 highly diverse techniques to treat the same problem are inevitable and that further research was therefore warranted.

The purpose of this thesis is to better understand which surgical techniques are preferred in the treatment of the different stages of primary OA at the base of the thumb. A systematic review of the literature until 2009 is performed (Chapter 2) to investigate which techniques have been proven successful. Additionally, when promising results of new techniques are observed, suggestions for future studies (RCT) are provided. In Chapter 3, we describe the results of a prospective single-arm study of a trapeziectomy with LRTI procedure, i.e., the Weilby arthroplasty. In this pilot study, we investigate if the results of the Weilby arthroplasty are similar compared to the results of other LRTI techniques in literature. Since the Weilby technique is standard surgical procedure in our clinic in the treatment of OA at the base of the thumb, we evaluate if this technique could be used as control group in future RCTs for comparison with other techniques. Based on the systematic review in Chapter 2, we report 3 RCTs (Chapter 4, 5 and 6) in which several techniques are compared (trapeziectomy, trapeziectomy with LRTI, CMC arthrodesis, total joint prosthesis). In Chapter 7, an update of our systematic review (Chapter 2) is reported, reviewing literature up to December 2012, and the findings of Chapters 2, 4, 5 and 6 are discussed. Where possible, treatment recommendations are provided.

THE AIMS OF THIS THESIS

- To investigate which surgical technique (trapeziectomy, trapeziectomy with LRTI, CMC arthrodesis, total joint prosthesis) is preferred in the treatment of the different stages of primary OA at the base of the thumb.
- To evaluate whether different types of suspensory ligament reconstruction (LRTI techniques) lead to different subjective and objective outcomes.
- To develop new treatment recommendations for patients with different stages of OA at the base of the thumb.

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**Surgical management of primary thumb
carpometacarpal osteoarthritis:
A systematic review article**

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ABSTRACT

The aim of this article is to provide an updated systematic review on the 8 most commonly used surgical procedures to treat trapeziometacarpal osteoarthritis. A thorough literature search was performed using predetermined criteria. A total of 35 articles fulfilled the inclusion criteria. Nine of these 35 articles were not included in previous systematic reviews. Systematic evaluation demonstrated the following: (1) there is no evidence that trapeziectomy or trapeziectomy with tendon interposition is superior to any of the other techniques. However, when interposition is performed, autologous tissue interposition seems to be preferable. (2) Trapeziectomy with ligament reconstruction or trapeziectomy with ligament reconstruction and tendon interposition (LRTI) is not superior to any of the other techniques. However, follow-up in the studies with a higher level of evidence was relatively short (12 mo); therefore, long-term benefits could not be assessed. In addition, trapeziectomy with LRTI seems associated with a higher complication rate. (3) Because the studies on thumb carpometacarpal (CMC) arthrodesis were of less methodological quality and had inconsistent outcomes, we are not able to conclude whether CMC arthrodesis is superior to any other technique. Therefore, high-level randomized trials comparing CMC arthrodesis with other procedures are needed. Nevertheless, findings in the newly included studies did show that nonunion rates in the literature are on average 8% to 21% and, complications and repeat surgeries are more frequent following CMC arthrodesis. (4) A study on joint replacement showed that total joint prosthesis might have better short-term results compared to trapeziectomy with LRTI. However, high-level randomized trials comparing total joint prosthesis with other procedures are needed. In addition, there is no evidence that the Artelon spacer is superior to trapeziectomy with LRTI. We conclude that, at this time, no surgical procedure is proven to be superior to another. However, based on good results of CMC arthrodesis and total joint prostheses, we postulate that there could be differences between the various surgical procedures. Therefore randomized clinical trials of CMC arthrodesis and total joint prostheses compared to trapeziectomy with long follow-up (>1 y) are warranted.

INTRODUCTION

Osteoarthritis (OA) at the base of the thumb can cause severe pain, weakness, and deformity and can result in marked disability. The main cause is weakening of the palmar beak ligament, resulting in increased metacarpal translation on the trapezium bone. In areas of high contact, shear stress forces can damage the articular cartilage, which can progress to degenerative osteoarthritis.

In the last decades, a variety of surgical techniques have been described, with pain relief, stability, mobility, and strength as the main goals of treatment. Such procedures include volar ligament reconstruction, metacarpal osteotomy, carpometacarpal (CMC) arthrodesis, joint replacement, and trapeziectomy. Trapeziectomy can be performed as a separate procedure or in combination with tendon interposition (TI), ligament reconstruction (LR), or ligament reconstruction combined with tendon interposition (LRTI).

In 2004, Martou et al.⁽¹⁾ published a systematic review of literature up to 2002. They included 26 articles, consisting of 8 reviews and 18 comparative studies based on specific criteria. Each of the techniques (CMC arthrodesis, trapeziectomy with or without biological/synthetic interposition, metacarpal osteotomy, and joint replacement) was found to be associated with unique benefits and risks. Martou et al. concluded that although the majority of retrieved review articles suggested that LRTI might be the best treatment option, most of the included studies had too many methodological flaws to warrant such a treatment recommendation. Furthermore, results from the articles on comparative studies, both randomized and nonrandomized, indicated that LRTI provides no additional benefit when compared with CMC arthrodesis and trapeziectomy alone or with TI.

A more recent systematic review from the Cochrane Collaborations with similar conclusions was published by Wajon et al.⁽²⁾ in 2005, reviewing literature up to 2004. In this review, only randomized, quasirandomized, or controlled trials were evaluated and, therefore, only 7 studies were included. Wajon et al. concluded that no procedure demonstrated superiority over another in terms of pain, physical function, patient global assessment, range of motion, or strength. Nevertheless, participants who had trapeziectomy had fewer complications than those who had the other commonly used procedures analyzed in the review. Those who had trapeziectomy with ligament reconstruction and tendon interposition (LRTI) had more complications, including scar tenderness, tendon adhesion or rupture, sensory change, or complex regional pain syndrome type 1. Due to the strict inclusion criteria used by Wajon et al., only 5 of 8 potential surgical procedures were evaluated (trapeziectomy, trapeziectomy with TI, trapeziectomy with LR, trapeziectomy with LRTI, and joint replacement (the Swanson silicone trapezium

implant)). Although we recognize that no definitive conclusions can be drawn from studies with less methodological quality, we postulate that volar ligament reconstruction, metacarpal osteotomy, CMC arthrodesis, or joint replacement procedures such as total joint prosthesis could be valuable treatment options in specific patient groups.⁽³⁻⁶⁾

In 2009, Wajon et al.⁽⁷⁾ updated the Cochrane Review first published in 2005, reviewing literature up to 2008. In this review, 9 studies were included, in which 6 of 8 potential surgical procedures were evaluated (trapeziectomy, trapeziectomy with TI, trapeziectomy with LR, trapeziectomy with LRTI, joint replacement [the Swanson silicone trapezium implant], and CMC arthrodesis). Furthermore, the review by Wajon et al. in 2009 identified one new, additional procedure, Artelon joint resurfacing. As in 2005, Wajon et al. concluded that, although it appears that no single procedure produces greater benefit in terms of pain and physical function, there was insufficient evidence to be conclusive. However, a firm conclusion that could be drawn was that trapeziectomy has fewer complications than trapeziectomy with LRTI.

Since 2002 (the systematic review by Martou et al.⁽¹⁾ published in 2004 reviewed literature up to 2002), several new studies on surgical procedures to treat trapeziometacarpal (TMC) osteoarthritis have been published. Although some of these studies were included in the reviews by Wajon et al.^(2,7) in 2005 and 2009 (reviewing up to 2008), some others were discarded owing to the stringent inclusion criteria. The aim of this report is to provide an updated, systematic review of surgical management and outcomes of the 8 most commonly used surgical procedures to treat TMC joint OA presented in literature: (1) volar ligament reconstruction, (2) metacarpal osteotomy, (3) CMC arthrodesis, (4) joint replacement, (5) trapeziectomy, (6) trapeziectomy with TI, (7) trapeziectomy with LR, and (8) trapeziectomy with LRTI.

In this article, we will evaluate whether there is evidence to revise the conclusions of Martou et al.⁽¹⁾ and Wajon et al.^(2,7) based on new evidence and evidence left out by previous reviews. Furthermore, we will provide suggestions for future studies that could help us understand differences in outcome for the different surgical procedures and whether there might be new treatment recommendations.

METHODS

The following keywords were used to search the PubMed/Medline database (1966 – December 2009): osteoarthritis, surgery, thumb, CMC, TMC, basal, arthrodesis, fusion, trapeziectomy, arthroplasty, osteotomy, replacement, prosthesis, ligament reconstruction. Combined searches of the first 3 terms with each of the surgical procedures were conducted to identify relevant

studies. Additional articles were identified by checking the references. Studies were initially screened for relevance based on title and abstracts. When an article was considered potentially relevant, studies were included if the following criteria were fulfilled:

- The study was a primary study and written in English.
- The treatment was a surgical procedure, either volar ligament reconstruction, metacarpal osteotomy, CMC arthrodesis, joint replacement, trapeziectomy, trapeziectomy with TI, trapeziectomy with LR, or trapeziectomy with LRTI.
- Pain, physical function, patient global assessment, range of motion, or strength was measured as an outcome.
- Only studies with a design classification of levels I to V were included, as classified by Jovell and Navarro-Rubio⁽⁸⁾ (Table 2.1).

The included studies were scored for design classification, subjective and objective outcomes, and authors' findings and were put into tables.

RESULTS

Study inclusion

Application of the inclusion criteria resulted in 35 included articles with design classifications of I to V (Table 2.1). Twenty-one studies were level V, 3 studies were level IV, 8 studies were level III, and 3 studies were level II. Nine articles of the included 35 were new studies that were not discussed before in a systematic review. Five studies were rejected in previous reviews, and

Table 2.1 Classification of study design as described by Jovell and Narvarro-Rubio

Level	Strength of evidence	Type of study design
I	Good	Meta-analysis of randomized controlled trials
II		Large-sample randomized controlled trials (n ≥ 25 for each group)
III	Good to fair	Small-sample randomized controlled trials (n < 25 for each group)
IV		Nonrandomized controlled prospective trails
V		Nonrandomized controlled retrospective trails
VI	Fair	Cohort studies
VII		Case control studies
VIII	Poor	Noncontrolled clinical series; descriptive studies
IX		Anecdotes or case reports

This classification was used to assess the methodological quality of the included papers.

4 studies were too recent to have been included by the previous reviewers. We excluded the randomized clinical trials (RCTs) of Davis et al.⁽⁹⁾ from 1997 (level II) and Downing et al.⁽¹⁰⁾ from 2001 (level II) because the patients in those studies were similar to those in the study by Davis et al.⁽¹¹⁾ from 2004 (level II). The great degree of heterogeneity of the included studies in terms of population, intervention, and outcome did not allow statistical pooling. Therefore, conclusions were drawn based on the main findings of the included studies.

Trapeziectomy and trapeziectomy with interposition

Historically, one of the oldest surgical procedures was originally described by Gervis⁽¹²⁾ in 1949. He introduced the concept of trapeziectomy without suspension arthroplasty or TI.

In their systematic review of literature up to 2002, Martou et al.⁽¹⁾ concluded, based on 9 included studies^(5, 13-20) (Table 2.2), that there is no evidence of a difference in either subjective or objective outcome measures between trapeziectomy with or without TI compared to CMC arthrodesis or trapeziectomy with LRTI. Also, they reported that interposition using Gore-Tex was associated with higher complication rates.⁽¹⁸⁾ Similarly, both reviews by Wajon et al.^(2, 7) concluded, based on 5 included studies^(11, 19, 21-23) (Table 2.2), that trapeziectomy alone had no superiority over the other techniques. However, trapeziectomy alone was found to have fewer adverse effects⁽⁷⁾ (10% vs 22% in trapeziectomy with LRTI). In addition, Wajon et al.⁽²⁾ reported that interposition using Permacol (Tissue Science Laboratories, Aldershot, UK) was associated with higher complication rates due to foreign-body reactions to the implant in 6 of 13 patients.⁽²¹⁾

When evaluating the studies that became available after the review by Martou et al. (literature up to 2002), we found 3 new studies⁽²⁴⁻²⁶⁾ on trapeziectomy alone or with TI that were discarded by the reviews by Wajon et al.^(2, 7) (literature up to 2008) and 1 new study⁽²⁷⁾ published after 2008 (Table 2.3). The first study by Raven et al.⁽²⁴⁾ was published in 2006 (level V). In this study, 54 patients were treated with either trapeziectomy with TI, resection arthroplasty (the joint surfaces of the metacarpal and the trapezium were resected), or CMC arthrodesis. No significant differences were reported among the 3 groups in pain, satisfaction, pain frequency, strength, or Disabilities of the Arm, Shoulder, and Hand (DASH) score. Twenty-two patients in the CMC arthrodesis group needed repeat surgery. The authors preferred the resection arthroplasty because it is technically simple and has equally good long-term results compared to trapeziectomy combined with tendon interposition or CMC arthrodesis. However, insufficient evidence was provided to support this claim.

A second study was published by Park et al.⁽²⁵⁾ in 2008 (level V). This study in 60 patients showed no significant differences between trapeziectomy, hemitrapeziectomy with osteochondral allograft,

and trapeziectomy with LRTI, in terms of DASH score and pinch strength. However, the surgical times for trapeziectomy and the osteochondral allograft were significantly shorter than for the LRTI procedure ($p = .001$). The authors suggested that the benefits of the shortened surgical time would be decreased costs and decreased tourniquet and anesthesia exposure for the patient.

The third new study is an RCT from Ritchie et al.⁽²⁶⁾ published in 2008 (level III), comparing trapeziectomy through anterior and posterior approaches on 20 patients in each group. Although both groups had significantly improved objective and subjective outcomes, the anterior approach group had significantly better strength, motion, satisfaction, and scar tenderness.

The fourth study is an RCT from Davis et al.⁽²⁷⁾ published in 2009 (level II), comparing 67 patients with a trapeziectomy to 61 patients with trapeziectomy with LRTI and K-wire immobilization. The results at one year follow-up showed that 81% of the trapeziectomy group reported no pain or only aching after use with no restrictions, compared to 67% of the LRTI group. The DASH and patient evaluation measure scores were reduced after surgery, indicating improved function. However, none of the outcome measures differed significantly between the 2 groups at 3 months or 1 year after surgery.

Overall, when evaluating the newly included studies⁽²⁴⁻²⁷⁾ (Table 2.3) in combination with the studies^(5, 13-20) included in the reviews by Martou et al. and those^(11, 19, 21-23) in both reviews by Wajon et al. (Table 2.2), there is no evidence of superiority of trapeziectomy, alone or with TI, over any of the other techniques. If interposition is performed, autologous tissue interposition seems preferable.^(18, 21)

Trapeziectomy with ligament reconstruction and trapeziectomy with ligament reconstruction and tendon interposition

Based on the work by Gervis⁽¹²⁾ on trapeziectomy and by Eaton and Littler⁽³⁾ on volar ligament reconstruction using the flexor carpi radialis tendon, Burton et al.⁽²⁸⁾ (level V) in 1986 were the first to describe the LRTI arthroplasty (Burton-Pellegrini technique). They used the flexor carpi radialis tendon and a bone tunnel at the base of the thumb metacarpal to maintain the trapezium height after resection of the trapezium bone and thus, theoretically, preserve thumb strength.

The systematic review by Martou et al.⁽¹⁾ concluded, based on 11 included articles^(4, 16, 17, 19, 28, 29-34) (Table 2.2), that trapeziectomy with LRTI had no additional benefits over CMC arthrodesis or trapeziectomy with or without TI. The systematic reviews by Wajon et al.^(2, 7) also concluded, based on 9 included articles^(11, 19, 22, 23, 35-39) (Table 2.2), that trapeziectomy with LRTI demonstrated no superiority over the other techniques compared in those reviews. However, Wajon et al.^(2, 7)

Table 2.2 Summary of findings of comparative studies discussed in previous reviews

Authors	Study classification	Discussed in review	No. of patients per group	Procedure	Authors' conclusion
Field et al. 2007	Level II	Wajon	32	Trapeziectomy	Patient satisfaction was comparable. There was no difference in grip or pinch strength, but the range of motion was slightly better in the trapeziectomy group without suspension.
			33	Trapeziectomy with LRTI	
Hart et al. 2006	Level III	Wajon	20	CMC arthrodesis	At 6-mo follow-up, objective and subjective outcomes (Buck-Gramko score) were significantly better in the CMC arthrodesis group. At final follow-up (mean 6.8 y), no significant differences were found, only palmar and radial abduction was significantly better in the LRTI group. Willingness to undergo surgery again under similar circumstances was significantly better in the CMC arthrodesis group. The authors state that they reserve CMC arthrodesis for younger active and LRTI for older patients.
			20	Trapeziectomy with LRTI	
Kriegs-Au et al. 2005	Level III	Wajon	15	Trapeziectomy with LR	Satisfactory results for both groups, with a small advantage for the group without tendon interposition. Tendon interposition does not affect the outcome after ligament reconstruction, and proximal migration of the thumb metacarpal did not influence the functional outcome.
			16	Trapeziectomy with LRTI	
Nilson et al. 2005	Level IV	Wajon	10	Artelon implant arthroplasty	No patients showed signs of synovitis. In both groups, all patients were pain free. The key pinch and tripod pinch strength increased compared to before surgery in the Artelon spacer group and was significantly better compared to the LRTI group. The biopsy examinations showed incorporation of the device in the surface of the adjacent bone and the surrounding connective tissue. No signs of foreign-body reaction were seen. The authors concluded that the Artelon spacer showed significantly better pinch strength.
			5	Trapeziectomy with LRTI	
De Smet et al. 2004	Level III	Wajon	22	Trapeziectomy	Both techniques gave favorable results and there were no significant differences for pain relief, patient satisfaction, mobility, DASH score, or strength.
			34	Trapeziectomy with LRTI	

Davis et al. 2004	Level II	Wajon	62 59 62	Trapeziectomy Trapeziectomy with TI Trapeziectomy with LRTI	The outcomes of these 3 variations of trapeziectomy were very similar at one-year follow-up evaluation. In the short term, at least, there appears to be no benefit to tendon interposition or ligament reconstruction.
Tägil et al. 2002	Level III	Wajon	13 13	Swanson arthroplasty Trapeziectomy with LRTI	Both methods gave good, but not complete, pain relief and neither produced better results than the other in the short term.
Schröder et al. 2002	Level V	Martou	18 18	CMC arthrodesis Trapeziectomy with TI	No differences in objective and subjective outcomes. Because the CMC arthrodesis group had fewer problems than the trapeziectomy with TI group, the CMC arthrodesis is preferred.
Mureau et al. 2001	Level V	Martou	32 24	CMC arthrodesis Trapeziectomy with TI	Patients in the trapeziectomy with TI group reported significantly less pain, less temperature intolerance, better thumb mobility, fewer pain symptoms, better thumb opposition, and better thumb CMC joint range of motion. No statistically significant differences were found in strength. Trapeziectomy with TI seems to be preferable to thumb CMC arthrodesis.
Hartigan et al. 2001	Level V	Martou	58 49	CMC arthrodesis Trapeziectomy with LRTI	The 2 procedures had similar results with regard to pain, function, and overall satisfaction, despite minimal differences in strength and motion. Complications were more frequent following CMC arthrodesis but did not affect the overall outcome.
Belcher et al. 2001	Level III	Wajon	13 13	Trapeziectomy with interposition of porcine dermal collagen xenograft (Permacol; Tissue Science Laboratories, Aldershot, UK) Trapeziectomy	The study was terminated prematurely because of apparent reactions to the implants; histology revealed foreign-body reactions. There was no difference in thumb movement or power after surgery between the 2 groups. However, improved grip strength was observed and improved function was reported only in the trapeziectomy alone group. Permacol patients reported greater pain and were less satisfied with their surgeries, so interposition of Permacol is detrimental to the results of trapeziectomy.

Table 2.2 continues on next page.

Table 2.2 *Continued*

Authors	Study classification	Discussed in review	No. of patients per group	Procedure	Authors' conclusion
Belcher et al. 2000	Level III	Martou/Wajon	19	Trapeziectomy	The LRTI lengthened the surgery by approximately 15 minutes. Both groups expressed equal satisfaction with the surgery, and there were no significant differences. Simple trapeziectomy is an effective surgery for osteoarthritis at the base of the thumb, and the addition of a ligament reconstruction was not shown to confer any additional benefit.
			23	Trapeziectomy with LRTI	
Lovel et al. 1999	Level V	Martou	42	Swanson arthroplasty	The Swanson implant group obtained significantly better results for pain at one year, carrying a milk bottle and taking a handbrake off a car, and overall function. The Swanson implant gives better results in the short term if there are no complications of the surgery.
			45	Trapeziectomy with LRTI	
Alhot et al. 1998	Level V	Martou	79	Guepar total joint prosthesis	Guepar prosthesis provides good results with low revision rates and deserves to be widely used. Indication for the trapeziectomy with LRTI are severe osteoarthritis, intensive hand use, and younger age.
			19	Trapeziectomy with LRTI	
Lehmann et al. 1998	Level V	Martou	27	Silicone arthroplasty	No significant differences in pain relief, range of motion, and strength between trapeziectomy with LRTI or silicon arthroplasty were observed. Therefore the use of Silastic implants might not be justified, given the potential for higher rate of long-term complications with silicone arthroplasty (as reported by other studies).
			76	Trapeziectomy with LRTI	
Atroshi et al. 1998	Level V	Martou	7	Osteotomy	Osteotomy should be limited to patients with early disease (Eaton and Glickel [1987] stage I and II) and patients with stage III OA after trapeziectomy with LR had better function at follow-up than patients after metacarpal osteotomy.
			10	Trapeziectomy with LR	

Muermans et al. 1998	Level V	Martou	10	Trapeziectomy with Gore-Tex interposition Trapeziectomy with Marlex interposition Trapeziectomy with TI	The results showed that TI and Marlex interposition gave similar results. Gore-Tex is not recommended due to a higher rate of complications, especially synovitis.
Gerwin et al. 1997	Level III	Wajon	11 9	Trapeziectomy with LR Trapeziectomy with LRTI	There was no difference between the 2 groups in range of motion of the thumb, grip strength, lateral pinch strength, the ability to perform activities of daily living, or subjective satisfaction with the procedure.
Livesey et al. 1996	Level V	Martou	8 11	Trapeziectomy with TI Trapeziectomy with LRTI	The LRTI group had a slower recovery but developed a stronger hand, had better dynamic thumb function despite reduced movement, and the trapezial space was better preserved. Calcification within the trapezial space correlated with better results, but this took 3 y to occur. The TI group had greater relief of pain and were more satisfied at an early stage.
Hollevoet et al. 1996	Level V	Martou	54 14 17	Trapeziectomy Trapeziectomy with APL shortening Trapeziectomy with LRTI or TI	Clinical assessment revealed no statistical difference in terms of pain, range of motion, and strength between the 3 procedures.
Lanzetta et al. 1995	Level V	Martou	26 8 28	Swanson silicon implant Hemiarthroplasty Trapeziectomy with LRTI	Hemiarthroplasties failed to gain satisfactory results, but both silicone arthroplasty and trapeziectomy with LRTI proved to be useful procedures. However, due to the risk of synovitis, the authors recommend trapeziectomy with LRTI.
Conolly et al. 1993	Level V	Martou	16 15 85	CMC arthrodesis Trapeziectomy with LRTI Silicone arthroplasty	Authors recommend CMC arthrodesis or silicone hemiarthroplasty for < stage III; stage IV should be treated with silicone arthroplasty or trapeziectomy with LRTI.

Table 2.2 continues on next page.

Table 2.2 *Continued*

Authors	Study classification	Discussed in review	No. of patients per group	Procedure	Authors' conclusion
Amadio et al. 1990	Level V	Martou	16	CMC arthrodesis	Two thirds of the patients were completely satisfied with results of the surgery. Results were poorer in patients who did heavy work. Choice of procedure had little effect on strength and satisfaction.
			24	Different types of joint replacements	
			7	Trapeziectomy with TI	
Burton et al. 1986	Level V	Martou	32	Swanson arthroplasty	The results showed that the trapeziectomy with LRTI compares favorably with the Swanson arthroplasty in terms of improved strength and increased first web space. LRTI is recommended.
			25	Trapeziectomy with LRTI	
Kvarnes et al. 1985	Level V	Martou	53	CMC arthrodesis	No differences in terms of pain relief, but authors recommend CMC arthrodesis because of significantly greater stability and strength.
			12	Trapeziectomy	
			13	Silicone arthroplasty	
Amadio et al. 1982	Level V	Martou	25	Trapeziectomy with TI	No significant differences in pain relief, range of motion, and pinch strength between trapeziectomy or Swanson silicon implant.
			25	Swanson silicon implant	

reported that trapeziectomy with LRTI had more adverse effects and trapeziectomy alone had fewer (including scar tenderness, tendon adhesion or rupture, sensory change, or complex regional pain syndrome type 1) and, therefore, concluded that trapeziectomy is safer. The 2009 review by Wajon et al.⁽⁷⁾ reported that 22% of participants who had trapeziectomy with LRTI had adverse effects, compared to 10% who had trapeziectomy.

When evaluating the studies that became available after the review by Martou et al.⁽¹⁾ (literature up to 2002), we included 3 new studies^(6,25,40) that were discarded by the reviews by Wajon et al.^(2,7) (literature up to 2008) and 3 new studies^(27,41,42) after 2008. A new level V retrospective study by Taylor et al.⁽⁴⁰⁾ in 2005 compared CMC arthrodesis, silicon arthroplasty, and trapeziectomy with LRTI and showed no significant differences in outcome. They did, however, find a higher rate of complications and repeat surgery in the arthrodesis group.

The study by Park et al.⁽²⁵⁾ published in 2008 (level V), comparing trapeziectomy, hemitrapeziectomy with osteochondral allograft, and trapeziectomy with LRTI, and the RCT by Davis et al.⁽¹¹⁾ published in 2009 (level II), comparing trapeziectomy and trapeziectomy with LRTI and K-wire immobilization,⁽²⁷⁾ also found no significant differences between trapeziectomy with LRTI and the other techniques in those studies.

The new studies by Ulrich-Vinther et al.⁽⁶⁾ from 2008 (level IV), comparing trapeziectomy with LRTI and total joint prosthesis, and the study by Jörheim et al.⁽⁴²⁾ from 2009 (level IV), comparing trapeziectomy with LRTI and the Artelon implant arthroplasty, showed no superiority of the LRTI over the other technique. Remaining results of these studies will be discussed in the paragraph on joint replacement procedures.

The study by Garcia-Mas et al.⁽⁴¹⁾ from 2009 (level V) compared 80 patients with partial trapeziectomy with LRTI to 15 patients with total trapeziectomy with LRTI. The techniques were performed in different groups (partial trapeziectomy with LRTI for stage II/III, and total trapeziectomy with LRTI for stage IV), and both resulted in good outcomes. The authors suggest that total trapeziectomy should be restricted for stage IV OA based on slightly better strength measurements and improved pain levels.

Overall, when evaluating the newly included studies^(6, 25, 27, 40-42) (Table 2.3) in combination with the studies included in the review by Martou et al.^(4, 16, 17, 19, 28, 29-34) (Table 2.2) and those^(11, 19, 22, 23, 35-39) in the reviews by Wajon et al. (Table 2.2), there is no evidence for superiority of trapeziectomy with additional LR or LRTI. The 3 studies with the highest study classification (level II) all had a mean follow-up of only 12 months and, therefore, long-term differences could not be assessed.^(11, 23, 27) Furthermore these 3 studies showed higher complication rates in the trapeziectomy with LRTI groups.

Table 2.3 Summary of findings of new comparative studies not discussed in previous reviews

Authors	Study classification	Discussed in review	No. of patients per group	Procedure	Authors' conclusion
Jörheim et al. 2009	Level IV	New	13 40	Artelon implant arthroplasty Trapeziectomy with LRTI	No significant difference between groups in terms of DASH, pain, range of motion, and strength. More patients in the LRTI group were satisfied. Two Artelon patients had revision to trapeziectomy with LRTI, and there were no repeat surgeries in the LRTI group. The authors concluded that the outcomes of the Artelon implant were not superior to those of trapeziectomy with LRTI, a factor to be considered when comparing treatment cost effectiveness.
Davis et al. 2009	Level II	New	67 61	Trapeziectomy Trapeziectomy with LRTI and K-wire immobilization	At one-year follow-up, 81% of the trapeziectomy group reported no pain or only discomfort after use with no restriction, compared with 67% of the LRTI group. The DASH and patient evaluation measure outcome scores reduced after surgery, indicating improved function. However, the pain, DASH, and patient evaluation measure scores, as well as key and tip thumb pinch and all the other clinical outcome measures, did not differ significantly between the 2 groups at either 3 mo or one year after surgery.
Garcia-Mas et al. 2009	Level V	New	80 15	Partial trapeziectomy with LRTI Total trapeziectomy with LRTI	The compared techniques were performed in different groups (partial trapeziectomy with LRTI for stage II/III; total trapeziectomy with LRTI for stage IV) and resulted in good outcomes. The authors suggest that total trapeziectomy should be restricted for stage IV OA, based on slightly better strength measurements and improved pain levels.
Ulrich Vinther et al. 2008	Level IV	New	36 62	Joint prosthesis Trapeziectomy with LRTI	Patients with joint prosthesis achieve faster convalescence with better comfort and improved strength and range of motion without any increased risk of complications than did patients treated with trapeziectomy with LRTI.

Park et al. 2008	Level V	New	60	Trapeziectomy Costochondral allograft Interposition arthroplasty Trapeziectomy with LRTI	No significant difference between groups in terms of DASH score and pinch strength. No difference between the techniques in terms of postoperative pinch strength and patient satisfaction, measured by DASH scores. The surgical times for trapeziectomy as well as the osteochondral allograft were significantly shorter than that of the LRTI. This presents further evidence that, potentially, "less is more" in the treatment of thumb CMC arthritis.
Ritchie et al. 2008	Level III	New	20 20	Trapeziectomy (posterior approach) Trapeziectomy (anterior approach)	Trapeziectomy resulted in significantly improved objective and subjective outcomes in both groups, but the anterior approach group had significantly better subjective power, motion, and satisfaction, and better objective key pinch and scar tenderness.
Raven et al. 2006	Level V	New	17 18 28	Trapeziectomy with TI Resection arthroplasty CMC arthrodesis	No significant differences between the 3 groups were found for the visual analogue pain and satisfaction scale, strength, or DASH score. Twenty-two patients in the CMC arthrodesis group needed repeat surgery. The authors preferred the resection arthroplasty because it is technically simple and has equally good long-term results compared to trapeziectomy combined with TI or CMC arthrodesis.
Taylor et al. 2005	Level V	New	36 22 25	CMC arthrodesis Silastic trapezial replacement Trapeziectomy or trapeziectomy with LR	Assessments included patient satisfaction, pain measurement, range of motion, tip and key pinch, and complication rates. There were no significant differences between the clinical outcomes of the treatments, though there was a higher rate of complications and repeat surgeries in the arthrodesis group.
Forseth et al. 2003	Level V	New	59 19	CMC arthrodesis (K-wire) CMC arthrodesis (plate and screw)	The K-wire and plate and screw fixation had comparable union rates (approximately 8%), but the plate and screw fixation group had a lower satisfaction rate and secondary surgery was more common.

Carpometacarpal arthrodesis

In the past decades, arthrodesis of the thumb CMC joint has been another popular technique to treat OA at the base of the thumb. One of the first reports was published by Muller in 1949.⁽⁴³⁾

The 6 included studies on CMC arthrodesis^(5, 14, 15, 20, 29, 34) in the systematic review by Martou et al.⁽¹⁾ (Table 2.2) showed highly diverse results of CMC arthrodesis compared to other techniques, in terms of strength, stability, and pain. Therefore, superiority of CMC arthrodesis could not be concluded. The systematic review by Wajon et al.⁽²⁾ from 2005 excluded all the above-mentioned studies on CMC arthrodesis because of limited methodological strength. The updated review by Wajon et al.⁽⁷⁾ in 2009 included one small RCT of Hart⁽³⁹⁾ from 2006 (level III) (Table 2.2) in which CMC arthrodesis is compared to trapeziectomy with LRTI. In that study, no significant differences were observed. However, Wajon et al. reported that the statistical significance of these scores is unclear, as standard deviations were not provided for statistical analysis.

Evaluating the studies that became available after the review by Martou et al.⁽¹⁾ (literature up to 2002), we included 3 new studies^(24, 40, 44) that were discarded by the reviews by Wajon et al.^(2, 7) A retrospective study by Forseth et al.⁽⁴⁴⁾ in 2003 (level V) compared arthrodesis using plate and screw fixation with a previously published K-wire fixation group. Forseth et al. showed that, although K-wire and plate and screw fixation had comparable nonunion rates (approximately 8%), the plate and screw fixation group had a lower satisfaction rate and secondary surgery was more common.

The previously mentioned studies by Taylor et al.⁽⁴⁰⁾ (level V) in 2005 and Raven et al.⁽²⁴⁾ (level V) in 2006 showed no significant differences of CMC arthrodesis compared to the other techniques in those studies.

The 3 newly included studies^(24, 40, 44) (Table 2.3), in combination with the included studies^(5, 14, 15, 20, 29, 34) in the review by Martou et al. (Table 2.2) and the included study⁽³⁹⁾ in the updated review by Wajon et al. in 2009 (Table 2.2), provide inconclusive and often conflicting findings on CMC arthrodesis compared to other techniques. Nevertheless, the studies do show that thumb CMC arthrodesis is indicated not only for young people with posttraumatic arthritis but also can be used in older patients with stage II and III OA.^(5, 40) Nonunion rates in literature are on average 8% to 21% and, although complications and reoperations are more frequent following CMC arthrodesis, it did not affect the overall outcome in some studies.^(24, 34, 40)

Joint replacement

In the 1960s, Swanson et al.⁽⁴⁵⁾ developed the trapezial Silastic replacement arthroplasties that filled the space produced by trapezial excision. The systematic review of this technique by Martou et al.⁽¹⁾ included 7 studies^(13, 14, 28, 29-31, 33) (Table 2.2) and concluded that silastic replacement arthroplasties have high complication rates that outweigh the pain relief and high, but short-term, patient satisfaction. Based on a small RCT from Tägil et al.⁽³⁶⁾ from 2002 (Table 2.2), Wajon et al.^(2,7) concluded that silicone arthroplasty had no additional benefits, but a difference in the adverse effects between trapeziectomy with LRTI compared with silicone arthroplasty was not observed.

No new studies on trapezial Silastic replacement arthroplasty were found after 2002. Evaluating the studies also included by Martou et al.^(13, 14, 28, 29-31, 33) and Wajon et al.⁽³⁶⁾ (Table 2.2), we also conclude that Silastic implants are associated with more long-term complications such as subluxation, fractures, and silicone synovitis.

The second type of joint replacement was developed at the end of the 1970s: total TMC joint replacement surgery. Many designs of cemented and, in recent years, uncemented prostheses have emerged. Total joint replacement was not discussed by Martou et al.⁽¹⁾ and Wajon et al.,^(2,7) although 2 studies^(15, 32) of total joint prostheses were included by Martou et al. (Table 2.2).

When evaluating the studies on total joint replacement that became available after 2002, we included the previously mentioned comparative prospective 1-year follow-up study by Ulrich-Vinther et al.⁽⁶⁾ from 2008 (level IV). This study compared the Elektra joint prosthesis (Small Bone Innovations Inc., Péronas, France) with trapeziectomy combined with LRTI and showed that patients with joint prosthesis (mean age 58 y) achieved faster convalescence, better patient comfort, better strength, and better range of motion without an increased complication rate than trapeziectomy with LRTI. Implant failure was observed in 2.8%.

Overall, the recent study⁽⁶⁾ (Table 2.3), in combination with the included studies^(15, 32) in the review by Martou et al. (Table 2.2), showed that total joint prosthesis is a good option to treat stage II and III OA and potentially can have better outcome, at least in the short term, than trapeziectomy with LRTI. Immediate stability, strength, and motion is generally realized, but implant loosening can occur. In addition, the decreased rates of implant failure in recent studies on joint replacement⁽⁶⁾ compared to earlier reports^(15, 32) suggest that improving quality of total joint prostheses could have a significant positive effect on outcome.

In the last few years, the T-shaped Artelon TMC spacer that is synthesized of a degradable polyurethaneurea was introduced. The Artelon TMC spacer was not discussed by Martou et al.⁽¹⁾

or by Wajon et al.⁽²⁾ in 2005. The updated review by Wajon et al.⁽⁷⁾ in 2009 included one small level IV study by Nilsson et al.⁽⁴⁶⁾ from 2005 (Table 2.2) in which they compared 10 patients with an Artelon spacer to 5 patients with trapeziectomy with LRTI. In both groups, all patients were pain free. Strength in the Artelon spacer group was significantly better than that in the LRTI group. The biopsy examinations showed incorporation of the device in the surface of the adjacent bone and the surrounding connective tissue. No signs of foreign-body reaction were seen.

We newly included the previously mentioned level IV study on the Artelon TMC spacer from Jörheim et al.⁽⁴²⁾ in 2009 (Table 2.3), in which 13 patients with a Artelon spacer were compared with 40 patients with a trapeziectomy with LRTI.⁽⁴²⁾ Although no significant differences between groups were found for the DASH score, pain, range of motion, or strength, more patients in the LRTI group were satisfied (80% vs 62% in the Artelon group). Two Artelon patients had revisions to the trapeziectomy with LRTI compared to no repeat surgeries in the LRTI group. The authors concluded that the outcomes of the Artelon implant were not superior to those of trapeziectomy with LRTI.

Metacarpal osteotomy

In 1973, Wilson⁽⁴⁷⁾ described the basal osteotomy in the treatment of TMC joint OA, in which an abduction osteotomy of the proximal end of the thumb metacarpal is performed by removing a radial-based bone wedge and closing the defect by abducting the distal fragment.

The systematic review by Martou et al.⁽¹⁾ included one study on metacarpal osteotomy (Atroshi et al.⁽⁴⁾) but did not comment on it in the results. The systematic reviews by Wajon et al.^(2,7) did not include any studies on metacarpal osteotomy because of limited methodological strength.

The retrospective study by Atroshi et al.⁽⁴⁾ from 1998 (level V) compared trapeziectomy with LR and thumb metacarpal osteotomy. The authors concluded that metacarpal osteotomy should be limited to patients with early disease (stage I and II OA). Furthermore, they showed that patients with stage III OA, after trapeziectomy with LR, had better function at follow-up than did patients after metacarpal osteotomy. No new studies on metacarpal osteotomy were found after 2002.

Volar ligament reconstruction

Volar ligament reconstruction was first described by Eaton and Littler⁽³⁴⁾ in 1973. They developed this procedure to reconstruct the volar beak ligament of the symptomatic, hypermobile first CMC joint without notable arthritis, using the flexor carpi radialis tendon. It is suggested to

be an effective technique for treating symptomatic laxity of the CMC joint of the thumb for stage I and II OA.

Neither Martou et al.⁽¹⁾ nor Wajon et al.^(2,7) included any studies concerning volar ligament reconstruction, and our research also could not find level I–V studies on volar ligament reconstruction in the present literature.

DISCUSSION

Because OA at the base of the thumb can result in considerable disability, selecting the optimal surgical procedure is highly relevant. The previous reviews on this topic by Wajon et al.^(2,7) in 2005 and 2009 had strict inclusion criteria, resulting in a small number of included studies that did not represent all commonly used surgical procedures. The aim of the current review was to provide an updated review on the 8 most common surgical procedures using less-strict inclusion criteria, to extract treatment recommendations, and to give suggestions for future studies. Because of the great degree of heterogeneity of the patient populations, the interventions, and the outcome measures, we did not perform a statistical pooling of the included studies.

Our search strategy identified 35 articles on 7 of the 8 surgical procedures commonly used in clinical practice (metacarpal osteotomy, CMC arthrodesis, joint replacement, trapeziectomy, trapeziectomy with TI, trapeziectomy with LR, and trapeziectomy with LRTI). No studies of level V or higher could be included concerning volar ligament reconstruction. Nine of these 35 articles had not been included in previous systematic reviews. Systematic evaluation of these 9 articles compared to the previously reviewed articles yielded a number of conclusions.

First, in line with previously reviewed articles on trapeziectomy alone and trapeziectomy with TI,^(11,19,21-23) we found (based on 2 new high-level randomized trials^(26,27) (level II and III)) that there is still no evidence of superiority of trapeziectomy alone or with interposition over any of the other techniques. If interposition is performed, autologous tissue interposition seems preferable, because 2 studies (level III and V) showed that nonautologous tissue interposition was associated with increased complications.^(18,21)

Also in line with previously reviewed articles^(11,19,22,23,35,36,38,39) on trapeziectomy with LR and trapeziectomy with LRTI, we found (based on a high level, level II randomized trial⁽²⁷⁾) that superiority of trapeziectomy with additional LR or LRTI is not supported by evidence. However, the 3 studies with the highest study classification (level II) all had a mean follow-up of only 12 months and, therefore, possible long-term benefits of LRTI compared to trapeziectomy alone or with TI could not be assessed.^(11,23,27) In addition, these 3 studies showed that trapeziectomy

with LRTI is associated with a higher complication rate compared to trapeziectomy without LRTI. It is, therefore, surprising that, despite the evidence that has been available since the review by Wajon et al.⁽²⁾ in 2005 that trapeziectomy alone is safer, some studies continue to use trapeziectomy with LRTI – and not trapeziectomy without LRTI – as a surgical technique by which other techniques are compared.^(6, 25, 39, 42) Apparently, clinicians and researchers are still convinced of the possible benefits of LRTI in the long term.

Because the previously reviewed studies^(5, 14, 15, 20, 29, 34) on thumb CMC arthrodesis and the newly included studies^(24, 40, 44) were of limited methodological quality (level V; only one level III study⁽³⁹⁾) and had inconsistent outcomes, we are unable to conclude whether CMC arthrodesis is superior to any other technique. Therefore, high-level randomized trials comparing CMC arthrodesis with other procedures are needed. Nevertheless, findings in the newly included studies did show that thumb CMC arthrodesis is not only primarily indicated for young people with posttraumatic arthritis but it can also be used for older patients with stage II and III OA.^(24, 40) Nonunion rates in the literature are, on average, 8% to 21% and, although complications and repeat surgeries are more frequent following CMC arthrodesis compared to trapeziectomy or trapeziectomy with LRTI, it did not affect the overall outcome in some studies.^(24, 40, 44)

When evaluating the studies on joint replacement procedures, we conclude (based on previously reviewed studies with less methodological quality [level V]^(13, 14, 28, 29-31, 33) and one level III study⁽³⁶⁾) that Silastic implants are not justified, given the increased long-term complications requiring revision, such as subluxation, fractures, and silicone synovitis. A newly included level IV study on total joint prosthesis⁽⁶⁾ suggests that total joint prostheses might be a good alternative with potentially better results, at least in the short term, compared to trapeziectomy with LRTI. Immediate stability, strength, and motion are realized, but implant loosening can occur. Because of the potentially good results of total joint prosthesis in studies with less methodological quality,^(6, 15, 32) high-level randomized trials comparing total joint prosthesis with other procedures are needed to verify possible benefits of these procedures. The improving quality of total joint prostheses could have a notable positive effect on outcome. In addition, the updated review by Wajon et al.⁽⁷⁾ in 2009 included a new additional procedure, the Artelon TMC spacer. However, we think of the Artelon TMC spacer just as another type of joint replacement procedure rather than a new additional procedure. A newly included study⁽⁴²⁾ on the Artelon CMC spacer (level IV) showed that there is no evidence that the Artelon spacer is superior to trapeziectomy with LRTI and, therefore, treatment cost effectiveness should be considered.

Finally, a previously reviewed study⁽⁴⁾ on metacarpal osteotomy (level V) suggests that osteotomies should be limited to patients with early disease (stage I and II OA).

Overall, we conclude that at this time no procedure is superior to another in terms of pain, physical function, patient global assessment, range of motion, or strength. However, given the lack of level I–III studies on some of the reviewed procedures (volar ligament reconstruction and metacarpal osteotomy for the early stages of OA and CMC arthrodesis and joint replacement for the advanced stages of OA) and based on good results of CMC arthrodesis^(5, 34) and total joint prostheses^(6, 15, 32) in studies with less methodological quality, we postulate that there could be differences between the various surgical procedures, certainly in the long term. Therefore, RCTs of carpometacarpal arthrodesis and total joint prostheses compared to trapeziectomy with long follow-up (<1 y) are warranted. Furthermore, because differences between the various techniques are small, researchers should focus on developing more sensitive outcome measures that are indicative of the specific changes in hand function after CMC OA.

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**Ligament reconstruction arthroplasty
for primary thumb carpometacarpal
osteoarthritis (Weilby technique):
A prospective cohort study**

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ABSTRACT

Purpose: The Weilby procedure is one of several accepted methods to treat primary thumb carpometacarpal osteoarthritis. We found no previous studies that included preoperative and postoperative subjective outcomes using validated questionnaires or preoperative and postoperative objective outcomes such as specific strength and range-of-motion measurements. Therefore, we performed a prospective cohort study in which we analyzed preoperative and postoperative objective and subjective outcomes after Weilby interposition tendoplasty.

Methods: Nineteen patients (20 thumbs) with primary thumb carpometacarpal osteoarthritis were treated with Weilby interposition tendoplasty. For subjective assessment, the Disabilities of the Arm, Shoulder, and Hand (DASH) outcome data collection instrument was used to evaluate preoperative and postoperative outcomes at 0, 3, 6, and 12 months. Furthermore, patients completed a specific personal questionnaire at 12 months of follow-up. Objective assessments included interphalangeal joint flexion/extension; metacarpophalangeal joint flexion/extension; and carpometacarpal joint palmar abduction, opposition, and extension. Tip pinch, key pinch, 3-point pinch, and overall grip strengths were also measured. The measurements were performed preoperatively and at 3, 6, and 12 months after surgery. All complications were registered.

Results: The DASH score was significantly improved, and 17 of 19 patients were satisfied with the procedure. The interphalangeal joint flexion/extension, metacarpophalangeal joint flexion/extension, and carpometacarpal joint extension did not significantly change. Carpometacarpal joint palmar abduction and opposition were significantly improved at 12 months. The tip pinch and key pinch strengths were increased but not significantly. The 3-point pinch and overall grip strengths were significantly improved at 12 months.

Conclusions: The Weilby procedure is a reliable alternative to treat primary thumb carpometacarpal osteoarthritis without requiring bone tunnel creation. It achieves pain relief, stability, mobility, and strength. The objective and subjective outcomes of this study compare favorably with those of earlier reports of the Weilby procedure and are similar to the published results of the more commonly performed Burton-Pellegrini technique.

Type of study/level of evidence: Therapeutic IV.

INTRODUCTION

Osteoarthritis at the base of the thumb can cause severe pain, weakness, and/or deformity and can result in marked disability. The main cause is weakening of the palmar beak ligament, resulting in increased metacarpal translation on the trapezium bone. In areas of high contact, shear stress forces can damage the articular cartilage, which can progress to degenerative osteoarthritis.^(1,2)

A variety of surgical techniques has been described in which pain relief, stability, mobility, and strength are the main goals of treatment. In 1949, Gervis⁽³⁾ originally described the concept of trapezial excision without suspension arthroplasty or tendon interposition. Several authors have reported excellent results of trapeziectomy alone⁽⁴⁻⁶⁾ or in combination with tissue interposition.⁽⁷⁾ However, trapeziectomy with or without tissue interposition has been criticized for weakening the thumb, because the procedure cannot prevent collapse of the first metacarpal bone.⁽⁸⁾ In 1973, Eaton and Littler⁽⁹⁾ described a method to reconstruct the volar beak ligament of a symptomatic hypermobile trapeziometacarpal joint without marked arthritis (Eaton and Littler stage I) by using the flexor carpi radialis (FCR) tendon. Based on the previous work of Gervis⁽³⁾ and the work of Eaton and Littler,⁽⁹⁾ several surgical techniques were described to restore function to the first ray, in which trapezium resection is combined with some form of suspension to support the thumb. The main goal of such suspensory ligament reconstruction is to maintain the trapezial height after resection of the trapezium bone and thus, at least theoretically, preserve thumb strength.⁽⁸⁾

In 1986, Burton and Pellegrini⁽⁸⁾ described ligament reconstruction tendon interposition arthroplasty using the FCR tendon (Burton-Pelligrini technique). In this method, the trapezium is excised, and half of the FCR tendon is used as a tendon graft donor, being advanced through a bone tunnel at the base of the first metacarpal to support the thumb. The remaining tendon is rolled in to a ball and interposed between the distal pole of the scaphoid and the base of the first metacarpal bone. In 1995, Tomaino et al.⁽¹⁰⁾ reported the results of a long-term follow-up (8–11 years) of this technique, in which 95% of the patients had excellent pain relief and were satisfied with the outcome. Other authors reported similar results with techniques based on the Burton-Pelligrini technique.⁽¹¹⁻¹³⁾

In 1978, Weilby^(14, 15) published an alternative technique that does not require bone tunnel creation at the base of the first metacarpal bone. In this procedure, the trapezium is removed, after which approximately one third of the FCR tendon is harvested and mobilized to its insertion on the second metacarpal base. Subsequently, the harvested tendon graft is used as a sling to wind together the abductor pollicis longus tendon and the remaining two thirds of the FCR tendon as a suspension and interposition arthroplasty. In 1988, Weilby⁽¹⁶⁾ reported

outcomes of the first 100 operated thumbs, of which 85% had complete pain relief. In 1987, Nylen et al.⁽¹⁷⁾ reported similar results with this technique. These now 20-year-old studies of the Weilby procedure are retrospective studies, and they do not include preoperative and postoperative subjective outcomes using validated questionnaires or preoperative and postoperative objective outcomes such as specific strength and range of motion (ROM) measurements. Therefore, we performed a prospective cohort study in which we analyzed preoperative and postoperative objective and subjective outcomes after Weilby interposition tendoplasty. We hypothesized that the Weilby technique, which does not require bone tunnel creation, is a reliable alternative to treat primary thumb carpometacarpal osteoarthritis. After this procedure, pain relief, stability, mobility and strength are obtained.

MATERIALS AND METHODS

Patients were enrolled in a prospective, single-arm study if they were diagnosed with primary thumb carpometacarpal osteoarthritis based on clinical and radiologic changes. The study was exempt from approval by the research review committee. Patients with rheumatoid or posttraumatic arthritis were excluded. Regardless of prior nonsurgical management such as splinting, exercise, physical therapy, treatment with nonsteroidal anti-inflammatory drugs, or intra-articular injections with steroids, all patients were initially treated with a removable splint for 3 months, and surgery was recommended only if the patient did not benefit from this management. None of the affected thumbs had been operated on previously, and none of the patients had a coexisting condition of the hand at the time of surgery. Indications for surgery were severe pain, loss of strength, and loss of motion of the base of the thumb causing marked disability during activities of daily living.

A power analysis showed that to achieve a power of 90%, a sample size of approximately 20 thumbs is recommended to detect a difference of 15.0 in the Disabilities of the Arm, Shoulder, and Hand (DASH) score with an estimated standard deviation of 20.0 and with a significance level (alpha) of .05 using a 2-sided 1-sample t-test. The difference of 15.0 and estimated standard deviation of 20 are based on a report by Gummesson et al.,⁽¹⁸⁾ who showed that a mean DASH score change of 15 discriminates between improved and unimproved subjects. Accordingly, Weilby interposition tendoplasty was performed on 20 thumbs of 19 consecutive patients (12 left and 8 right; 2 men and 17 women) in 2005 and 2006. All patients were right handed. The mean age was 58 years (range, 51–80 years). According to the radiographic criteria of Eaton and Glickel (1987),⁽¹⁹⁾ preoperatively 4 thumbs exhibited stage II primary osteoarthritis; 10 exhibited stage III; and 6 exhibited stage IV with scaphotrapezial involvement.

Surgical procedure

The Weilby interposition tendoplasties were all performed by a single surgeon and were based on the original reports of Weilby.⁽¹⁴⁻¹⁶⁾ Axillary block anesthesia was generally used, and surgeries were performed under tourniquet control. First, an incision was made along the radial border of the metacarpal of the thumb, after which the trapezium was removed. Great care was taken to avoid injury to the superficial radial nerve. A tendon strip about 10 cm in length and consisting of approximately one third of the width of the FCR tendon was dissected and tunneled to its insertion on the second metacarpal. This tendon graft was then intertwined in a figure-of-eight fashion (at least twice) around the abductor pollicis longus tendon and the rest of the FCR tendon, pulling those tendons together into the space created after excision of the trapezium bone. The figure-of-eight was locked by PDS 3-0 sutures (Ethicon Amersfoort, The Netherlands). The remaining tendon graft was wrapped upon itself as described by Carrol in 1987⁽²⁰⁾ and was interposed in the space left after the removal of the trapezium and pushed between the base of the first and second metacarpals. The joint capsule was closed, but K-wires were not inserted to stabilize the thumb. The thumb was immobilized in a spica cast for 4 weeks, after which the cast was replaced with a removable protective splint, and physiotherapy was started by a hand therapist.

Subjective assessment

The DASH outcome data collection instrument (Dutch Language Version) was used to evaluate preoperative and postoperative outcomes at 0, 3, 6, and 12 months. For further subjective assessment, all patients completed a nonvalidated specific personal questionnaire at 12 months of follow-up (Table 3.1).

Objective assessment

The following ROM measurements were assessed preoperatively and at 3, 6, and 12 months of follow-up: interphalangeal (IP) joint flexion/extension, metacarpophalangeal (MCP) joint flexion/extension, and carpometacarpal (CMC) joint palmar abduction (first web space) measured using the intermetacarpal distance in centimeters. To calculate the intermetacarpal distance, the thumb was placed in full palmar abduction, the easily identifiable mid-dorsal points on the subcutaneous surface of the first and second metacarpal heads were marked, and the separation between these was measured.⁽²¹⁾

Additional CMC joint opposition was measured using the Kapandji score (0 to 10), and CMC joint extension was measured in centimeters with the thumb in maximum radial abduction.

The strength measurements tip pinch strength, key pinch strength, and 3-point pinch strength were measured using a Baseline pinch gauge (Biometrics Ltd E-link H500 Hand Kit; Gwent, UK). The overall grip strength was measured using a Baseline hydraulic hand dynamometer (Biometrics Ltd E-link H500 Hand Kit).

All ROM and strength measurements were carried out by an independent hand therapist in accordance with a strict, well-defined, published protocol.^(21, 22)

All complications after surgery were registered in a separate database for a period of 12 months.

Statistical analysis

The changes from preoperative clinical evaluations at 12 months of follow-up for the various outcome measures were analyzed separately using a paired t-test. All tests were 2-sided, and differences were accepted as statistically significant with $p < .05$.

Table 3.1 Specific personal questionnaire

	Patients	%
Pain		
No pain	10	52.6
Seldom	5	26.3
After forceful activities	3	15.8
Rest pain	1	5.3
Night pain	0	0
Pain level		
Improved	17	89.5
Not improved	2	10.5
Worse	0	0
Willingness to have the surgery again under similar circumstances		
Yes	17	89.5
No	2	10.5
Overall satisfaction		
Excellent	9	47.4
Good	6	31.6
Acceptable	2	10.5
Fair	1	5.3
Poor	1	5.3

Percentages in categories may total more than 100% because of rounding.

RESULTS

Subjective outcomes

The mean preoperative DASH score was 51 (0 = no disability, 100 = maximum disability). At 3 months follow-up, the mean DASH score was 36, at 6 months it was 30.5, and at 12 months it was 30. The DASH score significantly improved ($p < .001$; Figure 3.1). Detailed values are given in Table 3.2.

The specific personal questionnaire at 12 months of follow-up showed that 17 of 19 patients had an improved pain level compared with that of the preoperative situation. Furthermore, 10 of 19 patients had complete pain relief, 5 patients reported no more than occasional ache, 3 patients reported mild pain with forceful activities, and 1 patient reported pain at rest. Seventeen of 19 patients responded that they would have the surgery again under similar circumstances. The results of the overall satisfaction rating showed that 9 of 19 patients had an excellent result, 6 patients had a good result, 2 patients had an acceptable result, 1 patient had a fair result, and 1 patient had a poor result. Detailed values are given in Table 3.1.

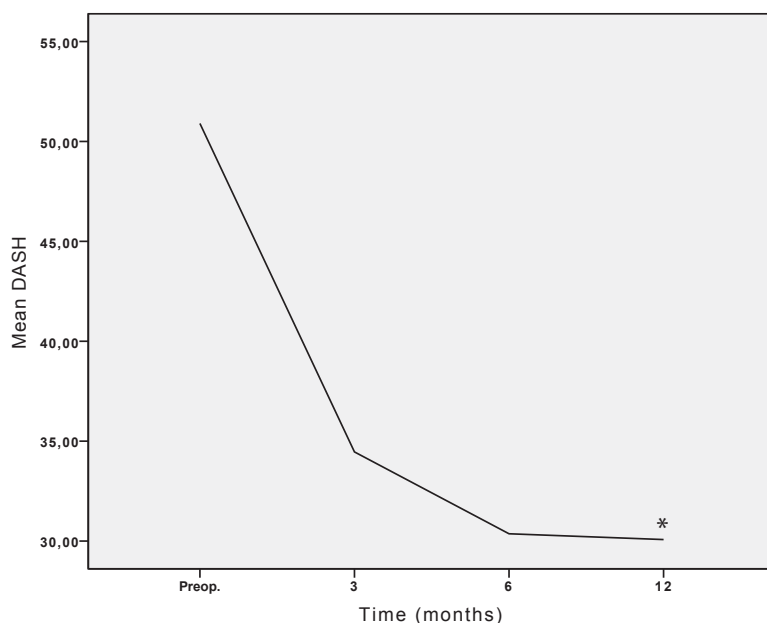


Figure 3.1 The mean preoperative DASH score was 51 (range, 21–72.5; SD, 14.8), 3 months postoperative was 36 (range, 1.6–59.1; SD, 17.1), 6 months postoperative was 30.5 (range, 1.6–62.5; SD, 16.7), and 12 months postoperative was 30 (range, 3–61; SD, 18.8). * Significantly improved value from preoperative clinical evaluations ($p < .001$).

Objective outcomes

Interphalangeal joint flexion/extension ($p = .972$; $p = .950$) and MCP joint flexion/extension ($p = .200$; $p = .545$) did not significantly change postoperatively. Preoperative CMC joint palmar abduction measured using the intermetacarpal distance was 5.4 cm. At 3 months of follow-up, the intermetacarpal distance had increased to 6.1 cm and at 6 months to 6.2 cm. At 12 months

Table 3.2 Analysis of the change in DASH score from preoperative clinical evaluations shows a significantly improved DASH ($p < .001$)

	Paired differences*				
	Mean	SD	SEM	95% confidence interval of the difference	
				Lower	Upper
DASH 0 to DASH 3	-14.93	9.63	2.27	-10.14	to -19.72
DASH 0 to DASH 6	-20.54	14.58	3.26	-13.71	to -27.36
DASH 0 to DASH 12	-20.83	20.09	4.49	-11.42	to -30.23

* Paired differences of the DASH scores. DASH 0 is mean DASH score preoperative, DASH 3 is mean DASH score at 3 months, DASH 6 is mean DASH score at 6 months, and DASH 12 is mean DASH score at 12 months.

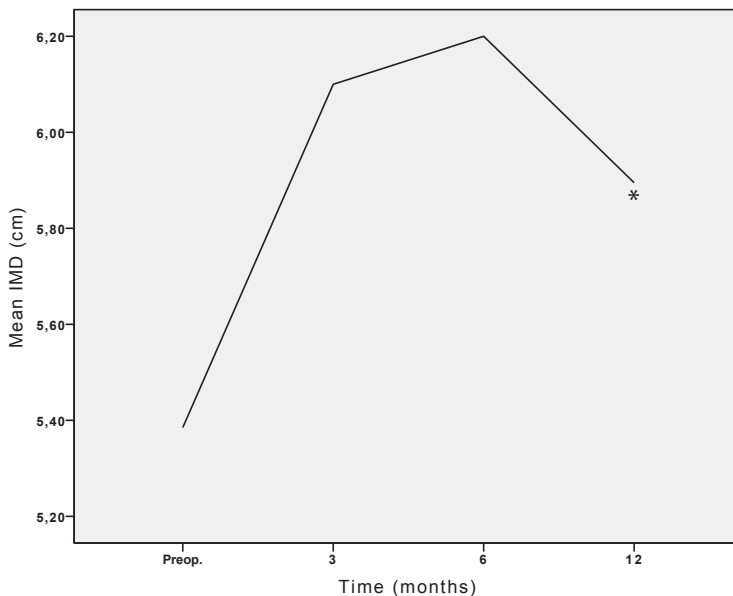


Figure 3.2 The mean preoperative intermetacarpal distance (cm) was 5.4 (range, 3.5–6.7; SD, 0.9), 3 months postoperative was 6.1 (range, 4.8–8.0; SD, 0.8), 6 months postoperative was 6.2 (range, 4.2–7.5; SD, 0.8), and 12 months postoperative was 5.9 (range, 4.0–7.0; SD, 0.7). * Significantly improved value from preoperative clinical evaluations ($p = .011$). IMD, intermetacarpal distance.

of follow-up, the intermetacarpal distance slightly decreased to 5.9 cm, but the net increase remained significant compared with the preoperative value ($p = .011$) (Figure 3.2, Table 3.3).

Preoperative thumb opposition measured using the Kapandji score was 8.3. The Kapandji score showed a significant improvement at 12 months of follow-up with a mean score of 9.2 ($p = .027$) (Figure 3.3, Table 3.3). Carpometacarpal extension did not change significantly ($p = .991$).

Table 3.3 Significantly improved objective outcomes at 12 months of follow-up

	Paired differences*					
	Mean	SD	SEM	95% confidence interval of the difference		p-value
				Lower	Upper	
IMD 0 to IMD 12	.51	.82	.18	.13	to .89	.011
Kapandji 0 to Kapandji 12	.85	1.59	.36	.11	to 1.59	.027
TPP 0 to TPP 12	.80	1.56	.35	.07	to 1.53	.034
OG 0 to OG 12	3.07	5.11	1.14	.68	to 5.46	.015

* Paired differences of the IMD (intermetacarpal distance), Kapandji score, TPP (3-point pinch strength), and OG (overall grip strength) at 12 months follow-up.

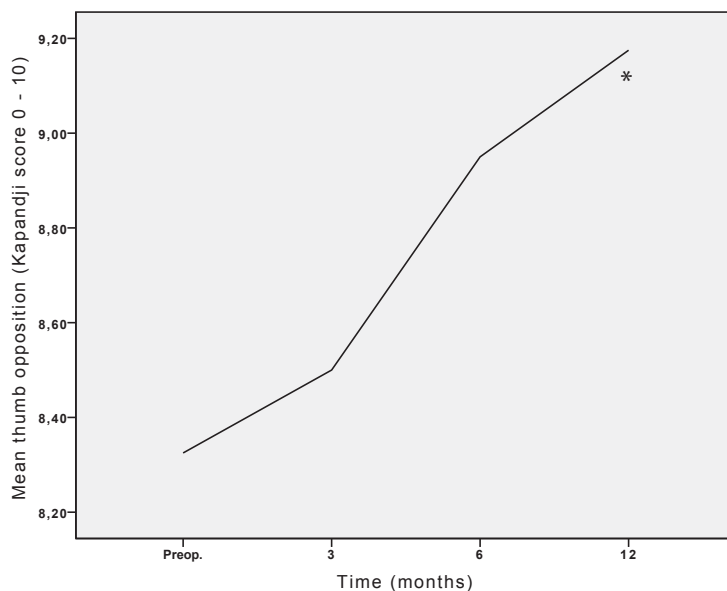


Figure 3.3 The mean preoperative thumb opposition (Kapandji score, 0–10) was 8.3 (range, 4–10; SD, 2.0), 3 months postoperative was 8.5 (range, 5–10; SD, 1.5), 6 months postoperative was 9.0 (range, 4–10; SD, 1.4), and 12 months postoperative was 9.2 (range, 8–10; SD, 0.8). * Significantly improved value from preoperative clinical evaluations ($p = .027$).

The strength measurements at 12 months of follow-up showed that the tip pinch strength increased but not significantly (mean preoperative = 4.3 kg; final follow-up = 4.4 kg; $p = .915$). The key pinch strength was increased as well, but also not significantly (mean preoperative = 5.3 kg; final follow-up = 5.6 kg; $p = .642$). The 3-point pinch strength was significantly improved at 12 months of follow-up, with a mean of 5.0 kg (preoperative 4.2 kg; $p = .034$) (Table 3.3). The overall grip strength was significantly improved at 12 months of follow-up, with a mean of 21.0 kg (preoperative 17.9 kg; $p = .015$) (Table 3.3). Figure 3.4 shows the tip pinch, key pinch, and the 3-point pinch strengths. Figure 3.5 shows the overall grip strength results.

Complications

Two patients experienced temporary paresthesia in the distribution of the superficial sensory branch of the radial nerve. One patient reported sensory loss of the palmar branch of the superficial radial nerve at the final follow-up, but this did not affect the patient's objective and

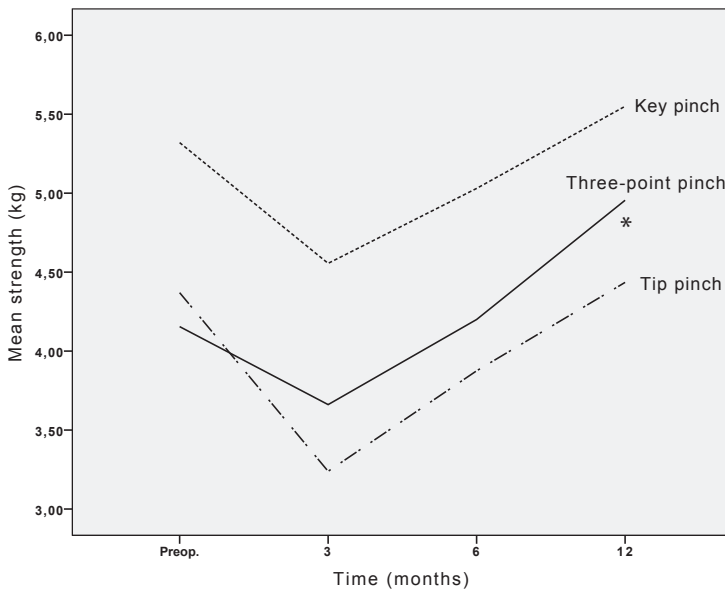


Figure 3.4 The mean tip pinch strength (kg) preoperatively was 4.3 (range, 1.0–12.5; SD, 4.14), 3 months postoperative was 3.2 (range, 0.8–6.6; SD, 1.47), 6 months postoperative was 3.9 (range, 1.3–9.0; SD, 1.67), and 12 months postoperative was 4.4 (range, 2.3–7.8; SD, 1.53). The key pinch strength (kg) preoperatively was 5.3 (range, 1.8–11.0; SD, 2.81), 3 months postoperative was 4.6 (range, 1.6–10.0; SD, 1.91), 6 months postoperative was 5.0 (range, 2.5–9.1; SD, 1.60), and 12 months postoperative was 5.6 (range, 3.1–7.6; SD, 1.21). The 3-point pinch strength (kg) preoperatively was 4.2 (range, 1.0–9.6; SD, 2.29), 3 months postoperative was 3.7 (range, 1.0–7.0; SD, 1.53), 6 months postoperative was 4.2 (range, 1.7–8.3; SD, 1.66), and 12 months postoperative was 5.0 (range, 2.7–7.3; SD, 1.36). * Significantly improved value from preoperative clinical evaluations ($p = .034$).

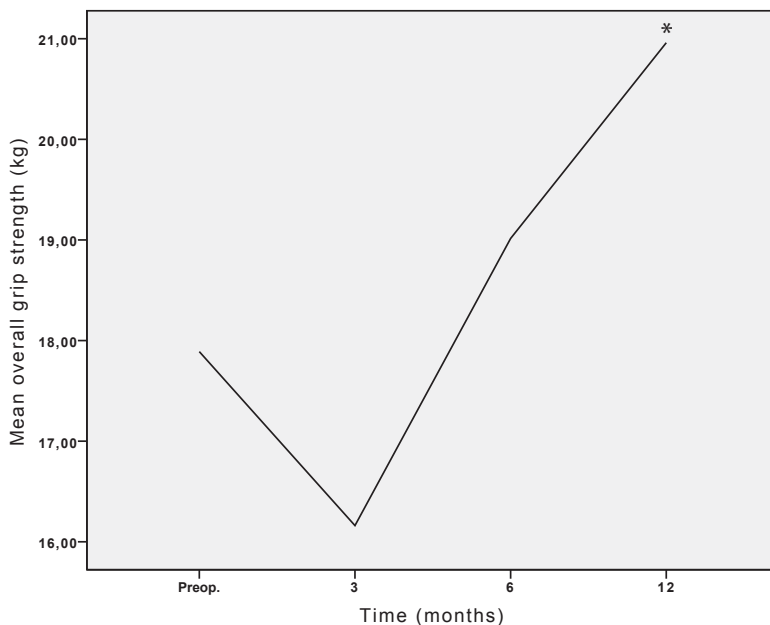


Figure 3.5 The mean overall grip strength (kg) preoperatively was 17.9 (range, 1.5–43.3; SD, 9.93), 3 months postoperative was 16.2 (range, 3.8–36.6; SD, 9.42), 6 months postoperative was 19.0 (range, 8.3–38.6; SD, 8.12), and 12 months postoperative was 21.0 (range, 11.5–40.6; SD, 7.91). * Significantly improved value from preoperative clinical evaluations ($p = .015$).

subjective outcomes. No reflex sympathetic dystrophy occurred during this study. One patient reported de Quervain's disorder, but the symptoms disappeared after an injection of steroids. Despite extensive conservative management and supervised hand therapy, 1 patient experienced pain at rest and impaired hand function at the 12-month examination. Radiographic analysis showed new radiocarpal degenerative changes in the wrist, which explained the impaired hand function; however, the patient declined further surgical management.

DISCUSSION

The earlier reports of the Weilby procedure were retrospective studies that did not include standardized outcome measures. The results in the study of Nylen et al.⁽¹⁷⁾ included overall satisfaction, pain relief, and return- to-work and complication rates.

The results in the study of Weilby⁽¹⁶⁾ included pain relief, ROM, and strength measurements compared with those of the contralateral thumb and complication rates. Our prospective cohort

study included preoperative and postoperative subjective outcomes assessed by the DASH score and a specific personal questionnaire. A study by De Smet et al.⁽²³⁾ showed the DASH score to be a valuable tool to evaluate the outcome of surgical treatment for osteoarthritis at the base of the thumb. Furthermore, our study includes preoperative and postoperative objective outcomes assessed by both specific ROM and strength measurements, as well as complication rates.

Analysis of the subjective outcomes of our patients showed a mean preoperative DASH score of 51 points. This is similar to the results of the study by De Smet,⁽²³⁾ who reported a mean DASH score of 47 points preoperatively in 15 patients with osteoarthritis at the base of the thumb. The postoperative DASH score in our study was significantly reduced compared with the preoperative value, with a mean score of 30 at the 12-month follow-up ($p < .001$). These results are similar to another study by De Smet et al.⁽²⁴⁾ that compared the outcomes of trapeziectomy without interposition or postoperative K-wire fixation versus trapeziectomy with ligament reconstruction and tendon interposition (i.e., Burton-Pelligrini technique) in a prospective study. The first group had a postoperative mean DASH score of 33 (range, 0–77; SD, 29.6), and the second had a DASH score of 27 (range, 0–94; SD, 22.8) with a mean follow-up of 34 months.⁽²⁴⁾ Our DASH score measurements were also decreased at 3 and 6 months of follow-up. As reported by Gummesson et al.⁽¹⁸⁾, a mean DASH score change of 15 discriminates between improved and unimproved subjects. The mean DASH score change in the current study was 15 points at 3 months of follow-up, 20.5 points at 6 months of follow-up, and 21 points at 12 months of follow-up (Table 3.2), which implies a significant improvement in perceived functional disability as early as 3 months ($p < .001$).

The results of the analysis of the specific personal questionnaire showed that 79% of the patients reported no more than an occasional ache, and 16% reported mild pain only with forceful activities. Only 1 patient had pain at rest (5%). These values are consistent with findings of the 1988 study of Weilby⁽¹⁶⁾, who reported that 85% of patients became free of pain and 15% had symptoms after strenuous work. Our results also showed that 90% of our patients were satisfied with the procedure (90% would have the surgery again; 90% had an improved pain level; 90% rated their overall satisfaction as excellent, good, or acceptable). Nylen et al.⁽¹⁷⁾ reported that only 73% of their patients were satisfied with the Weilby procedure; 27% were not. Our patient-satisfaction rating of 90% compares favorably with that of Nylen et al.⁽¹⁷⁾ and is in line with those reported by randomized controlled studies of the more commonly performed Burton-Pelligrini technique (De Smet et al.⁽²⁴⁾ reported 90% patient satisfaction; Kriegs-Au et al.⁽¹³⁾ reported 85%).

Measurement of the CMC joint palmar abduction (first web space) in most studies was done by determining the thumb web space simply by measuring angles. We used the intermetacarpal distance because a study by Murugkar et al.⁽²¹⁾ reported that the inter-rater reliability of the intermetacarpal distance is higher than that of angle measurements. The results of the intermetacarpal distance in our study showed that the first web space was significantly improved at 12 months of follow-up (mean intermetacarpal distance increased by 10%; $p = .011$). Measurements of thumb opposition using the Kapandji score demonstrated that CMC opposition was also significantly improved at 12 months (mean Kapandji score = 9.2, and 17 of 20 thumbs (85%) were able to touch the palmar crease of the little finger with the thumb tip; $p = .027$). Range-of-motion measurements in a randomized controlled study by Kriegs-Au et al.⁽¹³⁾ with a mean follow-up of 48 months showed in the Burton-Pelligrini technique group an improvement of the first web space of approximately 16% (using angle measurement), and only 9 of 16 thumbs (56%) were able to touch the palmar crease of the little finger with the thumb tip.

In the current study, strength measurements showed that both tip pinch and key pinch strength were increased and that 3-point pinch and overall grip strength were significantly increased postoperatively at 12 months compared with that at preoperative evaluations ($p = .034$; $p = .015$). A recent, randomized controlled study by Field and Buchanan⁽²⁵⁾ showed in their Burton-Pelligrini technique group at 12 months of follow-up a tip pinch strength, a key pinch strength, and an overall grip strength of 3.8, 4.9, and 22.0 kg, respectively (the corresponding values in our study were 4.4, 5.6, and 21.0 kg).

At 3 months follow-up of our patients' strength measurements (tip pinch, key pinch, 3-point pinch, and overall grip) showed decreased values compared with the preoperative values (Figures 3.4, 3.5). After the third month, the strength increased, and at the 12-month follow-up all of the strength measurements had improved from the preoperative evaluations. Although the strength measurements were decreased at 3 months, the DASH score after 3 months had improved by 15 points. As noted above, because a mean DASH score change of 15 points discriminates between improved and unimproved subjects⁽²⁵⁾, the observed reductions in strength measurements did not affect the patients' subjective outcomes after 3 months.

The complication rate we observed over the 12-month study period is consistent with those of the studies of Field et al.⁽²³⁾ and Kriegs-Au et al.⁽¹³⁾ (Burton-Pelligrini technique). Those authors also noted temporary paresthesia in the distribution of the superficial sensory branch of the radial nerve. Furthermore, they reported a few patients with severe reflex sympathetic dystrophy that sometimes resulted in impaired hand function at the final follow-up. In our study, one patient had impaired hand function at the 12-month follow-up caused by radiocarpal

degenerative changes. Our complication rates compare favorably with the earlier study of Nylen et al.⁽¹⁷⁾ (Weilby procedure). They reported 15 complications of surgery in 89 arthroplasties (5 patients had reflex sympathetic dystrophy, 2 patients had transient edema, 1 patient had trigger thumb, 3 patients had carpal tunnel compression, and 4 patients had loss of first metacarpal abduction).⁽¹⁷⁾ Weilby⁽¹⁶⁾ reported that 7% of his patients developed de Quervain's disorder and suggested that a routine release of the first extensor compartment during the procedure could prevent de Quervain's disorder. We do not recommend this because we observed only one episode of de Quervain's disorder after 12 months of follow-up, and it responded very well to an injection of steroids.

A limitation of the current study is that it had only a single arm. Therefore, we compared our results by reviewing the literature. Furthermore, our study had a relatively short follow-up of 12 months, and additional prospective randomized studies with longer follow-up periods are needed.

Based on the results of this study, we conclude that the Weilby procedure is a reliable alternative technique that avoids bone tunnel creation with results similar to those reported for the more commonly performed Burton-Pellegrini technique.

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**Trapeziometacarpal arthrodesis or
trapeziectomy with ligament reconstruction
in primary trapeziometacarpal osteoarthritis:
A randomized controlled trial**

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ABSTRACT

Background: While both trapeziectomy with ligament reconstruction and tendon interposition (LRTI) and trapeziometacarpal arthrodesis are commonly performed procedures for the treatment of trapeziometacarpal osteoarthritis, there is a lack of prospective studies with adequate follow up comparing these techniques. The purpose of this study was to compare the outcomes of both treatments for symptomatic osteoarthritis of the thumb trapeziometacarpal joint in a randomized trial.

Methods: Women aged 40 years or older were randomized to either trapeziectomy with LRTI or arthrodesis with plate and screws. Patients were evaluated preoperatively and postoperatively at 3 and 12 months by assessing pain, function (PRWHE and DASH questionnaires), ROM, strength, complication rate, and patients were asked if they would have the same surgery again under the same circumstances.

Results: Forty-three patients were enrolled in this study. Since we found significantly more moderate and severe complications following arthrodesis compared to trapeziectomy with LRTI (71% vs 29%, $p = .016$) the study was prematurely terminated before the sample size necessary to validly compare the two groups was reached. The higher complication rate for arthrodesis led to an increase in revision surgery (2/17). In addition, significantly more patients in the LRTI group (86%) would consider the same surgery again under the same circumstances as compared to the arthrodesis group (53%) ($p = .025$). In both groups, PRWHE and DASH scores significantly improved over time, but comparing both groups results were highly similar.

Conclusions: Women age 40 and over with trapeziometacarpal osteoarthritis have fewer moderate and severe complications after trapeziectomy with LRTI and are more likely to consider the surgery again under the same circumstances than those who undergo arthrodesis. Furthermore, 12 months after surgery, PRWHE and DASH scores were similar in both groups. Based on these results, we do not recommend routine use of arthrodesis with plate and screws in the treatment of women age 40 and over with stage II and III trapeziometacarpal osteoarthritis.

Evidence: Level I.

INTRODUCTION

Primary osteoarthritis (OA) of the trapeziometacarpal (TMC) joint is common, particularly in women in the fifth to seventh decade of life.^(1, 2) In a recent review of the literature⁽³⁾ we concluded no evidence is available that any surgical procedure to treat this condition is superior over another in terms of pain, function, satisfaction, range of motion (ROM), or strength. However, given the lack of high level randomized clinical trials (RCTs) on some of the reviewed procedures, we postulated there could be differences between the various surgical procedures, which warrants further research. This statement is particularly based on promising but inconsistent results in studies with less methodological quality of TMC arthrodesis⁽⁴⁻⁸⁾ and total joint prostheses.⁽⁹⁻¹¹⁾

Therefore, we conducted a RCT of arthrodesis using plate and screws compared to trapeziectomy with ligament reconstruction and tendon interposition (LRTI) in women age 40 and over with primary OA of the TMC joint. We hypothesize that, based on the fact complications and repeat surgeries are more frequent following arthrodesis in studies with limited evidence,⁽⁶⁻⁸⁾ women age 40 and over following trapeziectomy with LRTI would show better outcomes and better patient global assessment after 12 months.

METHODS

Participants

After approval of the scientific committee, patients with impaired function, which failed to improve after nonsurgical treatment, and who had stage II or III primary OA of the TMC joint (Eaton and Glickel classification)⁽¹²⁾ were enrolled in a RCT (single-centre, single-blind, parallel-group study). Four X-rays (posterior-anterior, lateral, oblique and Bett's view) were used and an independent radiologist determined the disease stage. To obtain a homogeneous group of primary OA patients, all subjects were women aged 40 years or older with unilateral or bilateral primary OA; this is a common strategy to increase the homogeneity of a study population. Men, people with previous thumb surgery and people with rheumatoid or posttraumatic OA were excluded.

The study was conducted in the Department of Hand and Wrist Surgery, Diaconessenhuis Zeist, the Netherlands. Subjects were randomly allocated for treatment with either trapeziectomy with LRTI or TMC arthrodesis.

Randomization

For equal distribution of subjects between type of surgery and surgeon, software randomly assigned subject numbers to a treatment group and a surgeon using balanced block sizes of 20 subjects. Sequentially numbered envelopes containing the assignment were used. After inclusion and informed consent, subjects were assigned to the next envelope and therefore to a treatment group and a surgeon. Two European board certified hand surgeons performed all surgeries.

Surgical procedures

The ligament reconstruction of the trapeziectomy with LRTI procedure was based on the original reports of Weilby that does not require a bone tunnel.^(13–15) The procedure was modified by adding a tendon interposition, as described by Burton and Pellegrini.⁽¹⁶⁾ Vermeulen et al. described that this is a reliable technique to treat primary OA and shows similar results to the more commonly performed LRTI techniques with a bone tunnel at the base of the first metacarpal.⁽¹⁷⁾ First, an incision was made along the radial border of the first metacarpal, after which the trapezium was removed. A tendon graft about 10 cm in length and consisting of one third of the flexor carpi radialis (FCR) tendon width was dissected and tunneled to its insertion on the second metacarpal. This tendon graft was then intertwined in a figure-of-eight fashion (at least twice) around the abductor pollicis longus tendon and the rest of the FCR tendon, pulling those tendons together into the space created after trapeziectomy. The figure-of-eight was locked by PDS 3-0 sutures (Ethicon Amersfoort, The Netherlands). The remaining tendon graft was wrapped upon itself and interposed in the trapezial space⁽¹⁸⁾ and the joint capsule was closed. The thumb was immobilized in a spica cast for 4 weeks, after which the cast was replaced by a removable protective splint and a hand therapist started standardized hand therapy. The therapy was focused on reducing edema and regaining functionality by increasing mobility and stability. Thumb strengthening was initiated when patient could tolerate this, which was generally between 4 and 6 weeks after surgery.

The arthrodesis was performed with plate and screws by a dorsal approach. Exposure of the TMC joint was performed by splitting the interval between the extensor pollicis brevis and extensor pollicis longus tendons. The joint capsule was elevated and the joint was exposed. After the correct position of the arthrodesis was determined the opposing articular surfaces were denuded to cancellous bone using an oscillating saw. The correct position of the arthrodesis was such that the distal phalanx of the thumb rested on the middle phalanx of the index finger of a clenched fist, as described by Leach and Bolton.^(5, 19) Next, the joint was stabilized and compressed by using 2.3 mm screws and a T-plate (Leibinger non-locking plate; Stryker/

Germany). Bone grafts or inter-fragmentary screws were not used during the procedure. The Arthrodesis group received the same immobilization period and standardized hand therapy compared to the trapeziectomy with LRTI group, except that strengthening exercises were started after union was confirmed by X-ray generally between 6 and 8 weeks after surgery.

Primary outcomes

Our primary outcome measure for pain and physical function was the patient rated wrist/hand evaluation (PRWHE) (Dutch Language Version) questionnaire (0 = no pain and able to do activities – 100 = worst pain and unable to do activities).⁽²⁰⁾ The questionnaire has two sub scores for pain and function and a total score. The PRWHE is a wrist and hand specific questionnaire with items about the affected wrist and hand alone. The more frequently used DASH questionnaire, on the contrary, has an upper limb specific character and is not only specified for the affected hand. A report of MacDermid and Tottenham showed that the PRWHE questionnaire is more responsive in detecting clinical changes over time compared to the DASH.⁽²¹⁾ Subjects were evaluated preoperatively, and postoperatively at 3 and 12 months.

Secondary outcomes

For comparison with current literature, the DASH questionnaire (Dutch Language Version) was also used (0 = no disability – 100 = severe disability).⁽²²⁾ Subjects were evaluated preoperatively, and postoperatively at 3 and 12 months.

In addition, at 12 months, we asked the subject if she would have the same surgery again under the same circumstances. Furthermore, we registered how many weeks after surgery subjects returned to work or normal daily life activities.

All complications were registered for a period of 12 months and were divided in 3 categories: (1) mild, (2) moderate, and (3) severe. Mild complications were defined as complications with a minor clinical relevance, such as scar tenderness or sensory disturbances. We defined moderate complications as clinically relevant complications that were delaying patients' recovery, but not needing revision surgery and that were resolved 12 months after surgery. Examples are delayed union (bone healing between 3 and 6 months confirmed by X-ray), mild complex regional pain syndrome (CRPS) type I, tendinitis, and neuromas treated with cortisone steroid injections. Severe complications were defined as complications that resulted in revision surgery, pain at rest or impaired hand function at the 12-month examination. Examples are nonunion (failure of bone healing within 6 months confirmed by X-ray) and severe CRPS type I, or tendinitis and neuromas that did not improve with steroids and were treated with surgery.

Additionally, we evaluated the following active ROM measurements preoperatively and at 3 and 12 months: interphalangeal (IP) joint flexion/extension, metacarpophalangeal (MCP) joint flexion/extension, and carpometacarpal (CMC) joint palmar abduction (first web space) measured using the intermetacarpal distance (IMD). To calculate the IMD, the thumb was placed in full palmar abduction, the easily identifiable mid-dorsal points on the subcutaneous surface of the first and second metacarpal heads were marked, and the separation between these was measured in millimeters.⁽²³⁾ Furthermore, CMC joint opposition was measured using the Kapandji score (1 to 10: 1 = the thumb reaches the lateral side of the second phalanx of the index finger, 10 = the thumb reaches the distal volar crease of the hand).⁽²⁴⁾ The strength measurements tip pinch, key pinch, and 3-point pinch strength were measured using a baseline pinch gauge. The overall grip strength was measured using a baseline hydraulic hand dynamometer (Biometrics Ltd E-link H500 Hand Kit; Gwent, UK). The mean of three measurements was recorded as an outcome variable. All ROM and strength measurements were performed by independent and blinded hand therapists in accordance with a strict and published-protocol.^(23, 25)

Sample size

Estimating the appropriate sample size to achieve a power of 80%, approximately 45 subjects per group was needed to detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level. The clinically relevant difference of 15 points (SD 25) was based on a report by MacDermid and Tottenham.⁽²¹⁾

Statistical methods

To test the study hypothesis, a generalized estimated equations approach was used. Under the assumption that missing data are random and not due to group allocation or treatment effect, this model estimates missing data values, thereby allowing the use of data from all participants, irrespective of whether they were measured at all time points. Each outcome measure was used as a separate response variable, and group (trapeziectomy with LRTI vs TMC Arthrodesis) and time (baseline vs 3 months post-operative vs 12 months post-operative) were inserted in the model as predictors. The interaction of group and time was used to determine the efficacy of the intervention, since a significant interaction effect of group and time indicates that the change over time was significantly different between both groups. The threshold for significance was set at .05.

Comparison of number of weeks before subjects returned to work or normal daily life activities were analyzed with a Mann-Whitney test. All complications and the question if subjects would have the same surgery under the same circumstances were analyzed with a Chi-Square test.

Because the study was prematurely terminated, sufficient power was not reached for most primary and secondary outcomes. Accordingly, we were not allowed to make a statistical comparison because the target sample size to ensure adequate power was not reached for most outcome measures. Therefore, most between-group comparison data is reported without p-values. Only in case outcome measures did reached statistical significance, p-values will be provided (see results section).

Registration

Trail number: NTR 1353.

Funding

This research received no funding.

RESULTS

Forty-three consecutive subjects were enrolled in this study conducted between 2008 and 2011. Figures 4.1 and 4.2 show the postoperative oblique X-rays for both surgical procedures.



Figure 4.1 Postoperative oblique X-ray of trapeziectomy with LRTI procedure.



Figure 4.2 Postoperative oblique X-ray of arthrodesis with plate and screws.

Due to a significant difference in moderate and severe complications between the 2 groups, the study was prematurely terminated before the appropriate estimated sample size ($n = 90$) was reached. As a result, sufficient power was not reached for most primary and secondary outcomes. Table 4.1 presents baseline characteristics in both groups. Figure 4.3 shows the flow chart of the study in which no subjects were lost to follow-up.

Complications

Table 4.2 presents all complications registered during 12 months. Six complications were observed in the trapeziectomy with LRTI group, of which 3 mild, 3 moderate, and no severe, compared to 15 complications in the arthrodesis group, of which 6 mild, 6 moderate, and 3 severe. Between-group comparison indicated significantly more moderate and severe complications following arthrodesis ($p = .016$). The 3 severe complications in the arthrodesis group consisted of 2 subjects with symptomatic nonunion without broken or loose hardware requiring revision surgery. The subject with severe CRPS I had pain at rest and impaired hand function at the 12-month examination.

Functional outcome

Comparing baseline measurements to the 3 and 12 months follow-up in both groups PRWHE pain (for all comparisons, $p < .001$), PRWHE activities ($p < .007$), PRWHE total ($p < .001$), and

Table 4.1 Baseline characteristics in both groups

Characteristics	Trapeziectomy + LRTI	Arthrodesis
No. of patients	21	17
Age (years) [†]	59 ± 6.3	59 ± 6.0
Dominance		
Right	18	17
Left	3	0
Operated hand		
Right	9	9
Left	12	8
Dominant is operated hand (%)	47	53
Classification		
Stage II	7	6
Stage III	14	11

[†] Mean (± SE).

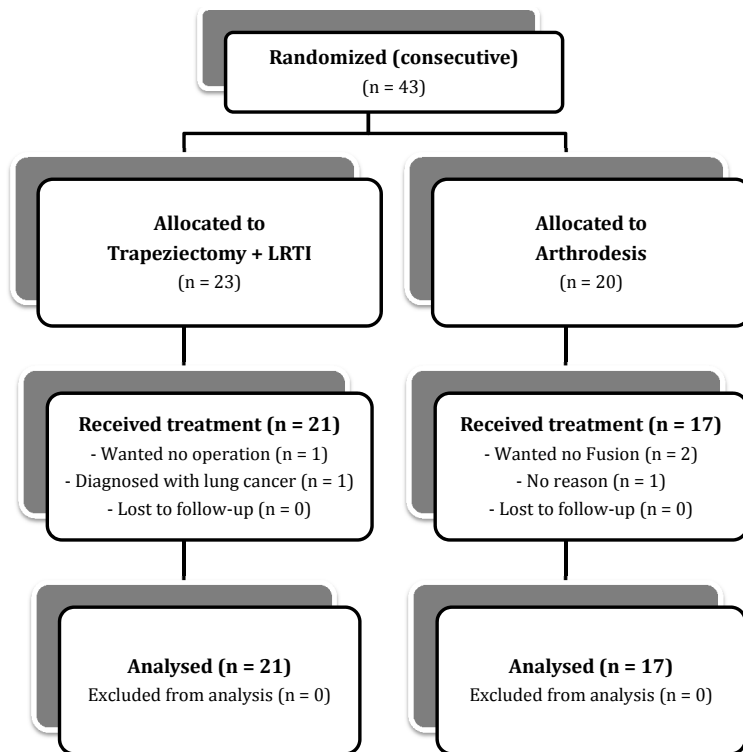


Figure 4.3 Flow chart of the selection, inclusion and drop-outs of the study.

Table 4.2 Complications recorded in both groups, grouped into mild, moderate, and severe

	Trap + LRTI	Arthrodesis
Mild		
Scar tenderness		3
Sensory disturbances	3	3
Moderate		
Tendinitis successfully treated with steroids	2	
Neuroma successfully treated with steroids		2
Delayed union		3
Mild CRPS type I	1	1
Severe		
Tendinitis requiring additional surgery		
Neuroma requiring additional surgery		
Nonunion requiring additional surgery		2
CRPS type I		1
Total: n (% of 21 complications in total)	6 (29%)	15 (71%)

Significant difference in moderate and severe complications between the groups ($p = .016$).

the DASH ($p < .046$) all significantly improved. Between-group comparisons of the change scores from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) after surgery showed highly similar results in improvement in both groups (Table 4.3; no p -values reported due to insufficient statistical power).

IP flexion/extension and palmar abduction (IMD) did not significantly change over time in both groups. MCP flexion significantly decreased ($p < .031$) and the MCP extension significantly

Table 4.3 Mean (\pm SE) scores on the clinical outcome measures

		Baseline	3 months	12 months
Questionnaires				
PRWHE Pain (0-50)	Trap + LRTI	33.9 \pm 2.1	21 \pm 2.5	16 \pm 2.7
	Arthrodesis	39.5 \pm 1.7	19.7 \pm 3.7	19.9 \pm 3.9
PRWHE Activities (0-50)	Trap + LRTI	28.8 \pm 2.2	19.0 \pm 2.5	11.2 \pm 2.2
	Arthrodesis	34.9 \pm 2.1	19.4 \pm 3.4	17.7 \pm 4.3
PRWHE Total (0-100)	Trap + LRTI	62.6 \pm 4.1	39.7 \pm 4.8	27.1 \pm 4.8
	Arthrodesis	74.4 \pm 3.4	39.1 \pm 6.8	37.5 \pm 8.1
DASH (0-100)	Trap + LRTI	44.3 \pm 3.3	31.5 \pm 3.3	20.6 \pm 3.0
	Arthrodesis	33.9 \pm 2.1	33.9 \pm 2.2	33.9 \pm 2.3
Active ROM				
Flexion IP ($^{\circ}$)	Trap + LRTI	65.1 \pm 2.3	61.3 \pm 1.9	65.0 \pm 1.9
	Arthrodesis	64.5 \pm 3.7	62.6 \pm 1.9	62.4 \pm 3.7
Extension IP ($^{\circ}$)	Trap + LRTI	-15.3 \pm 3.7	-14.0 \pm 3.9	-20.1 \pm 4.1
	Arthrodesis	-14.1 \pm 3.9	-11.8 \pm 3.8	-16.3 \pm 6.1
Flexion MCP ($^{\circ}$)	Trap + LRTI	45.3 \pm 3.8	34.0 \pm 2.4	37.9 \pm 2.3
	Arthrodesis	50.1 \pm 2.4	41.3 \pm 1.9	42.4 \pm 4.2
Extension MCP ($^{\circ}$)	Trap + LRTI	-6.7 \pm 3.1	-15.6 \pm 2.9	-16.1 \pm 2.8
	Arthrodesis	-7.2 \pm 4.1	-16.7 \pm 2.8	-19.3 \pm 4.1
Palmar abduction (IMD) (mm)	Trap + LRTI	60.3 \pm 1.4	58.1 \pm 1.3	58.6 \pm 2.1
	Arthrodesis	52.3 \pm 1.9	55.1 \pm 1.8	55.0 \pm 2.0
Kapandji (0-10)	Trap + LRTI	9.1 \pm 0.3	7.7 \pm 0.4	9.1 \pm 0.2
	Arthrodesis	8.6 \pm 0.4	7.1 \pm 0.5	7.3 \pm 0.8
Strength				
Grip strength (Kg)	Trap + LRTI	21.2 \pm 1.1	15.0 \pm 1.2	23.2 \pm 1.1
	Arthrodesis	15.8 \pm 2.1	14.6 \pm 1.3	18.7 \pm 3.9
Tip-pinch (Kg)	Trap + LRTI	2.8 \pm 0.2	2.3 \pm 0.2	3.1 \pm 0.3
	Arthrodesis	2.2 \pm 0.3	2.3 \pm 0.4	3.3 \pm 0.6
3-point-pinch (Kg)	Trap + LRTI	3.7 \pm 0.3	2.6 \pm 0.3	3.7 \pm 0.3
	Arthrodesis	2.9 \pm 0.4	3.1 \pm 0.5	3.8 \pm 0.5
Key-pinch (Kg)	Trap + LRTI	4.8 \pm 0.4	2.9 \pm 0.2	4.4 \pm 0.3
	Arthrodesis	3.7 \pm 0.5	3.9 \pm 0.4	4.3 \pm 0.5

P -values of between-group comparisons of the change scores from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) are not reported due to insufficient statistical power.

increased compared to baseline measurements ($p < .013$) in both groups. Furthermore, Kapandji scores in both groups were significantly lower at 3 months ($p < .006$) but return to baseline values at 12 months. Between-group comparisons of the change scores in all active ROM measurements from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) showed highly similar results in both groups (Table 4.3; no p-values reported due to insufficient statistical power).

The tip pinch strength did not significantly change over time in both groups. Overall grip, 3-point pinch, and key-pinch strength were all significantly decreased at 3 months ($p < .011$) but returned to baseline value at 12 months in the trapeziectomy with LRTI group. The arthrodesis group showed no significant change over time. Between-group comparisons of the change scores in overall grip and key pinch strength from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) showed highly similar results in both groups (Table 4.3; no p-values reported due to insufficient statistical power).

When we asked the subjects if they considered the surgery again under the same circumstances, 18 of 21 subjects (86%) in the trapeziectomy with LRTI group responded with yes compared to only 9 of 17 subjects (53%) in the arthrodesis group. This is a significant difference ($p = .025$) in favor of the trapeziectomy with LRTI group.

Subjects following trapeziectomy with LRTI returned to work after 12.7 (SD 6.3) weeks and subjects with an arthrodesis 10.6 (SD 5.7) weeks after surgery.

DISCUSSION

The main finding of this study was that, for women aged 40 and over, arthrodesis results in significantly more moderate and severe complications compared to trapeziectomy with LRTI, leading to more frequent revision surgery. Based on this secondary outcome measure, we decided to terminate the study prematurely. Accordingly, sufficient power was not reached for most primary and secondary outcome measures and findings for these outcome measures should be evaluated keeping this in mind. Our primary outcomes showed that in both groups PRWHE and DASH scores significantly improved over time, while changes between both groups were highly similar. Furthermore, we observed a significant difference in favor of the trapeziectomy with LRTI group if we asked the patients if they considered the surgery again under the same circumstances.

Although it is generally assumed that trapeziectomy with LRTI results in a more mobile thumb compared to arthrodesis,⁽²⁶⁾ analysis of the ROM measurements showed highly similar results

in both groups. Furthermore, in both groups, MCP flexion was significantly reduced while MCP extension was significantly increased at 12 months, indicating that both techniques could not prevent MCP hyperextension. This finding may be explained in the LRTI group by a stable platform being removed during excision of the trapezium. However, this would not be predicted after arthrodesis. Apparently, the inability to extend the TMC joint after fusion is compensated with hyperextension of the MCP joint. The between-group comparisons of the strength measurements revealed highly similar results at 12 months follow-up, which is consistent with other reports.^(7, 27, 28) Our findings therefore do not support the argument that patients after TMC arthrodesis have a better strength compared to other techniques.^(5, 29)

Despite the fact that this study is the first level I single-centre, single-blind randomized trial comparing TMC arthrodesis to trapeziectomy with LRTI, there are some limitations. An important limitation is that we did not include the full number of subjects that we originally estimated as necessary to achieve statistical power. As a result most primary and secondary outcome measures were underpowered due to which we did not report p-values for these comparisons. During the inclusion of this study, the surgeons, who were not blinded to treatment allocation, reported to observe more complications following arthrodesis. Therefore, an independent statistician performed an early statistical analysis of the complications, indicating a significantly higher complication rate in the arthrodesis group. Because these moderate and severe complications resulted in more revision surgeries, we decided to terminate the study. Another limitation is that, although we attempted to blind the hand therapists, some of the more experienced hand therapist, performing the ROM and strength measurements, may have derived the surgical procedure that was performed due to the difference in scar between the procedures. Additionally, the results of this study are mainly applicable to arthrodesis performed with plate and screws and are not generalizable to other techniques of arthrodesis compared with other arthroplasty techniques. Because we studied a homogenous group of women aged 40 and over with primary OA, our results may not apply to men, or to people with rheumatoid or posttraumatic osteoarthritis.

The results of previous comparative studies on arthrodesis in the treatment of TMC OA are of limited methodological quality (most are comparative retrospective studies^(4-8, 27-30) and only one level II RCT⁽²⁶⁾) and showed inconsistent outcomes. The level II RCT⁽²⁶⁾ compared TMC arthrodesis to trapeziectomy with LRTI and found, in line with our study, no significant difference in pain and function at final follow-up (mean 6.8 years), only palmar and radial abduction was significantly better in the trapeziectomy with LRTI group. Complications were described, but not statistically analyzed. The authors concluded that they reserve arthrodesis for younger active patients and trapeziectomy with LRTI for older patients, without data to support

this claim. Additionally, Wajon et al.⁽³¹⁾ reported on this RCT that the statistical significance of these scores were unclear, as standard deviations were not provided for statistical analysis. The findings on adverse effects in previous literature showed that average nonunion rates are ranging from 8 to 21%.⁽⁵⁻⁸⁾ This is similar with our results in which 2 of 17 (12%) subjects had a nonunion. In this study, none of the subjects who had a delayed union or nonunion smoked. Another noticeable study was performed by Hartigan et al.,⁽⁵⁾ who retrospectively compared arthrodesis with trapeziectomy with LRTI and showed that results were similar for pain and function. In line with other reports on complication rates,^(6,7) they found more complications and revision surgeries following arthrodesis compared to trapeziectomy with LRTI. Nevertheless, that did not affect patients' global assessment. In our study, however, we observed significantly more moderate and severe complications in the arthrodesis group that did affect patients' global assessment, because subjects following arthrodesis were less likely to consider the surgery again under the same circumstances.

In summary, this RCT showed significantly more moderate and severe complications following TMC arthrodesis compared to trapeziectomy with LRTI, leading to more frequent revision surgery and the premature termination of the study. Because of the premature termination, most primary and secondary outcomes were underpowered. Nevertheless, the findings showed that subjects after trapeziectomy with LRTI were more likely to consider the surgery again under the same circumstances and have fewer moderate and severe complications compared to subjects treated with arthrodesis 12 months after surgery, while PRWHE and DASH scores are similar. Therefore, we do not recommend routine use of arthrodesis with plate and screws in the treatment of stage II or III TMC OA in women age 40 and over.

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**Trapeziectomy or total joint
arthroplasty in primary thumb
carpometacarpal osteoarthritis:
A randomized controlled trial**

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Submitted.

ABSTRACT

Purpose: The purpose of this study was to determine which surgical procedure, trapeziectomy without ligament reconstruction and/or tendon interposition or total joint arthroplasty, results in better outcomes in patients diagnosed with primary thumb carpometacarpal osteoarthritis.

Methods: A randomized controlled trial was performed. Women aged 40 years and over, diagnosed with stage II or III primary thumb carpometacarpal osteoarthritis were enrolled in this study. Patients were randomized to either trapeziectomy or total joint arthroplasty (second generation cemented Guepar prosthesis). Primary outcome measure was the Patient Rated Wrist/Hand Evaluation questionnaire (PRWHE). Secondary outcome measures were the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH), patient satisfaction, grip- and pinch force, active range of motion and complications. Patients were evaluated preoperatively and postoperatively at 3 and 12 months.

Results: Fifty-five patients were enrolled in this study. Twenty-six patients underwent trapeziectomy and 29 patients total joint arthroplasty. Since the manufacturer has stopped the production of the TJA the study was prematurely terminated. Although in both groups the PRWHE scores significantly improved over time, there was no significant difference between both groups. Three month after surgery the total joint arthroplasty group was significantly more improved with respect to key- and three-point pinch, and IP extension compared to the trapeziectomy group. One year after surgery the total joint arthroplasty group showed a statistically significant greater improvement on DASH and key-pinch force compared to the trapeziectomy group. Furthermore, no significant difference in complications between both groups was observed.

Conclusions: Although differences are small, this study suggests that patients treated with total joint arthroplasty may have better (functional) outcomes 1 year after surgery compared to patients treated with trapeziectomy. However, long-term results are warranted to evaluate subjective and objective outcomes and implant failure rates over the years.

Type of study/level of evidence: Randomized controlled trial / therapeutic, level I.

INTRODUCTION

Osteoarthritis (OA) of the carpometacarpal joint of the thumb (CMC-I) is the second most common location of degenerative joint disease of the hand⁽¹⁾ and mostly affects middle-aged women.⁽²⁾ Symptoms such as severe pain, instability and weakness are accompanied by loss of manual abilities. Several surgical procedures have been described for the treatment of primary thumb CMC OA.

Although trapeziectomy without ligament reconstruction and tendon interposition (LRTI) is associated with fewer side effects compared to other procedures, several systematic reviews report that none of these procedures has proven to be superior.⁽³⁻⁵⁾ Moreover, the disadvantages of trapeziectomy are instability, loss of thumb strength,⁽⁶⁻⁸⁾ and scaphometacarpal abutment caused by proximal migration of the first metacarpal bone.^(8,9) In order to prevent these adverse effects, other surgical techniques including total joint arthroplasty (TJA) are proposed. TJA is designed to preserve thumb length, stability, and to restore mobility and strength. The main disadvantages of TJA in the treatment of CMC-I OA are loosening of the prosthesis, subluxation, and material fatigue.⁽¹⁰⁻¹²⁾ Nevertheless, the decreased rate of implant failure in a recent study⁽¹³⁾ compared to earlier reports,^(14,15) suggests that the continuously improving quality of the implants could have a significantly positive effect on outcome.

Although the outcomes of TJA are generally good⁽³⁾, the results have never been compared in a prospective randomized controlled trial. Vermeulen et al. concluded in a recent systemic review that randomized clinical trials in which trapeziectomy is compared to TJA are therefore warranted.⁽³⁾ The aim of the present study is to determine which surgical procedure, trapeziectomy without LRTI or TJA with a cemented ball-and-socket prosthesis, has better outcome 1 year after surgery.

MATERIALS AND METHODS

Study design and setting

Patients were enrolled in a single-center, single-blind, randomized controlled trial. Participants were included between December 2007 and January 2011 at a general non-university teaching hospital (Hand Center, Isala Zwolle, The Netherlands).

Participants

Eligible participants were women, aged 40 years and over, diagnosed with primary CMC OA of the thumb with stage II or III according to the classification of Eaton and Glickel (1987),⁽¹⁶⁾ and were not responding to conservative treatment. Four X-rays (posterior-anterior, lateral, oblique and Bett's view) were used and an independent radiologist determined the disease stage. Participants with OA of the first CMC and the scaphoid-trapezium-trapezoid joint (stage IV), or with previous thumb surgery were excluded from the study. Additionally, patients with co-morbidity such as carpal-tunnel syndrome, Dupuytren, rheumatoid arthritis or other (systemic) diseases, which could influence rehabilitation after surgery were excluded as well.

The local institutional review board approved the study protocol (trial registration number: NL17317.075.07), and informed consent was obtained from each patient.

Surgical procedures

Patients were randomly assigned to receive either trapeziectomy or TJA with a second generation prosthesis (Guepar, Paris, France). Surgical procedures were randomly performed by three experienced hand surgeons. Both procedures were performed through a dorsal radial skin incision. Approach of to the joint was between the extensor pollicis brevis and extensor pollicis longus tendons, after which the joint capsule was transversally incised and the trapezium bone was removed in the trapeziectomy group. In the TJA group the trapeziometacarpal joint was resected and both the trapezium and metacarpal bone were reamed until stable cortical bone was achieved. Next, a second generation cemented Guepar prosthesis, consisting of a retentive 9 mm trapezoid cup and a metacarpal component with a neck of sufficient length (4 or 6 mm), was implanted and the stability during full range of motion was tested.

After surgery, patients who underwent a trapeziectomy were immobilized with a plaster cast for 4 weeks. Patients who had had a TJA were immobilized for 1 week with a compressive dressing. The wrist was immobilized in a neutral position and the thumb in radial abduction. After the immobilization period, standardized hand therapy was started once a week up to 3 months after surgery for both groups. Hand therapy was focused on reducing edema and regaining functionality by increasing mobility, stability, and strength of the thumb.

Outcomes

Primary endpoint with respect to level of pain and physical function was measured with the Dutch version of the Patient Rated/Wrist Hand Evaluation questionnaire (0 = no pain and able to do activities – 100 = worst pain and unable to do activities).⁽¹⁷⁾

Secondary outcome measures were DASH score – Dutch Language Version (0 = no disability – 100 = severe disability)⁽¹⁸⁾, grip force, and pinch grip (tip-to-tip, three-point and key pinch). Grip strength was measured with the G200 set in the second position and pinch measurements were recorded with the H500 (Biometrics Ltd. E-link H500 Hand kit; Newport, UK).

Active radial and palmar abduction of the thumb was recorded by measuring the Intermetacarpal Distance (IMD) in millimeters (mm).⁽¹⁹⁾ Active flexion and extension of the interphalangeal (IP) joint and metacarpophalangeal (MP) joint of the thumb were measured in degrees with the DeVore goniometer (Hand Therapy Devices, Tucson, AZ, USA) at the dorsal side of the thumb. Opposition of the thumb was measured using the Kapandji opposition score (1 to 10: 1 = the thumb reaches the lateral side of the second phalanx of the index finger, 10 = the thumb reaches the distal volar crease of the hand).⁽²⁰⁾

Patient satisfaction with the outcome of the surgery was assessed using a Visual Analog Scale (0–10: 0 = completely satisfied). Furthermore, patients were asked if they would have the same surgery again under the same circumstances (yes/no).

All complications after surgery were registered for a period of 1 year. Complications were divided in three categories: (1) mild complications, (2) moderate complications, and (3) severe complications. Mild complications were defined as complications with a minor clinical relevance, such as scar tenderness or sensory disturbances. We defined moderate complications as clinically relevant complications that were delaying the patients' recovery, but not needing revision surgery and were resolved 1 year after surgery. Examples are mild CRPS type I, tendinitis, and neuromas, treated with cortisone steroid injections. Finally, severe complications were defined as complications that resulted in revision surgery, pain at rest or impaired hand function at the 1-year examination. Examples are severe CRPS type I, tendinitis, and neuromas (both not improving with steroids and were treated with surgery). Furthermore, symptomatic implant failure, like loosening, luxation, and material fatigue resulting in revision surgery in the TJA group and symptomatic scaphometacarpal abutment resulting in revision surgery in the trapeziectomy group were considered to be a severe complications too. Patients were assessed preoperatively and postoperatively at 3 and 12 months. Clinical assessments were conducted by the first author, who was blinded for allocation.

Sample size

Estimating the appropriate sample size to achieve a power of 80%, approximately 45 subjects per group were needed to detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level. The clinically relevant difference of 15 points (SD 25) was based on a report by MacDermid and Tottenham.⁽²¹⁾

Randomization

Participants were randomly assigned (block size of 4) to 1 of 2 treatment groups following a computer-generated list (www.randomization.com). An independent employee (involved in the planning of the surgery program) assigned each new patient to the next consecutive surgical procedure on the randomization list, and planned the surgery. Before the randomization procedure was started, an independent investigator first completed the data collection and preoperative measurements.

Statistical methods

To compare the outcomes of surgical procedures, a generalized estimated equations approach was used. Under the assumption that missing data are random and not due to group allocation or treatment effect, this model estimates missing data values, thereby allowing the use of data from all participants, irrespective of whether they were measured at all-time points. Each outcome measure was used as a separate response variable, and group (trapeziectomy vs total joint arthroplasty) and time (baseline vs 3 months post-operative vs 12 months post-operative) were inserted in the model as predictors. The interaction of group and time was used to determine the efficacy of the intervention, since a significant interaction effect of group and time indicates that the change over time was significantly different between both groups. The threshold for significance was set at .05.

Differences in patient satisfaction between both groups were compared with the Mann-Whitney U-test. The differences between both groups for repeating the same surgery and complications were compared with the Chi²-test. Analyses followed the intention-to-treat principle.

Funding

The research group received no specific grant from any funding agency in the public, commercial or non-profit sectors.

RESULTS

Due to financial reasons, the manufacturer has stopped the production of the Guepar prosthesis. Therefore, the study was prematurely terminated before the appropriate estimated sample size was reached (55 out of the required 90 patients). As a result, sufficient power was not reached for most primary and secondary outcomes and findings for these outcome measures should be evaluated keeping this in mind. Fifty-five consecutive patients were enrolled in this study. Figure 5.1 shows the flow chart of the study. None of the reported dropouts were due to group allocation or treatment effect. Table 5.1 presents the demographic and baseline characteristics of both groups. The outcome parameters (questionnaires, grip-/pinch-strength and AROM) are presented in Table 5.2. Figure 5.2 shows X-rays of both surgical procedures (trapeziectomy and TJA (Guepar prosthesis)).

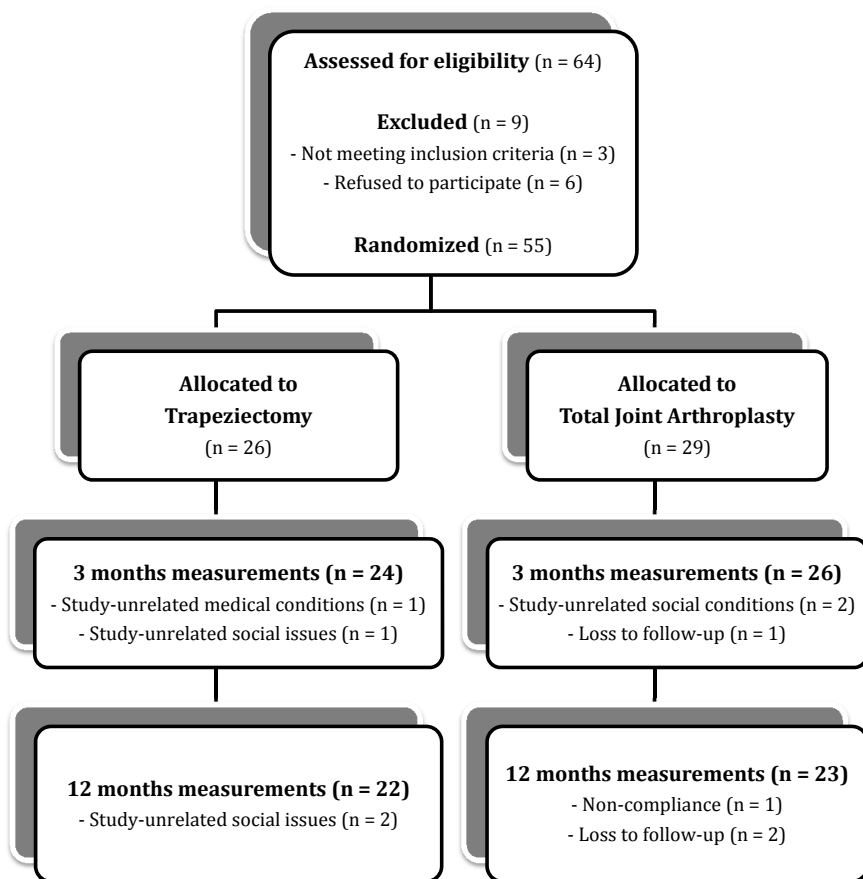


Figure 5.1 Flow chart.

Table 5.1 Baseline characteristics of the patients in both groups

	Trapeziectomy (n = 24)	Total joint arthroplasty (n = 26)
Age (years) [†]	59.1 (7.4)	60.5 (8.1)
Duration of symptoms (months) [‡]	24 (12–63)	36 (17–60)
Dominant side left/right (n)	7/17	2/24
Affected side left/right (n)	13/11	12/14
Operation on dominant hand (n)	8	11
Eaton and Glickel's stage II/III (n)	13/11	14/12

[†] Mean (SD); [‡] median (Q1–Q3).

Functional outcome

Comparing baseline measurements to the 3 and 12 months follow-up in both groups PRWHE pain, PRWHE activities, PRWHE total, and the DASH all significantly improved (for all comparisons, $p < .001$). Between-group comparisons of the change scores from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) after surgery showed highly similar results in improvement in both groups. However, the between group comparison of the DASH score showed a significant difference in favor of the TJA at the 12 months follow-up ($p = .002$; Table 5.2).

Between-group comparisons of the change scores in overall grip force and tip pinch strength from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) showed highly similar results in both groups. When we compared three-point pinch and key pinch strength between both groups, both were significantly better at 3 months in the TJA group. At 12 months follow-up only the key pinch strength was significantly better in the TJA group compared to the trapeziectomy group (Table 5.2).

Between-group comparisons of the change scores in all active ROM measurements from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) showed highly similar results in both groups. Only IP joint extension was significantly higher in the TJA group compared to the trapeziectomy group at the 3 months follow-up ($p = .008$; Table 5.2).

Patient global assessment

The median overall satisfaction score was not significantly different between the groups ($p = .689$). In the trapeziectomy group satisfaction was 1 (Q1–Q3: 0–4) and in the prosthesis

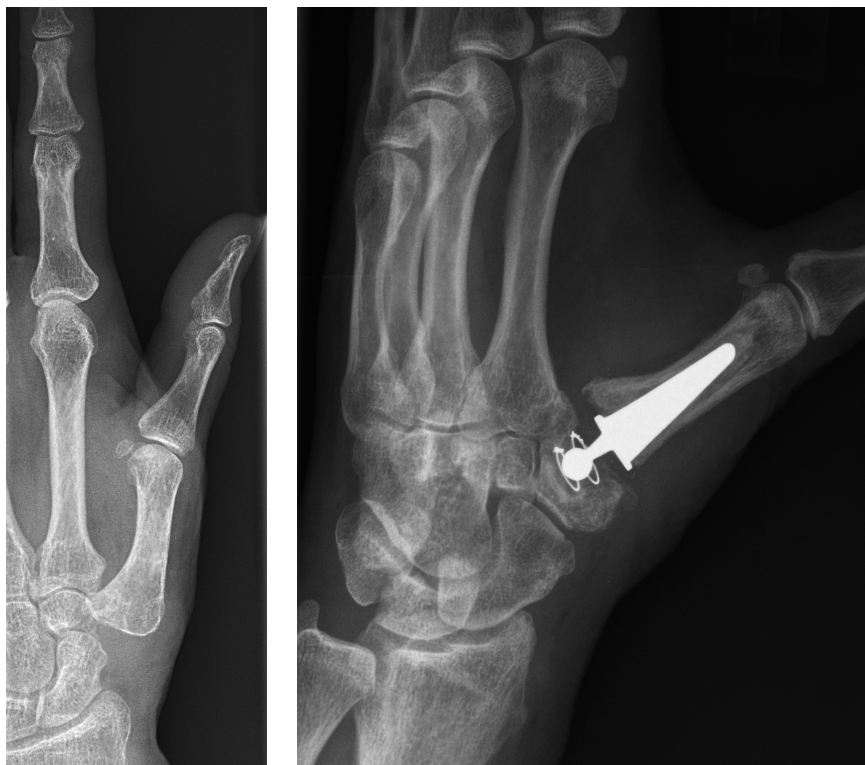


Figure 5.2 X-rays of both surgical procedures (trapeziectomy and TJA (Guepar prosthesis)).

group 0.5 (Q1–Q3: 0–3). Additionally, after 1 year, 9 of 24 (38%) patients who underwent a trapeziectomy and 5 of 26 (19%) patients with a prosthesis answered ‘No’ when we asked whether they would consider the same surgery again under the same circumstances (no significant difference ($p = .284$)).

Complications

All complications are presented in Table 5.3. Eight complications were observed in the trapeziectomy group and nine in the prosthesis group (no significant difference ($p = .540$)). In both groups there was one severe complication. In the trapeziectomy group one revision surgery with an additional LRTI procedure (i.e. Weilby arthroplasty) was necessary due to a symptomatic scaphometacarpal abutment. In the TJA group one revision surgery was performed, due to a symptomatic luxation of the prosthesis a new cup was implanted.

Table 5.2 Mean (\pm SE) scores on the clinical outcome measures and their changes over time. P-values of between-group comparisons of the change scores from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) are shown.

	Baseline ^e	3 month ^y	1 year ^x	Δ 3 month ^{z,s} (95% CI)	p-value	Δ 1 year ^{t,s} (95% CI)	p-value
PRWHE-Total (0–100)	Trap	65.9 \pm 2.7	34.7 \pm 4.5**	25.6 \pm 5.9**	.067	11.3 \pm 7.4 (-3.2 to 25.8)	.126
	TJA	72.6 \pm 2.7	30.6 \pm 3.5**	21.0 \pm 4.4**	(-0.7 to 22.3)		
PRWHE-Pain (0–50)	Trap	33.2 \pm 1.4	17.5 \pm 2.4**	14.1 \pm 3.0**	.431	5.9 \pm 3.7 (-1.3 to 13.1)	.109
	TJA	36.4 \pm 1.4	18.1 \pm 2.2**	11.4 \pm 2.4**	(-4.0 to 9.4)		
PRWHE-Activities (0–50)	Trap	33.8 \pm 1.6	16.4 \pm 2.2**	11.8 \pm 2.7**	.085	5.6 \pm 7.1 (-1.2 to 12.5)	.109
	TJA	35.7 \pm 1.4	13.0 \pm 1.7**	8.1 \pm 2.0**	(-0.7 to 11.5)		
DASH (0–100)	Trap	46.5 \pm 3.6	24.2 \pm 2.6**	29.0 \pm 4.4**	.513	16.1 \pm 5.3 (5.8 to 26.4)	.002**
	TJA	51.2 \pm 3.5	25.7 \pm 3.5**	17.6 \pm 3.2**	(-6.6 to 13.1)		
Grip force (kg-f)	Trap	17.4 \pm 1.5	17.1 \pm 1.3	20.1 \pm 1.6	.354	-1.9 \pm 2.4 (-6.6 to 2.8)	.423
	TJA	15.6 \pm 1.5	17.4 \pm 1.5*	20.2 \pm 1.7*	(-6.6 to 2.4)		
Tip pinch (kg-f)	Trap	2.9 \pm 0.4	3.0 \pm 0.2	3.4 \pm 0.2	.576	-0.3 \pm 0.5 (-1.2 to 0.7)	.705
	TJA	2.7 \pm 0.3	3.1 \pm 0.3*	3.5 \pm 0.3*	(-1.3 to 0.7)		
Three-point pinch (kg-f)	Trap	4.0 \pm 0.6	3.0 \pm 0.3	4.3 \pm 0.3	.030*	-0.8 \pm 0.7 (-2.2 to 0.7)	.298
	TJA	3.2 \pm 0.4	3.7 \pm 0.4*	4.3 \pm 0.4*	(-2.8 to -0.1)		
Key pinch (kg-f)	Trap	4.7 \pm 0.5	3.5 \pm 0.3**	4.5 \pm 0.3	.009*	-1.5 \pm 0.7 (-2.8 to -0.1)	.030*
	TJA	3.8 \pm 0.3	4.3 \pm 0.4*	5.1 \pm 0.4*	(-3.0 to -0.4)		

Palmar abduction (mm)	Trap	66.3 ± 1.4	65.5 ± 2.9	68.9 ± 1.4	-3.8 ± 3.0	.207	0.1 ± 2.0	.946
	TJA	63.3 ± 1.3	66.4 ± 1.1*	65.8 ± 1.1	(-9.7 to 2.1)		(-3.7 to 4.0)	
Radial abduction (mm)	Trap	65.5 ± 1.4	66.9 ± 1.1	67.4 ± 1.2	-1.5 ± 1.7	.375	-2.4 ± 2.0	.230
	TJA	62.4 ± 1.4	65.4 ± 1.0*	66.7 ± 1.2*	(-5.0 to 1.9)		(-6.2 to 1.5)	
Flexion MCP (dgr)	Trap	48.5 ± 2.0	38.1 ± 2.0**	42 ± 2.4**	-4.9 ± 2.6	.059	-2.9 ± 2.9	.311
	TJA	48.7 ± 2.1	43.3 ± 2.5**	44.9 ± 3.0**	(-10.0 to 0.2)		(-8.5 to 2.7)	
Extension MCP (dgr)	Trap	-14.9 ± 3.4	-22.2 ± 3.5*	-22.4 ± 4.0*	-2.6 ± 4.9	.591	-5.9 ± 6.1	.331
	TJA	-20.1 ± 4.1	-24.8 ± 3.9	-21.7 ± 3.8	(-12.3 to 7.0)		(-17.8 to 6.0)	
Flexion IP (dgr)	Trap	63.0 ± 2.5	62.0 ± 2.6	61.9 ± 2.3	-4.1 ± 4.5	.364	-7.4 ± 4.6	.111
	TJA	61.2 ± 3.1	64.4 ± 2.7	67.5 ± 3.2	(-13.0 to 4.8)		(-16.5 to 1.7)	
Extension IP (dgr)	Trap	-17.1 ± 3.4	-11.4 ± 2.8*	-17.1 ± 3.4	9.7 ± 3.6	.008	7.7 ± 5.0	.120
	TJA	-11.8 ± 2.4	-16.4 ± 3.0	-19.8 ± 2.7*	(2.5 to 16.8)		(-2.0 to 17.4)	
Kapandji (0–10)	Trap	9.3 ± 0.6	8.7 ± 0.2	8.7 ± 0.7	-0.4 ± 0.5	.439	-0.7 ± 0.7	.370
	TJA	8.7 ± 0.3	8.5 ± 0.3	8.8 ± 0.3	(-1.2 to 0.5)		(-2.1 to 0.8)	

Abbreviations: Δ indicates change; CI, confidence interval; PRW/HE, Patient Rated Wrist/Hand Evaluation; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; kg-f, kilogram-force; mm, millimeters; dgr, degrees; [§] Values are mean ± standard error of the mean; [†] Between groups difference of mean change at three months from baseline; [‡] Between groups difference of mean change at one year from baseline; * p < .05 and ** p < .005 compared to the situation before surgery.

Table 5.3 Complications

	Trapeziectomy (n = 24)	Prosthesis (n = 26)
Mild		
Scar tenderness	5	6
Sensory changes	1	2
Moderate (treated with steroids)		
Tendinitis	1	
Neuromas		
Severe (revision surgery)		
CRPS-1		
Tendinitis		
Neuromas		
Scaphometacarpal abutment	1	
Dislocation		1

DISCUSSION

In this randomized controlled trial the results of trapeziectomy without LRTI and TJA in women aged 40 and over with primary OA of the first CMC joint were compared. The main finding of the study was that 1 year after surgery we found no significant differences between both groups on the total PRWHE or on the pain and activities subscores. However, the p-values indicate a trend that the prosthesis group showed more improvement on PRWHE and the subscales compared to the group receiving trapeziectomy. This finding is supported by the fact that patients treated with TJA improved significantly more on the DASH score (secondary outcome measure) with an effect size that is clinically relevant and also showed significantly more improvement on key-pinch force compared to patients treated with trapeziectomy.

The result that TJA has potentially better outcomes, at least in the short term (12 months), is in line with the previous comparative study on TJA by Ulrich-Vinther et al. in which the outcomes of the Elektra joint prosthesis (Small Bone Innovations Inc., Péronas, France) were compared to trapeziectomy with LRTI.⁽¹³⁾ In this non-randomized prospective study, patients with a TJA achieved faster convalescence with faster and better pain relief, stronger grip function and improved range of motion. However, bias might have been introduced because patients were allowed to choose freely between both techniques.

Our findings that the TJA group improved significantly more on three-point pinch, key-pinch, and IP extension measurements at 3 months follow-up seem to be clinically less relevant,

while subjective outcome measures like DASH and PRWHE were not significantly different at 3 months follow-up. Furthermore, these small differences at 3 months could be explained by the cast immobilization period of 4 weeks in the trapeziectomy group, compared to 1-week immobilization with a compressive dressing in the TJA group. Because of the difference in immobilization after surgery the follow-up time interval of 3 months is not a time point when both groups were at the same stage of healing.

The main disadvantage of a TJA is implant failure. Lemoine (2009)⁽²²⁾ and Masméjean et al. (2003)⁽²³⁾ reported a series of patients treated with the same second generation cemented Guepar prosthesis. After a mean follow-up of 50 and 27 months in respectively 6 and 10% of the patients radiographic abnormalities were observed. However, these radiographic abnormalities were not correlated with pain. Furthermore, these studies concluded that implant loosening can occur, but most patients are asymptomatic. Additionally, several studies reported revision rates of other cemented prosthesis.^(10-12, 14, 24-26) In these studies revision rates varies between 8% and 44%, with a mean follow-up between 53 and 120 months. In our study the complication rate was comparable between both groups. One revision surgery was necessary in the TJA group due to a symptomatic luxation of the prosthesis (4%). This was similar to the trapeziectomy group in which one revision surgery with an additional LRTI procedure was necessary due to a symptomatic scaphometacarpal abutment (4%). Although this study is the first level 1, randomized controlled trial comparing trapeziectomy without LRTI with total joint arthroplasty, there are limitations that should be addressed. As previously mentioned, the manufacturer had stopped the production of the TJA. Therefore, the study was prematurely terminated before the appropriate estimated sample size was reached (55 out of the required 90 patients). As a result, sufficient power was not reached for most primary and secondary outcomes and findings for these outcome measures should be evaluated keeping this in mind. Since highly similar ball-and-socket prostheses are available, the results of the study still draw attention to important issues.

Furthermore, as previously described, to achieve a power of 80% and detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level our estimated sample size was approximately 45 subjects per group and was based on a report by MacDermid and Tottenham (2004).⁽²¹⁾ However, a more recent study of Sorensen et al. (2013) reported that the sample size calculations in patients analysed with PRWHE questionnaire should be performed with a difference of 14 points between both groups and that the standard deviation is approximately 15 instead of 25, which is confirmed by the standard deviation found in Chapter 5.⁽²⁷⁾ With these numbers, a sample size estimation would result in approximately 20 subjects per group. Based on this estimation we believe that the

sample size in present study (26 in trapeziectomy group; 29 in TJA group) is more adequate than would be expected based on our original calculations.

Additionally, in order to have a homogeneous study group, only women aged 40 and over with primary OA were included. Therefore, our results may not apply to men, or to patients with co-morbidity of the wrist/hand (i.e., carpal tunnel syndrome, rheumatoid arthritis, or posttraumatic OA).

Another limitation is that, because failure rates of TJA are historically high,^(14, 15) a follow-up period of 1 year is inadequate to assess success or failure of a TJA. Furthermore, routine X-rays during follow-up were not performed and therefore asymptomatic implant failure in the TJA group (e.g., asymptomatic loosening, or (sub)luxation) or asymptomatic scaphometacarpal abutment in the trapeziectomy group could have been overlooked. Maybe, asymptomatic radiographic abnormalities in both groups could become symptomatic over the years. Therefore, long-term results are warranted to evaluate subjective and objective outcomes and implant failure rates over the years. However, we believe that present RCT brings out important issues about (functional) outcomes of trapeziectomy and TJA (ball-and-socket prosthesis) during the first 1 year after surgery. In order to assess the superiority of one of these surgical procedures in the long run, this study will continue measuring the same outcomes 5 years after surgery.

Overall, we conclude that TJA has benefits compared to a trapeziectomy without LRTI in the short-term (12 months follow-up). Because, patients after TJA showed greater improvement in hand function (i.e. DASH score) and have better key-pinch force compared to patients treated with trapeziectomy. However, long-term results are warranted to evaluate subjective and objective outcomes and implant failure rates over the years.

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**LRTI with or without bone tunnel creation
at the base of the first metacarpal bone in
primary osteoarthritis at the base of the
thumb: A randomized controlled trial**

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Submitted.

ABSTRACT

Background: While several ligament reconstructions have been described to treat primary osteoarthritis at the base of the thumb, which ligament reconstruction is superior is still debated. We conducted a randomized trial comparing the Burton-Pellegrini technique (arthroplasty with a bone tunnel at the base of the first metacarpal) with the Weilby technique (arthroplasty that preserves the structural integrity of the base of the first metacarpal).

Methods: Women aged 40 years or older with stage IV osteoarthritis were randomized to either of both treatments. Patients were evaluated preoperatively and postoperatively at 3 and 12 months by assessing pain, function (PRWHE and DASH questionnaires), ROM, strength, duration to return to work or activities, satisfaction with the results, and complication rate.

Results: Seventy-nine patients were enrolled in this study. Our main findings were that at 3 months PRWHE pain and PRWHE total were significantly more improved in the Burton-Pellegrini group compared to the Weilby group. At 12 months, however, no significant differences were found for all PRWHE and DASH scores between both groups. In addition, we observed no significant differences between groups in strength, duration to return to work or activities, patient satisfaction, and complication rates.

Conclusion: Based on the present study, we conclude that patients after the Burton-Pellegrini technique have better function and less pain 3 months after surgery than for the Weilby group, indicating a faster recovery. However, twelve months after surgery, functional outcome is similar. Because of the faster recovery, we prefer the Burton-Pellegrini technique in the treatment of stage IV osteoarthritis.

Level of evidence: Level I.

INTRODUCTION

Osteoarthritis (OA) at the base of the thumb can result in significant disabilities.^(1, 2) Two recent randomized controlled trials (RCT) found no benefit of ligament reconstruction and tendon interposition (LRTI) after trapeziectomy in the long-term (> 5 years) compared to trapeziectomy alone.^(3, 4) However, because only 10 % of the patients in these studies had scaphotrapeziotrapezoid (STT) joint OA (Stage IV OA according to the radiographic criteria of Eaton and Glickel⁽⁵⁾), these results primarily apply to stage II and III OA (radiographic OA only at the trapeziometacarpal (TMC) joint). Because stage IV OA is characterized by more cartilage and ligament damage, we postulate that the thumb has an increased tendency to collapse in the palm (zig-zag deformity). Therefore, an additional LRTI after trapeziectomy could still be a valuable treatment option in stage IV OA patients.

Several ligament reconstructions have been described using different tendon grafts. Some techniques use bone tunnels at the base of the first metacarpal, while others avoid the use of such tunnels. Which kind of ligament reconstruction is superior is still an ongoing debate. The drilling process to create a bone tunnel may be associated with severe complications, such as damage of the superficial radial nerve and bony fragmentation of the first metacarpal. So far, however, different LRTI procedures have not been compared in a RCT. Therefore, we conducted a RCT in women with stage IV OA at the base of the thumb comparing the Burton-Pellegrini (BP) technique and the Weilby technique. The BP technique is a LRTI arthroplasty with a bone tunnel at the base of the first metacarpal, while Weilby's LRTI arthroplasty preserves the structural integrity of the first metacarpal base by not using a bone tunnel. We hypothesized that patients following the Weilby technique (without bone tunnel) show similar outcomes and patient satisfaction at 3 and 12 months follow-up with possibly less complications.

PATIENTS AND METHODS

Participants

After approval of the scientific committee, patients with symptomatic OA and impaired functional activities, who failed to improve after nonsurgical treatment and who had stage IV OA of the thumb base (Eaton and Glickel classification: radiological evidence of OA at the TMC and STT joint)⁽⁵⁾ were enrolled in a single-centre, single-blind, parallel-group RCT. Three X-rays (posterior-anterior, lateral, and Bett's view) were used by an independent radiologist to determine the disease stage. To obtain a homogeneous group of primary OA patients, we

only included women aged 40 years or older with unilateral or bilateral primary OA; This is a common strategy to increase the homogeneity of a study population.⁽³⁾ Patients with previous thumb surgery and patients with rheumatoid or posttraumatic OA were excluded. The study was conducted in the Department of Hand and Wrist Surgery, Diakonessenhuis Zeist, the Netherlands. Patients were randomly allocated for treatment with either a LRTI based on the original reports of Burton and Pellegrini⁽⁶⁾ or a LRTI based on the original reports of Weilby.^(7,8)

Randomization

For equal distribution of patients between type of surgery and surgeon, software randomly assigned patient numbers to a treatment group and a surgeon using balanced block sizes of 20 patients. Sequentially numbered envelopes containing the assignment were used. After inclusion and informed consent, patients were assigned to the next envelope and therefore to a treatment group and a surgeon. Two European board certified hand surgeons performed all surgeries.

Burton-Pellegrini technique

An incision was made along the radial border of the first metacarpal, after which the trapezium was removed. A tendon graft about 10 cm in length and consisting of approximately one half of the FCR tendon was dissected and tunneled to its insertion on the second metacarpal. This tendon graft was passed through a bone tunnel perpendicular to the nail made with a 3.5 mm drill bit. The bone tunnel had an oblique orientation through the joint surface of the first metacarpal exiting the radial cortex approximately 7 mm distal of the joint surface. The graft was fixed firmly to the periosteum at the radial site of the thumb metacarpal and the trapeziometacarpal joint capsule with PDS 3-0 sutures (Ethicon Amersfoort, The Netherlands). Its excess length was rolled up, sutured into a ball, and placed in the trapezial space. The thumb was immobilized in a spica cast for 4 weeks, after which the cast was replaced by a removable protective splint and a hand therapist started standardized hand therapy that was focused on reducing edema and regaining functionality by increasing mobility, stability, and strength of the thumb.

Weilby technique

The trapezium was removed and the FCR tendon was harvested as described previously. The tendon graft was then intertwined in a figure-of-eight fashion (at least twice) around the abductor pollicis longus (APL) tendon and the rest of the FCR tendon, pulling those tendons

together into the space created after trapeziectomy. The figure-of-eight was locked by PDS 3-0 sutures. The remaining graft was wrapped upon itself and was interposed in the space left after removal of the trapezium and pushed between the base of the first and second metacarpal.⁽¹²⁾ The Weilby group received the same standardized hand therapy and immobilization period as the BP group.

Primary outcomes

Our primary outcome measure for pain and physical function was the patient rated wrist/hand evaluation (PRWHE, Dutch Language Version) questionnaire (0 = no pain and able to do activities – 100 = worst pain and unable to do activities).⁽⁹⁾ The questionnaire has two sub scores for pain and function and a total score. The PRWHE is a wrist and hand-specific questionnaire with items about the affected wrist and hand alone. The more frequently-used DASH questionnaire has an upper limb-specific character and is not only specified for the affected hand. A report of MacDermid and Tottenham showed that the PRWHE questionnaire is more responsive in detecting clinical changes over time compared to the DASH.⁽¹⁰⁾ Patients were evaluated pre-operatively and postoperatively at 3 and 12 months.

Secondary outcomes

For comparison with current literature, the DASH questionnaire (Dutch Language Version) was also used (0 = no disability – 100 = severe disability).⁽¹¹⁾ Patients were evaluated pre-operatively, and postoperatively at 3 and 12 months.

At 12-months, a patient global assessment was performed by analyzing overall satisfaction (0 = completely dissatisfied, 10 = completely satisfied) and the patient was asked if she would have the same surgery again under similar circumstances. Furthermore, we registered how many weeks after surgery patients returned to work or normal daily life activities.

All complications after surgery were registered for a period of 12 months and were divided in 3 categories: (1) mild, (2) moderate, and (3) severe. Mild complications were defined as complications with a minor clinical relevance, such as scar tenderness, temporary sensory disturbances, or infection. We defined moderate complications as clinically relevant complications that were delaying patients' recovery, but not needing revision surgery and that were resolved 12 months after surgery. Examples are mild complex regional pain syndrome (CRPS) type I, tendinitis, and neuromas treated with cortisone steroid injections. Severe complications were defined as complications that resulted in revision surgery, pain at rest or impaired hand function

at the 12-month examination. Examples are severe CRPS type I, tendinitis, and neuromas that did not improve with steroids and were treated with surgery. Also carpal tunnel release for carpal tunnel syndrome was scored as a severe complication needing revision surgery, although mild symptoms of carpal tunnel syndrome could have been present preoperative.

Additionally we evaluated the following active range of motion (ROM) measurements preoperatively and at 3 and 12 months: interphalangeal (IP) joint flexion/extension, metacarpophalangeal (MCP) joint flexion/extension, and carpometacarpal (CMC) joint palmar abduction (first web space), measured using the intermetacarpal distance (IMD). To calculate the IMD, the thumb was placed in full palmar abduction, the easily identifiable mid-dorsal points on the subcutaneous surface of the first and second metacarpal heads were marked, and the separation between these was measured in millimeters.⁽¹²⁾ Furthermore, CMC joint opposition was measured using the Kapandji score (1 to 10: 1 = the thumb reaches the lateral side of the second phalanx of the index finger, 10 = the thumb reaches the distal volar crease of the hand).⁽¹³⁾ The tip pinch, key pinch, and 3-point pinch strength were measured using a baseline pinch gauge. Overall grip strength was measured using a baseline hydraulic hand dynamometer (Biometrics Ltd E-link H500 Hand Kit; Gwent, UK). The mean of three measurements was recorded as an outcome variable. All ROM and strength measurements were performed by independent and blinded hand therapists in accordance with a strict and previously-published protocol.^(12, 14)

To calculate the degree of proximal migration of the first metacarpal, radiographic evaluation was performed at 12-month follow-up. For practical reasons and to reduce radiation exposure, we evaluated the first 20 consecutive patients. Standard Bett's view radiographs were made with the hand at rest, with maximal pinch stress, and with the thumb tip opposed to the index finger. Distance between the distal articular surface of the scaphoid and the proximal articular surface of the first metacarpal was measured. The index of the height of the arthroplasty space was calculated by dividing the scaphoid-metacarpal distance by the length of the first metacarpal.⁽¹⁵⁾ The indices were used to compare the degree of proximal thumb migration between both groups at rest and during stress with the preoperative indices.

Sample size

We estimated that, to achieve a power of 80%, approximately 45 patients per group were needed to detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level. For this sample size estimation, we used a clinically relevant difference of 15 points (SD 25), based on a report by MacDermid and Tottenham.⁽¹⁰⁾

Statistical analysis

The intention-to-treat principle was applied and to test the study hypothesis, a generalized estimated equations approach was used. Assuming that data were missing at random and not due to group allocation or treatment effect, this model estimates missing data values, thereby allowing the use of data from all participants. Each outcome measure was used as a separate response variable, and group (Weilby vs. BP) and time (baseline vs. 3 months post-operative vs. 12 months post-operative) were inserted in the model as predictors. The interaction of group and time was used to determine the efficacy of the intervention, since a significant interaction effect of group and time indicates that the change over time was significantly different between both groups. The threshold for significance was set at .05.

We used a Mann-Whitney test to compare overall patient satisfaction, the number of weeks before patients returned to work or normal daily life activities, and the proximal migration of the first metacarpal bone. All complications and the question if patients would have the same surgery under the same circumstances were analyzed with a Chi-Square test.

Registration

Trail number: NTR 1674.

Funding

This research received no funding or other support.

RESULTS

Seventy-nine consecutive patients were enrolled in this study conducted between 2008 and 2012. Table 6.1 presents baseline characteristics in both groups and Figure 6.1 shows the study flow chart. One patient in the BP group received a Weilby procedure because of poor bone quality that did not allow making a bone tunnel at the base of the first metacarpal. Due to the intention to treat principle, this patient was analyzed in the BP group.

Pain and function

Within-group comparisons of preoperative measurements with 3 and 12 months showed significant improvement in both groups for PRWHE-pain (for all comparisons, $p < .001$), PRWHE-activities ($p < .001$), PRWHE-total ($p < .001$), and the DASH ($p < .003$).

Table 6.1 Baseline characteristics in both groups

Characteristics	BP group	Weilby group
No. of patients	36	36
Age (years) [†]	64.7 ± 9.1	63.5 ± 8.5
Dominance		
Right	32	33
Left	2	2
Both	2	1
Operated hand		
Right	15	17
Left	21	19
Dominant is operated hand (%)	18 (50%)	18 (50%)
Classification		
Stage IV	36	36

[†] Mean (± SD).

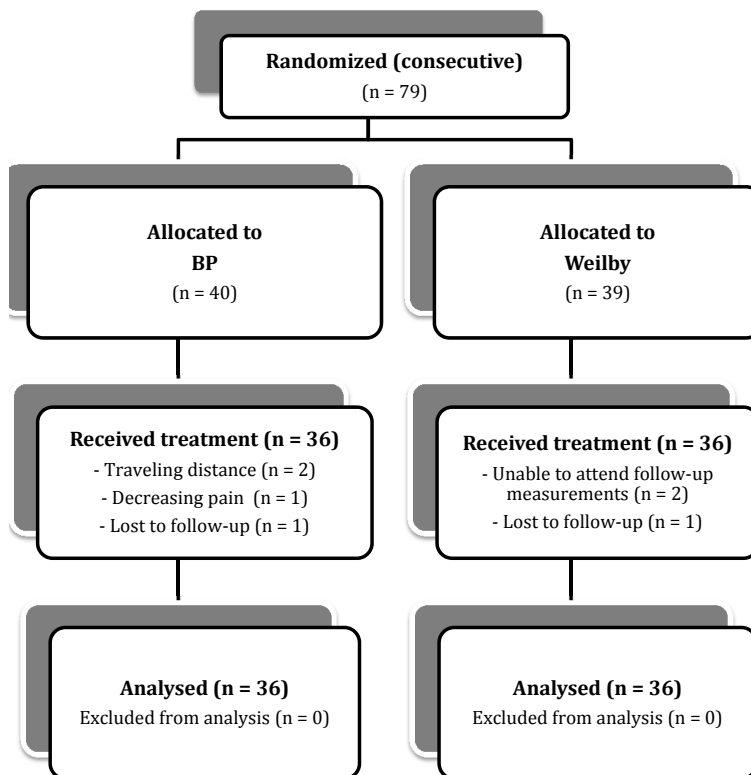


Figure 6.1 Flow chart of the selection, inclusion and drop-outs of the study.

Between-group comparisons of the changes from preoperative values to 3 months (Δ short-term) after surgery showed a significantly larger improvement in the BP group for PRWHE-pain and PRWHE-total (Table 6.2) while PRWHE-activities and the DASH score showed

Table 6.2 Mean (\pm SE) scores on the clinical outcome measures and their changes over time

		Baseline	3 months	12 months	p-value (Δ short-term)	p-value (Δ long-term)
Questionnaires						
PRWHE Pain (0-50)	BP group	35.9 \pm 0.9	18.0 \pm 2.3	17.6 \pm 2.7	.023	.732
	Weilby group	34.4 \pm 1.7	25.1 \pm 2.3	17.3 \pm 2.4		
PRWHE Activities (0-50)	BP group	35.4 \pm 1.4	19.8 \pm 2.6	15.2 \pm 2.7	.098	.224
	Weilby group	32.0 \pm 1.8	22.6 \pm 2.1	16.0 \pm 2.2		
PRWHE Total (0-100)	BP group	71.4 \pm 1.8	37.7 \pm 4.7	32.6 \pm 5.2	.031	.393
	Weilby group	66.5 \pm 3.4	47.7 \pm 4.1	33.3 \pm 4.5		
DASH (0-100)	BP group	47.3 \pm 2.8	30.4 \pm 3.1	27.2 \pm 3.6	.082	.448
	Weilby group	46.1 \pm 2.3	37.3 \pm 3.1	29.6 \pm 2.7		
Active ROM						
Flexion IP ($^{\circ}$)	BP group	59.4 \pm 2.6	57.5 \pm 2.4	62.2 \pm 2.3	.779	.611
	Weilby group	58.0 \pm 2.1	57.1 \pm 1.6	59.0 \pm 1.6		
Extension IP ($^{\circ}$)	BP group	-15.9 \pm 4.1	-10.9 \pm 3.3	-18.4 \pm 2.8	.356	.120
	Weilby group	-19.2 \pm 2.7	-9.4 \pm 2.7	-11.6 \pm 4.4		
Flexion MCP ($^{\circ}$)	BP group	48.3 \pm 2.2	36.2 \pm 1.7	40.5 \pm 2.1	.792	.662
	Weilby group	47.1 \pm 2.1	35.9 \pm 2.2	38.1 \pm 1.8		
Extension MCP ($^{\circ}$)	BP group	-13.0 \pm 3.0	-15.3 \pm 2.6	-21.8 \pm 3.2	.239	.227
	Weilby group	-6.9 \pm 2.8	-14.8 \pm 2.6	-21.8 \pm 2.3		
Palmar abduction (IMD) (mm)	BP group	55.1 \pm 1.3	53.2 \pm 1.8	56.2 \pm 2.0	.319	.595
	Weilby group	54.4 \pm 0.9	54.9 \pm 1.1	57.0 \pm 1.1		
Kapandji (0-10)	BP group	9.0 \pm 0.2	8.1 \pm 0.2	9.2 \pm 0.2	.902	.586
	Weilby group	8.9 \pm 0.3	7.9 \pm 0.3	8.9 \pm 0.2		
Extension CMC (mm)	BP group	27.7 \pm 2.0	18.8 \pm 1.8	18.8 \pm 1.8	.705	.001
	Weilby group	22.5 \pm 1.7	14.9 \pm 1.8	23.7 \pm 1.6		
Strength						
Grip strength (Kg)	BP group	15.0 \pm 1.2	13.4 \pm 1.1	19.0 \pm 1.2	.923	.369
	Weilby group	14.8 \pm 1.0	13.4 \pm 0.9	17.5 \pm 0.9		
Tip-pinch (Kg)	BP group	2.2 \pm 0.2	1.8 \pm 0.1	2.6 \pm 0.2	.288	.775
	Weilby group	2.3 \pm 0.2	2.3 \pm 0.2	2.7 \pm 0.2		
3-point-pinch (Kg)	BP group	2.6 \pm 0.3	2.2 \pm 0.2	3.1 \pm 0.2	.450	.357
	Weilby group	2.9 \pm 0.3	2.3 \pm 0.2	3.2 \pm 0.2		
Key-pinch (Kg)	BP group	3.6 \pm 0.3	2.8 \pm 0.2	3.5 \pm 0.3	.526	.990
	Weilby group	3.6 \pm 0.3	3.0 \pm 0.3	3.5 \pm 0.5		

P-values of between-group comparisons of the change scores from baseline to 3 months (Δ short-term) and from baseline to 12 months (Δ long-term) are shown.

a trend toward significance at 3 months. Between-group comparisons of the change scores from preoperative values to 12 months (Δ long-term) showed no significant difference in improvement between both groups (Table 6.2).

Active ROM

For active ROM, within-group comparison indicated that IP flexion and extension did not significantly change over time in both groups. MCP flexion was significantly decreased ($p < .001$) in both groups at 3 months and 12 months compared to preoperative measurements. The MCP extension was significantly increased at 3 months ($p = .014$) in the Weilby group only. At 12 months the MCP extension was significantly increased in both groups ($p < .050$). Palmar abduction (IMD) was significantly improved at 12 months in the Weilby group ($p = .044$), while the BP group showed no significant changes over time. Kapandji scores in both groups were significantly lower at 3 months ($p < .006$) but returned to preoperative values at 12 months. Furthermore, CMC extension significantly decreased compared to preoperative values at 3 months ($p < .001$) and 12 months ($p = .001$) in the BP group, while the CMC extension in the Weilby group was significantly decreased at 3 months ($p = .003$) and returned to preoperative values at 12 months.

Between-group comparison of the change scores in the active ROM measurements from preoperative values to 3 months (Δ short-term) and from preoperative values to 12 months (Δ long-term) was only significantly different for CMC extension at 12 months in favor of the Weilby group. All other active ROM measurements showed no significant differences between groups (Table 6.2).

Strength

The tip pinch strength did not significantly change over time within both groups. Overall grip strength was significantly improved compared to preoperative values at 12 months in both groups ($p < .004$). The 3-point pinch was also significantly improved at 12 months in the BP group ($p = .005$), while strength in the Weilby group was significantly decreased at 3 months ($p = .030$) but turned to preoperative measurements at 12 months. Similarly, key-pinch strength in both groups was significantly decreased at 3 months ($p < .031$) and also returned to preoperative values at 12 months.

Between-group comparisons of the change scores in tip pinch, overall grip, 3-point pinch and key pinch strength from preoperative values to 3 months (Δ short-term) and from preoperative values to 12 months (Δ long-term) were not significantly different between groups (Table 6.2).

Complications

Table 6.3 presents all complications registered at 12-month follow-up. Sixteen complications, of which 13 moderate to severe, were observed in the BP group compared to 12 complications, of which 11 moderate to severe, in the Weilby group. Between-group comparison indicated no significant differences between the complications in both groups ($p = .836$).

Patient global assessment

Overall satisfaction was not significantly different between the groups: The mean overall satisfaction in BP group was 7.6 (SD 2.7) compared to 7.1 (SD 2.7) in the Weilby group ($p = .592$). When we asked the patients if they would considered the same surgery again under the same circumstances, 68% of the patients in the BP group responded with yes and 67% of the patients in the Weilby group ($p = .927$).

Return to work or activities

Following the BP technique, patients returned to work after 9.5 (SD 5.6) weeks while patients with the Weilby technique 10.1 (SD 6.1) weeks after surgery, which was not significantly different ($p = .937$).

Table 6.3 Complications recorded in both groups, grouped into mild, moderate, and severe

	BP group	Weilby group
Mild		
Scar tenderness	2	
Sensory changes	1	
Infection		1
Moderate		
Tendinitis successfully treated with steroids	7	6
Neuroma successfully treated with steroids	1	
Mild CRPS type I		2
Severe		
Tendinitis requiring revision surgery	1	
Neuroma requiring revision surgery	1	
Carpal tunnel syndrome requiring surgery	3	3
CRPS type I		
Total: n	16	12

No significant differences in mild, moderate and severe complications between groups.

Proximal migration

The proximal migration in the BP group had mean ratio of .21 (SD .03) preoperative, .11 (.04) postoperative without pinch stress, and .09 (.05) postoperative with maximal pinch stress. In the Weilby group, these values were .18 (.07) preoperative, .12 (.06) postoperative without pinch, and .06 (.07) postoperative with maximal pinch stress. Comparison showed no significant difference between the groups.

DISCUSSION

The main findings of this study were that at 3 months PRWHE-pain and PRWHE-total were significantly more improved in the BP group compared to the Weilby group and that PRWHE-activities and DASH score showed a trend toward significance at 3 months, also in favor of the BP group. Furthermore, the difference of 15 points on the PRWHE-total score at 3 months in favor of the BP group is a clinically relevant difference.⁽¹⁰⁾ At 12 months no significant differences were found for all PRWHE and DASH scores between groups. These findings show that patients following the BP technique have better function and less pain 3 months after surgery, indicating a faster recovery in the BP group, while the outcome at 12 month is similar in both groups. Additionally, we found 2 more moderate and severe complications in the BP group compared to the Weilby group; However, this difference was not significant. Based on these results we refuted our hypothesis that the Weilby technique shows similar outcomes with less complications compared to the BP technique.

The finding that early recovery is better in the BP group is important patient information and may be caused by the fact that the Weilby technique intertwines the FCR graft in a figure-of-eight fashion around the APL and the rest of the FCR, pulling those tendons together. We postulate that this direct pull on the APL and FCR, both functional tendons may result in an unphysiological tension that could cause impaired function and increased pain in the early months after recovery. In the BP technique, the FCR graft is passed through a bone tunnel at the first metacarpal base and is fixed firmly to the periosteum, which prevents tension on functional tendons.

Analysis of the active ROM measurements showed that in both groups MCP flexion is significantly reduced while MCP extension is significantly increased at 12 months (MCP hyperextension), indicating that both ligament reconstructions could not prevent the collapse of the thumb in the palm (typical zig-zag deformity). Additionally, there were no significant differences in active ROM between groups, except for a significantly better CMC extension at

12 months in the Weilby group. We postulate, however, that the 5 mm better CMC extension in the Weilby group may be of minor clinical relevance, because the more functionally important PRWHE and DASH scores were not significantly different at 12 months. Furthermore, both LRTI techniques are evenly effective in regaining strength after 12 months.

The duration to return to work or activities, the overall satisfaction and if patients were considering the same surgery all were slightly in favor of the BP group, but again none of these differences reached significance. Additionally, both ligament reconstructions were evenly effective in preserving the space after excision of the trapezium bone.

Despite that this is the first level I RCT comparing two LRTI techniques, there are some limitations. An important limitation is that due to organizational changes we could not include the full 45 patients in each group that we needed based on our estimated sample size, ending with the inclusion of approximately 40 patients in each group. If more patients were included some of the differences between groups that showed trends towards significance, such as the PRWHE-activities and DASH score at 3 months (Table 6.2), may have become significant in favor of the BP group. However, this would only strengthened the conclusion that patients after the BP technique have a faster recovery.

Furthermore, as previously described, to achieve a power of 80% and detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level our estimated sample size was approximately 45 subjects per group and was based on a report by MacDermid and Tottenham (2004).⁽¹⁰⁾ However, a more recent study of Sorensen et al. (2013) reported that the sample size calculations in patients analyzed with PRWHE questionnaire should be performed with a difference of 14 points between both groups and that the standard deviation is approximately 15 instead of 25.⁽¹⁶⁾ With these numbers, a sample size estimation would result in approximately 20 subjects per group. Based on this estimation we believe that the sample size in present study (approximately 40 patients in each group) is more adequate than would be expected based on our original calculations.

Additionally, we included a relatively homogeneous study group of only women with a severe type IV OA. As a result, our results should not be extrapolated to the male population or to less severe OA types.

The number of studies comparing different ligament reconstruction techniques is limited. We found 1 retrospective comparative study⁽¹⁷⁾ comparing two suspension techniques using an APL sling, one with a Mitek anchor and another without. The study reported that Mitek anchor fixation improved radiological maintenance of the scaphometacarpal space, but was associated with an impaired postoperative function and pain when compared with the

suspension procedure without Mitek anchor. The authors hypothesized that a too-tight tendon fixation may be unphysiological and may cause pain and reduce strength. In our study, we also found that unphysiological tension on the APL and FCR tendon in the Weilby group resulted in impaired function and more pain early after the procedure.

In summary, based on strong evidence presented in this study, we conclude that the Burton-Pellegrini technique has better function and less pain 3 months after surgery than the Weilby group, indicating a faster recovery. However, twelve months after surgery, functional outcome is similar. Because of the better early recovery, the present study suggests that the Burton-Pellegrini technique should be preferred.

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General discussion



The aim of this general discussion is to provide an update of our systematic review published in 2011 (reviewing literature up to December 2009; Chapter 2)⁽¹⁾ on the surgical treatment of symptomatic OA at the base of the thumb, combined with the results of the 3 RCTs described in Chapter 4, 5, and 6. Based on the findings in these studies, the research questions, as outlined in the introduction section, are answered. Furthermore, treatment recommendations and future perspectives are provided.

Research questions as outlined in the introduction section

- Which surgical technique (trapeziectomy, trapeziectomy with LRTI, CMC arthrodesis, total joint prosthesis) is preferred in the treatment of the different stages of primary OA at the base of the thumb?
- Do different types of suspensory ligament reconstruction (LRTI techniques) have different subjective and objective outcomes?

A thorough literature search was performed using predetermined criteria, as outlined in Chapter 2, reviewing literature up to December 2012. A total of 45 articles fulfilled the inclusion criteria of literature with level I to V as classified by Jovell & Navarro-Rubio (see Table 2.1 in Chapter 2).⁽²⁾ Eight of these 45 articles (1 meta-analysis of Li et al. (Table 7.1)⁽²⁸⁾ and 7 comparative studies (Table 7.2)) were not included in our previous systematic review (Chapter 2). Twenty-five studies were level V, 3 studies were level IV, 8 studies were level III, 6 studies were level II, and 3 studies were level I. We excluded the RCTs of Davis et al. 1997⁽³⁾ (level II) and Downing et al. 2001⁽⁴⁾ (level II) because the patients in those studies were similar to the study of Davis et al. in 2004⁽⁵⁾ (level II). Of the 5 published systematic reviews (level I) we excluded 2 studies. Firstly, we excluded the meta-analysis of Wajon et al. from 2005,⁽⁶⁾ because we included the updated meta-analysis of Wajon et al. from 2009.⁽⁷⁾ Secondly, we excluded the systematic review of Martou et al. from 2004,⁽⁸⁾ because all included studies were also analysed in the updated systematic review of Vermeulen et al. in 2011 (Chapter 2).⁽¹⁾

The great degree of heterogeneity of the included studies in terms of population, intervention, and outcome did not allow statistical pooling. Therefore, conclusions were drawn based on the main findings of the included studies and on the results of the 3 RCTs described in Chapter 4 (level III), 5 (level II), and 6 (level II).

Because in some cases the various surgical techniques have minor differences in technical aspects of the procedure, it is difficult to compare the different techniques. Therefore, all included surgical procedures were subdivided in categories (Table 7.3).

Trapeziectomy and trapeziectomy with interposition

In our systematic review published in 2011 (Chapter 2, summarized in Table 7.1), reviewing literature up to December 2009, we concluded^(5, 9, 10-17) that there is no evidence of superiority of trapeziectomy alone or with interposition over any of the other techniques. If interposition is performed, autologous tissue interposition is preferable, since several studies (level III and V) showed that non-autologous tissue interposition (Gore-tex; Silastic implants; Permacol™) was associated with increased complications.^(9, 11, 18-25) Additionally, we concluded^(26, 27) there is no evidence that the Artelon spacer (yet another non-autologous interposition) is superior and therefore treatment cost effectiveness should be considered.

The meta-analysis of Wajon et al. 2009 (Table 7.1),⁽⁷⁾ reviewing literature up to 2008, showed similar results on trapeziectomy alone and trapeziectomy with TI. They concluded that these techniques did not have greater benefit in terms of pain and physical function. Furthermore, they showed that trapeziectomy has significantly fewer complications than trapeziectomy with LRTI: 10% compared to 22% ($p = .01$), respectively. Furthermore, Wajon et al. included 1 small level IV study of Nilsson et al. 2005⁽²⁷⁾ in which they compared 10 patients with an Artelon spacer with 5 patients with trapeziectomy with LRTI. They also concluded that the outcomes of the Artelon implant were not superior to the other techniques.

When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009), we found 6 new studies⁽²⁸⁻³³⁾ on trapeziectomy alone or with interposition (Table 7.1 and Table 7.2). The newly included meta-analysis of Li et al.⁽²⁸⁾ (level I) (Table 7.1), reviewing literature from 2002 up to 2008 and comparing trapeziectomy and trapeziectomy with LRTI, demonstrated no statistically significant differences in postoperative strength, pain, and DASH score. The complication rate in the trapeziectomy with LRTI group was 23.6% compared to 16.8% in the trapeziectomy group. However, this difference in favor of the trapeziectomy was not significant ($p = .13$).

When evaluating the newly included comparative studies, the small comparative study of Sandvall et al. (level V)⁽²⁹⁾ compared trapeziectomy (hematoma distraction arthroplasty) and trapeziectomy with LRTI. They concluded the LRTI technique and trapeziectomy were comparable on all levels of objective and subjective measurements (DASH, pain relief, strength and ROM). Both groups satisfied the principal goals to provide a stable, mobile, pain-free thumb.

The new comparative study of Maru et al. (level V)⁽³²⁾ compared trapeziectomy with Pyrocarbon interposition implant (Pi2). The mean DASH scores at follow up were 27 after a trapeziectomy and 35 after a Pi2 arthroplasty ($p = .001$). There was no difference in the VAS for pain, SF-36 scores, or other parameters assessed. Six out of 18 (33%) thumbs in the Pi2 group had multiple

Table 7.1 Summary of findings of included systematic reviews on the surgical treatment of primary osteoarthritis of the base of the thumb

Authors	Study design	Literature up to the year	Number of included studies	Included surgical procedures	Authors' conclusions
Li et al. 2011	Meta-analysis	2002–2008	6 (Level I t/m III)	Trapeziectomy Trapeziectomy with LRTI	Two systematic reviews and four randomized controlled trials were identified and included. There were no statistically significant differences in postoperative grip strength; tip pinch strength; key pinch strength; pain visual analogue scale score; DASH score; and number of adverse events. No studies reported health costs or quality of life. Authors' conclusion: Neither procedure produced greater benefit in terms of outcomes investigated.
Vermeulen et al. 2011	Systematic review	2009	35 (Level II t/m V)	Trapeziectomy Trapeziectomy with interposition (tendon or non-autologous materials) Trapeziectomy with LR Trapeziectomy with LRTI Artelon implant arthroplasty Arthrodesis Joint replacement procedures (Swanson silicone prothese) Total joint prosthesis (cemented Guerpar / uncemented Elektra)	Systematic evaluation demonstrated the following: (1) there is no evidence that trapeziectomy or trapeziectomy with tendon interposition is superior to any of the other techniques. However, when interposition is performed, autologous tissue interposition seems to be preferable. (2) Trapeziectomy with ligament reconstruction or trapeziectomy with ligament reconstruction and tendon interposition (LRTI) is not superior to any of the other techniques. However, follow-up in the studies with a higher level of evidence was relatively short (12 mo); therefore, long-term benefits could not be assessed. In addition, trapeziectomy with LRTI seems associated with a higher complication rate. (3) Because the studies on thumb carpometacarpal (CMC) arthrodesis were of less methodological quality and had inconsistent outcomes, we are not able to conclude whether CMC arthrodesis is superior to any other technique. Therefore, high-level randomized trials comparing CMC arthrodesis with other procedures are needed. Nevertheless, findings in the newly included studies did show that nonunion rates in the literature are on average 8% to 21% and, complications and repeat surgeries are more frequent following CMC arthrodesis. (4) A study on joint replacement showed that total joint prosthesis might have better short-term results compared to trapeziectomy with LRTI. However, high-level randomized trials comparing total joint prosthesis with other procedures are needed. In addition, there is no evidence that the Artelon spacer is superior to trapeziectomy with LRTI.

Wajon et al. 2009	Meta-analysis	2008	9 (Level II t/m III)	<p>Trapeziectomy</p> <p>Trapeziectomy with interposition</p> <p>Trapeziectomy with LR</p> <p>Trapeziectomy with LRTI</p> <p>Artelon implant arthroplasty</p> <p>Arthrodesis</p> <p>Joint replacement procedure (Swanson silicon prosthesis)</p>	<p>Seven surgical procedures were identified. Studies reported results of a mixed group of participants with Stage II-IV osteoarthritis, with a range of improvement for pain and physical function. The majority of studies included in this review had an unclear risk of bias which raises some doubt about the results. No procedure demonstrated any superiority over another in terms of pain, physical function, patient global assessment or range of motion. Of participants who underwent trapeziectomy with ligament reconstruction and tendon interposition, 22% had adverse effects (including scar tenderness, tendon adhesion or rupture, sensory change, or Complex Regional Pain Syndrome (Type 1)) compared to 10% who underwent trapeziectomy. Trapeziectomy with ligament reconstruction and tendon interposition is therefore associated with 12% more adverse effects (RR = 2.21, 95% CI 1.18 to 4.15). Authors' conclusions: Although it appears that no one procedure produces greater benefit in terms of pain and physical function, there was insufficient evidence to be conclusive. Trapeziectomy has fewer complications than trapeziectomy with LRTI.</p>
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Table 7.2 Summary of findings of new comparative studies (2010–2012) on the surgical treatment of primary osteoarthritis of the thumb not discussed in previous reviews

Authors	Study classification	No. of patients per group	Procedure	Authors' conclusion
Gangopadhyay et al. 2012	Level II	53	Trapeziectomy	Only women were included. The outcomes of these 3 variations of trapeziectomy were similar (pain, strength, ROM and complications) after a minimum follow-up of 5 years. There appears to be no benefit to tendon interposition or ligament reconstruction after trapeziectomy in the longer term.
		46	Trapeziectomy with TI	
		54	Trapeziectomy with LRTI	
Salem et al. 2012	Level II	59	Trapeziectomy	There were no significant differences between the two treatments in any subjective or objective outcome measure at 6 year follow-up. 82% of the thumbs were painless or only ached after use. The DASH and Patient Evaluation Measure scores were significantly better than preoperatively. Thumb key pinch strength did not differ significantly between the two treatment groups and was not significantly different from the preoperative key pinch strength. This study does not provide evidence to support the use of LRTI and temporary K-wire stabilization after trapeziectomy.
		55	Trapeziectomy with LRTI	
Maru et al. 2012	Level V	18	Pyrocarbon interposition implant (Pi2)	The mean DASH scores at follow up were 27 for those that had a trapeziectomy and 35 for those that had a Pi2 arthroplasty (p = .001). There was no difference in the VAS for pain, SF-36 scores, or other parameters assessed. Six out of 18 (33%) thumbs in the Pi2 group had multiple operations, usually for dislocation or subluxation of the implant. The early results of Pi2 arthroplasty show a high complication rate compared with trapeziectomy and no identifiable benefit.
			18	

Nordback et al. 2012	Level V	23	<p>Trapeziectomy with APL sling and Mitek anchor</p> <p>Trapeziectomy with APL sling without Mitek anchor</p>	<p>Mitek anchor fixation was associated with a shorter convalescence period. However, in spite of an improved radiological maintenance of the scaphometacarpal space, mitek anchor fixation was associated with an impaired postoperative function and residual pain when compared with the conventional suspension ligamentoplasty procedure. Patient's satisfaction was comparable in both groups. In our series stabilization of the suspension ligamentoplasty procedure by the insertion of a mitek anchor did not bring the hoped benefits to the patients with a trapeziometacarpal arthritis.</p>
Vandenbergh et al. 2012	Level V	233	<p>Trapeziectomy with LRTI</p> <p>La Caffiniere and Roseland total joint prosthesis (both cemented)</p>	<p>A questionnaire was sent to all 519 patients, 322 (with 382 procedures) responded. No significant differences were found when comparing impairment, pain, patient satisfaction and disability. Given the fact that the superiority of a prosthesis cannot be proven and the cost of the implant is greater, we recommend the trapeziectomy with ligament reconstruction and tendon interposition as opposed to arthroplasty as the first choice in the treatment of basal joint osteoarthritis of the thumb.</p>
Nilsson et al. 2010	Level II	72	<p>Artelon implant arthroplasty</p> <p>Trapeziectomy with LRTI (APL, ECRL or FCR)</p>	<p>Swelling and pain were more common in the Artelon group and 6 implants were removed because of such symptoms. 5 of these patients did not receive antibiotics preoperatively according to the study protocol. Statistically significant pain relief was achieved in both groups, with perceived pain gradually decreasing during the follow-up period. In the intention-to-treat analysis but not in the per-protocol analysis, significantly better pain relief (VAS) was obtained in the control group. Patient-perceived disability evaluated by the DASH questionnaire improved in both groups. The Artelon CMC spacer did not show superior results compared to tendon interposition arthroplasty.</p>
Sandvall et al. 2010	Level V	11	<p>Trapeziectomy with LRTI</p> <p>Trapeziectomy</p>	<p>Conclusions: The LRTI and trapeziectomy alone were comparable on all levels of objective and subjective measurements (DASH, pain relief, strength and ROM). Both groups satisfied the principal goals to provide a stable, mobile, pain-free thumb.</p>

Table 7.3 Categories of the surgical techniques described in the included studies

Category	Techniques described in included studies
Volar ligament reconstruction	Non
Metacarpal osteotomy	Radial wedge metacarpal osteotomy
Trapeziectomy	Trapeziectomy (hematoma distraction arthroplasty)
Trapeziectomy with interposition	Tendon; Gore-tex; marlex; Permacol TM; Swanson silicone implant; Kessler silicone implant, Pyrocarbon implant (Pi2); Artelon implant; Spongostan; Costochondral allograft
Trapeziectomy with LR	Trapeziectomy with LR i.e. APL, FCR, and ECRL
Trapeziectomy with LRTI	Trapeziectomy with LRTI i.e. APL, FCR, and ECRL
Carpometacarpal arthrodesis	K-wires; plate and screws; screws
Joint replacement procedures	Cemented total joint prosthesis: Guerpar, La Caffiniere, Roseland, and Mayo implant; uncemented total joint prosthesis: Elektra prosthesis

operations, usually for dislocation or subluxation of the implant. The early results of Pi2 arthroplasty show a high complication rate compared with trapeziectomy and no identifiable benefit.

The newly included long-term follow-up (5 to 18 years) randomized study of Gangopadhyay et al. (level II),⁽³⁰⁾ comparing trapeziectomy, trapeziectomy with TI, and trapeziectomy with LRTI found no benefit to TI or LRTI in the long-term. In addition, the recent 6-years follow-up study of Salem and Davis (level II)⁽³¹⁾ comparing trapeziectomy alone and trapeziectomy with LRTI also showed no evidence to support the use of LRTI after trapeziectomy.

The study of Nilson et al. (level II)⁽³³⁾ compared the Artelon implant arthroplasty (non-autologue interposition after partial trapeziectomy) and trapeziectomy with LRTI (APL, ECRL, or FCR). The results showed that swelling and pain were more common in the Artelon group and 6 implants were removed because of such symptoms. 5 of these patients did not receive antibiotics preoperatively which was required according to the study protocol. Statistically significant pain relief was achieved in both groups, with perceived pain gradually decreasing during the follow-up period. In the intention-to-treat analysis but not in the per-protocol analysis, significantly better pain relief (VAS) was obtained in the LRTI group. Patient-perceived disability evaluated by the DASH questionnaire improved in both groups. The Artelon CMC spacer did not show superior results compared to tendon interposition arthroplasty.

The results of the RCT comparing trapeziectomy with total joint prosthesis (Guepar) (Chapter 5) will be discussed in the joint replacement procedure paragraph.

Overall, when evaluating the newly included studies⁽¹⁸⁻³³⁾ (Table 7.1 and 7.2) in combination with the included reviews of Wajon et al.⁽⁷⁾ and Vermeulen et al.⁽¹⁾ (Table 7.1) there is no evidence of superiority of trapeziectomy alone or with interposition over any of the other techniques. However, trapeziectomy alone has fewer complications than trapeziectomy with LRTI. If interposition is performed, autologous tissue interposition is preferable, because several studies showed that non-autologous tissue interposition, i.e., Gore-tex, Permacol™, Silastic implants (Swanson silicone spacer), and Pyrocarbon (Pi2) were all associated with increased severe complications, like synovitis, foreign body reaction, dislocation, or subluxation.^(1, 9, 11, 18-25, 33) Furthermore, non-autologous interpositions, e.g., the Artelon spacer,⁽³²⁾ are more expensive and therefore should not be used without evidence of superiority.

Trapeziectomy with ligament reconstruction and trapeziectomy with ligament reconstruction and tendon interposition

In our initial systematic review (Chapter 2, summarized in Table 7.1) we concluded on trapeziectomy with LR and trapeziectomy with LRTI that superiority of trapeziectomy with additional LR, or LRTI is not supported by evidence.^(5, 10, 12, 13, 15, 17, 25, 26, 34-39) It should be noted, however, that the three studies with the highest study classification (level II) all had a mean follow-up of only 12 months and therefore possible long-term benefits of a LRTI compared to trapeziectomy alone or with TI could not be assessed at that time.^(5, 13, 17) Additionally, these three studies showed that trapeziectomy with LRTI is associated with a higher complication rate compared to trapeziectomy without LRTI.

The meta-analysis of Wajon et al.⁽⁷⁾ also concluded that trapeziectomy with LRTI demonstrated no superiority over the other techniques compared in those reviews. Furthermore, Wajon et al. reported that trapeziectomy with LRTI had significantly more adverse effects (including scar tenderness, tendon adhesion or rupture, sensory change, or Complex Regional Pain Syndrome Type 1) than trapeziectomy alone: 22% vs. 10% ($p = .01$), respectively. Therefore, they concluded that trapeziectomy is safer.

When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009), we found 7 new studies^(28-32, 40, 41) on trapeziectomy with LR or trapeziectomy with LRTI (Table 7.1 and Table 7.2). The newly- included meta-analysis of Li et al.⁽²⁸⁾ (level I) (Table 7.1), as described in the previous paragraph, comparing trapeziectomy and trapeziectomy with LRTI, showed that there were no statistically significant differences in postoperative strength, pain, DASH score, and number of adverse events.

As described in more detail in the previous paragraph, the newly included studies of Sandvall et al. (level V)⁽²⁹⁾, Salem et al. (level II)⁽³¹⁾, and Gangopadhyay et al. (level II)⁽³⁰⁾, all showed no additional benefit of a LRTI after trapeziectomy.^(19, 20, 25)

The new study of Nordback et al. (level V)⁽⁴⁰⁾ compared trapeziectomy with APL sling with and without Mitek anchor fixation. Mitek anchor fixation was associated with a shorter convalescence period. However, in spite of an improved radiological maintenance of the scaphometacarpal space, Mitek anchor fixation was associated with an impaired postoperative function and residual pain when compared with the conventional suspension ligamentoplasty procedure. Patient's satisfaction was comparable in both groups. In their series stabilization of the suspension ligamentoplasty procedure by the insertion of a Mitek anchor did not bring benefits to the patients with CMC OA of the thumb.

The new comparative studies of Vandenberghe et al. (level V)⁽⁴¹⁾ comparing trapeziectomy with LRTI and joint replacement procedures, will be discussed in the paragraph on joint replacement procedures.

The previously described study of Nilson et al. (level II)⁽³²⁾ showed that trapeziectomy with LRTI was not superior to the Artelon CMC spacer.

The results of Chapter 4 comparing trapeziectomy with LRTI and CMC arthrodesis will be discussed in the arthrodesis paragraph.

In Chapter 6 we described a RCT comparing the Burton-Pellegrini technique (arthroplasty with a bone tunnel at the base of the first metacarpal) and the Weilby technique (arthroplasty that preserves the structural integrity of the base of the first metacarpal) in patients with stage IV OA. Seventy-nine patients were enrolled in this study. Our main findings were that at 3 months PRWHE pain and PRWHE total were significantly more improved in the Burton-Pellegrini group compared to the Weilby group. At 12 months, however, no significant differences were found for all PRWHE and DASH scores between both groups. In addition, we observed no significant differences between groups in strength, duration to return to work or activities, patient satisfaction, and complication rates. Based on these findings, we conclude that patients after the Burton-Pellegrini technique have better function and less pain 3 months after surgery than for the Weilby group, indicating a faster recovery. However, twelve months after surgery, functional outcome is similar. Because of the faster recovery, we prefer the Burton-Pellegrini technique in the treatment of stage IV osteoarthritis.

Overall, when evaluating the results of the newly included studies^(28-32, 40, 41) (Table 7.1 and 7.2) in combination with the reviews of Wajon et al.⁽⁷⁾, Vermeulen et al.⁽¹⁾ (Table 7.1), and Chapter

6, there is no evidence for superiority of trapeziectomy with additional LR or LRTI, not even long term, based on the new studies of Gangopadhyay et al.⁽³⁰⁾ and Salem et al.⁽³¹⁾ (both level II and follow-up > 5 years). Furthermore, the findings showed that a higher complication rate after trapeziectomy with LRTI has to be taken in to account. The complication rates after an additional LRTI will be further discussed in the main conclusions paragraph below. Based on Chapter 6, we concluded that if a LRTI technique is performed the Burton Pellegrini is preferable, because of the faster recovery compared to the Weilby technique.

Carpometacarpal arthrodesis

In our previous systematic review (Chapter 2, summarized in Table 7.1) the included studies on thumb CMC arthrodesis were of limited methodological quality (most studies were level V^(14, 19, 21, 38, 42-46) and only one level III study⁽³⁶⁾) and had inconsistent outcomes. Therefore, we were not able to conclude whether CMC arthrodesis was superior to any other technique and recommended a high-level randomized trial comparing CMC arthrodesis with other procedures. Nevertheless, findings did show that CMC arthrodesis is not only primarily indicated for young people with posttraumatic arthritis but it can also be used for older patients with stage II and III OA.^(14, 38) Non-union rates in literature are on average 8–21% and although complications and reoperations are more frequent following CMC arthrodesis compared to trapeziectomy or trapeziectomy with LRTI it did not affect the overall outcome in some studies.^(14, 38, 46)

The meta-analysis of Wajon et al.⁽⁷⁾ included one small RCT of Hart (2006) (level III)⁽³⁷⁾ (Table 7.3) in which CMC arthrodesis of the thumb was compared to trapeziectomy with LRTI. In that study no significant differences were observed. However, Wajon et al. reported that the statistical significance of these scores is unclear, as standard deviations were not provided for statistical analysis.

When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009)⁽¹⁾, we found no comparative studies on CMC arthrodesis.

In Chapter 4 we compared the outcomes of trapeziectomy with LRTI (Weilby arthroplasty) and thumb CMC arthrodesis (plate and screws) in stage II and III OA in a randomized trial. Since we found significantly more moderate and severe complications following arthrodesis compared to trapeziectomy with LRTI (71% vs 29%, $p = .016$) the study was prematurely terminated. The increased complication rate led to an increase in revision surgery. In addition, significantly more patients in the LRTI group (86%) would consider the same surgery again under the same circumstances as compared to the arthrodesis group (53%) ($p = .025$). In both groups, PRWHE and DASH scores significantly improved over time, although no significant differences between

both groups were found. Because patients after trapeziectomy with LRTI had fewer moderate and severe complications and were more likely to consider surgery again under the same circumstances compared to patients treated with arthrodesis, we do not recommend routine use of arthrodesis with plate and screws in the treatment of stage II en III CMC OA of the thumb.

Overall, when evaluating the results of Chapter 4 in combination with the included studies in the reviews of Wajon et al.⁽⁷⁾ and Vermeulen et al.⁽¹⁾ (Table 7.1), we can conclude that CMC arthrodesis of the thumb has a higher rate of clinically-important complications, more specifically a higher incidence of delayed union and nonunion needing revision surgery. Because of the higher complication rate, patients are less likely to consider surgery again. Although, a few studies on CMC arthrodesis report decreased ROM^(14, 38) and increased strength^(19, 45) compared to other techniques, it did not significantly effects subjective outcome measures in those studies (e.g., DASH scores or overall satisfaction). Based on the above, we conclude that CMC arthrodesis of the thumb should not routinely be recommended in the treatment of stage II en III OA and should be reserved for specific indications.

Joint replacement procedures (total joint prosthesis)

In our previous systematic review (Chapter 2, summarized in Table 7.1) we concluded that total joint prosthesis might be a good alternative with potentially better results, at least in the short term, compared to trapeziectomy with LRTI. Immediate stability, strength, and motion are realized, but implant loosening may occur. Because of the promising results of total joint prosthesis in studies with less methodological quality^(34, 43, 47), high level randomized trials comparing total joint prosthesis with other procedures are needed to verify possible benefits of these procedures.

When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009), we found 1 new study on a total joint prosthesis: The retrospective study of Vandenberghe et al. (level V)⁽⁴¹⁾ compared trapeziectomy with LRTI and total joint prosthesis (La Caffiniere and Roseland prosthesis, both cemented). Although this study had an unequal number of patients in both groups and the LRTI group had more severe pathology, i.e. including STT arthritis and greater loss of trapezium height, no significant differences were found when comparing impairment, pain, patient satisfaction and disability. Given the fact that the superiority of the prosthesis cannot be proven and the cost of the implant is greater, they recommend trapeziectomy with LRTI as the first choice in the treatment of basal joint osteoarthritis of the thumb.

In Chapter 5 we compared the outcomes of trapeziectomy and total joint prosthesis (cemented Guepar prosthesis) in a RCT. The results showed that although in both groups the PRWHE

scores significantly improved over time, there was no significant difference between both groups. Three months after surgery the group receiving a prosthesis showed significantly more improvement with respect to key- and three point pinch, and IP extension compared to the group after a trapeziectomy. Twelve months after surgery the prosthesis group showed clinically relevant and statistically significant more improvement on DASH compared to the group receiving a trapeziectomy. Moreover, the prosthesis group showed also more improvement with respect to key-pinch force twelve months after surgery compared to the other group. So, although differences are small, this study suggests a tendency that patients after a total joint arthroplasty may have better functional outcomes and experience less pain in the short-term (12 months) compared to patients treated with a trapeziectomy.

In summary, when evaluating the results on joint replacement procedures (total joint prosthesis) in the treatment of symptomatic OA of the first CMC joint in the newly included study⁽⁴¹⁾ (Table 7.2) in combination with the included studies in the reviews of Wajon et al.,⁽⁷⁾ Vermeulen et al.⁽¹⁾ (Table 7.1), and Chapter 5 we concluded that the differences are small. While Vandenberghe et al. (level V)⁽⁴¹⁾ concluded that results of the prosthesis are comparable and costs are greater, the RCT in Chapter 5 (level II) shows results in favor of the prosthesis in the short-term, which is supported by the study of Ulrich-Vinther et al. (level IV)⁽³⁴⁾ that also shows favorable results of the prosthesis in the short-term (12 months). Because the overall results of total joint prosthesis are only slightly better in the short-term and the costs are inevitably higher, long-term results are warranted to evaluate subjective and objective outcomes and implant failure rates over the years to determine the additional value of the total joint prosthesis. The decreased revision rates of the implants in recent studies on total joint prosthesis (Ulrich-Vinther et al.: 2.8%;⁽³⁴⁾ RCT Chapter 5: 3.8%) compared to earlier reports (Amadio et al.: 40%)⁽⁴³⁾ suggest that improving quality of total joint prostheses could have a significant positive effect on outcome.

Metacarpal osteotomy

In our systematic review (Chapter 2, summarized in Table 7.1) we concluded based on the retrospective study of Atroshi et al.⁽⁴⁸⁾ 1998 (level V) that osteotomies should be limited to patients with early disease (stage I and II OA). When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009), we found no comparative studies on metacarpal osteotomies and therefore no additional conclusions could be drawn.

Volar ligament reconstruction

Although volar ligament reconstruction is suggested to be an effective technique for treating symptomatic laxity of the CMC joint of the thumb for stage I and II OA, our systematic review (Chapter 2, summarized in Table 7.1) could not find any level I–V studies on volar ligament reconstruction. When evaluating the studies that became available after the review of Vermeulen et al. (literature up to 2009), we still did not find any comparative studies on volar ligament reconstruction in present literature and therefore any effectiveness of this technique could not be assessed.

Main conclusions

Because OA at the base of the thumb can result in significant disability, selecting the optimal surgical procedure is highly relevant. Patients should only be operated on when not responding to conservative treatment and when suffering from interference with occupational or recreational activities. The radiological classification of Eaton and Glickel does not have direct treatment implications and have only a supporting role in diagnosing basal thumb OA. Therefore, it is important to evaluate if patients have symptomatic OA only at the first CMC joint or at the first CMC and STT joint, rather than focusing on which radiological stages of the disease they have. Symptomatic OA only at the first CMC joint or at the first CMC and STT joint should determine which surgical technique is performed.

Patients with symptomatic OA only at the first CMC joint

Based on the best available evidence in literature and the results of this thesis we conclude that patients with symptomatic OA only at the first CMC joint are best treated with trapeziectomy. Because strong evidence is available that trapeziectomy alone has fewer complications than trapeziectomy with LRTI (based on the meta-analysis of Wajon (level I)⁽⁷⁾ and the systematic review of Vermeulen (level I).⁽¹⁾ Although the additional value of an interposition after trapeziectomy is questionable (Gangopadhyay et al., level II),⁽³⁰⁾ we conclude if an interposition is performed, that an autologous TI is preferable, because several studies showed that non-autologous interpositions are associated with increased severe complications (several studies with level I–V).^(1, 9, 11, 18-25, 33) Furthermore, costs of non-autologous interposition are higher.⁽³²⁾

Based on the previous paragraph on thumb CMC arthrodesis we conclude that, although asymptomatic nonunion occurs, nonunion may be the most important factor for overall outcome and revision surgery rate in patients treated with CMC arthrodesis. Therefore, we evaluated the included studies on CMC arthrodesis and compared the incidence of nonunion

of studies with and without bone grafting. In 8 out of 10 of the studies included in this updated systematic review reporting on CMC arthrodesis and in Chapter 4, nonunion rates as well as the fusion technique with or without autogenous bone graft was described in detail and could be analyzed.^(14, 19, 21, 37, 38, 42-44) Overall, nonunion was seen in 27 out of 194 fusions (13.9 %) (range 0–37%). When comparing nonunion in fusions with and without a bone graft, we found that 4 out of 39 fusions with a bone graft had nonunion (10.3%), while 23 out of 155 fusions without a bone graft had nonunion (14.8%), which was not significantly different (A Chi-Square test: $p = .45$). Based on the above, we conclude that routine use of CMC arthrodesis in the treatment of patients with symptomatic OA only at the first CMC joint is not recommended, because too many complications occur due to delayed union and non-union (regardless of the use of bone grafting), resulting in patients not preferring a fusion again in the same circumstances (Vermeulen et al. (level I)⁽¹⁾ and Chapter 4 (level III)).

Furthermore, we conclude, based on the fact that the results of total joint prosthesis are only slightly better in the short-term (Vermeulen et al., level I;⁽¹⁾ Chapter 5, Level II, Ulrich-Vinther et al., level IV⁽³⁴⁾) and because costs are inevitably higher (Vandenberghe et al., level V)⁽⁴¹⁾, that total joint prosthesis should only be used in a trial setting. Long-term results are warranted to evaluate subjective and objective outcomes, and to study implant failure rates over the years to reveal the possible additional benefits of the total joint prosthesis compared to trapeziectomy.

Patients with symptomatic OA at both the first CMC and STT joint

For patients with symptomatic OA at the first CMC and STT joint, we conclude, based on the included systematic reviews (Wajon et al.⁽⁷⁾, Vermeulen et al.⁽¹⁾, Li et al.⁽²⁸⁾ (Table 7.1)), and the results of this thesis (Chapter 6), that there is no evidence for superiority of trapeziectomy with additional LR or LRTI, not even in the long-term (Gangopadhyay et al.⁽³⁰⁾ and Salem et al.⁽³¹⁾ (both level II and follow-up > 5 years)). Although these studies are both randomized trials with a relative large sample size that report long-term results, a number of questions remain.^(30, 31) For example, in both studies, only approximately 10% of the patients in each group had scaphotrapeziotrapezoid (STT) joint OA (Stage IV OA according to the radiographic criteria of Eaton and Glickel⁽⁴⁹⁾) while the majority of patients had stage II en III OA. Accordingly, the results of these studies primarily apply to stage II and III OA. Since stage IV OA is characterized by more cartilage and soft-tissue damage (ligament wear) than stage II en III, we postulate that the thumb has an increased tendency to collapse in the palm, resulting in a typical zig-zag deformity of the thumb. Therefore, we believe that an additional ligament reconstruction after trapeziectomy could still be a valuable treatment option in patients with stage IV OA (patients with symptomatic OA at the first CMC and STT joint). However, a RCT comparing

trapeziectomy and trapeziectomy with LRTI is warranted to confirm the possible benefits of a LRTI after trapeziectomy in patients with symptomatic OA at the first CMC and STT joint. Based on Chapter 6 we concluded that if a LRTI technique is performed the Burton Pellegrini is preferable, because of the faster recovery.

In the previous paragraph we suggested that symptomatic OA at both the first CMC and STT joint may best be treated with an additional LRTI, although sufficient evidence is lacking. Furthermore, we described that a LRTI after trapeziectomy resulted in more adverse effects. Therefore, we evaluated the evidence on adverse effects after an additional LRTI. The meta-analysis of Wajon et al.⁽⁷⁾ (level I) (Table 7.1) showed that trapeziectomy has significantly fewer complications than trapeziectomy with LRTI: 10% compared to 22% ($p = .01$), respectively. The meta-analysis of Li et al.⁽²⁸⁾ (level I) (Table 7.1) showed that the complication rate in the trapeziectomy group was 16.8% compared to 23.6% in the trapeziectomy with LRTI group; However, this difference in favor of the trapeziectomy was not significant ($p = .13$). Furthermore, these meta-analyses looked at all complications together and did not differentiate between clinically relevant complications (e.g., delaying patients' recovery, for example due to revision surgery or CRPS I) from clinically less-relevant complications (e.g., minor adverse effects not delaying patients' recovery, such as sensibility disturbances). Maybe the higher probability of complications after an additional LRTI is due to the more comprehensive technique, but whether these complications are all clinically relevant is questionable, because present literature does not report the clinical relevance of the complications. Therefore, further research is warranted.

Treatment recommendations (Table 7.4)

The aim of this thesis was to answer the two previously described research questions and to develop new treatment recommendations. The first question 'Which surgical techniques (trapeziectomy, trapeziectomy with LRTI, CMC arthrodesis, total joint prosthesis) are preferred in the treatment of the different stages of primary OA at the base of the thumb?' is answered by the following recommendation: Based on the present evidence, patients with symptomatic OA only at the first CMC joint are best treated with trapeziectomy, because trapeziectomy has less complications compared to a trapeziectomy with LRTI or trapeziectomy with a non-autologous interposition. CMC arthrodesis of the thumb should not be routinely used because of the high complication rate caused by delayed and non-union, regardless the use of a bone graft. Additionally, total joint prosthesis should only be performed in a trial setting. If patients have clinical symptoms at both the first CMC and STT joint, we postulate that trapeziectomy with an additional LRTI (Burton Pellegrini technique) is the best treatment option.

Table 7.4 Treatment recommendations for patients with symptomatic OA

First CMC joint	First CMC and STT joint
Trapeziectomy	Trapeziectomy with LRTI (Burton Pellegrini)
Total joint prosthesis (only in trial setting)	

Answering the second research question, we conclude that different types of suspensory ligament reconstruction (LRTI techniques) have different subjective short-term outcomes (PRWHE scores at 3 months in favor of the Burton Pellegrini technique) and more or less the same objective outcomes. Therefore, if a LRTI technique is used we recommend the Burton Pellegrini technique (arthroplasty with a bone tunnel at the base of the first metacarpal) over the Weilby technique (arthroplasty that preserves the structural integrity of the base of the first metacarpal).

Limitations of this thesis

Although we believe that the conclusions of this thesis resulted in important and clear treatment recommendations based on a thorough systematic review of the literature and significant differences between the various surgical techniques researched in the 3 RCTs described in Chapter 4, 5, and 6, there are some limitations.

An important limitation is that we did not include the full number of patients in the 3 RCTs that we originally estimated as necessary to achieve statistical power. Accordingly, sufficient power was not reached for most primary and secondary outcome measures and findings for these outcome measures should be evaluated keeping this in mind. As previously described (Chapter 5 and 6), to achieve a power of 80% and detect a difference of 15 points (SD 25) between both groups in the PRWHE questionnaire with a two-sided 5% significance level our estimated sample size was approximately 45 subjects per group and was based on a report by MacDermid and Tottenham (2004).⁽⁵⁰⁾ However, a more recent study of Sorensen et al. (2013) reported that the sample size calculations in patients analyzed with PRWHE questionnaire should be performed with a difference of 14 points between both groups and that the standard deviation is approximately 15 instead of 25.⁽⁵¹⁾ With these numbers, a sample size estimation would result in approximately 20 subjects per group. Based on this estimation we believe that the sample size in Chapter 4 (23 trapeziectomy with LRTI (Weilby) group; 20 in CMC arthrodesis group), Chapter 5 (26 in trapeziectomy group; 29 in TJA group), and Chapter 6

(40 in Burton-Pellegrini group; 39 patients in the Weilby group) is more adequate than would be expected based on our original calculations.

Furthermore, it should be noted that we studied in Chapter 4, 5, and 6 a homogenous group of women aged 40 and over with primary OA of the thumb and therefore the results of these 3 RCTs may not apply to men, or to people with rheumatoid or posttraumatic osteoarthritis.

Future perspectives

As previously described, we suggest that trapeziectomy with an additional LRTI may be the best treatment option when both the first CMC and STT joint are involved, but that future well-designed research is needed to confirm this. Additionally, the improved quality of the total joint prosthesis in recent years warrants a new comparative study with trapeziectomy in patients with symptomatic OA only at the first CMC joint.

In this thesis, outcome measures which were clinically important were complication rates, subjective outcomes (PRWHE, DASH), and if patients consider the same surgery again. Objective outcomes, such as active ROM or strength, seem to be clinically less important and have not been sensitive in detecting differences between interventions. Therefore, it is important that researchers develop new outcome measures. Maybe more sensitive outcome measures could detect small differences between the various techniques.

Additionally, as previously described, complication rate is an important outcome measure. Therefore, we believe it is crucial when evaluating complications after surgery in future studies that researchers differentiate between clinically important complications (e.g. delaying patients' recovery, like revision surgery or CRPS I) and clinically less important complications (e.g. minor adverse events not delaying patients' recovery, such as sensibility disturbances). Since most studies find very small or no functional differences, significant difference in clinically relevant complications causing delayed recovery may be the most crucial factor to determine which surgical technique is used.

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Summary
Samenvatting



Summary

Osteoarthritis at the base of the thumb can result in significant disabilities. In **Chapter 2** a systematic review is described reviewing literature up to December 2009 on the 8 most commonly used surgical techniques. A thorough literature search was performed using predetermined criteria. A total of 35 articles fulfilled the inclusion criteria, nine of which were not included in previous systematic reviews.

Systematic evaluation demonstrated the following: (1) there is no evidence that trapeziectomy or trapeziectomy with tendon interposition is superior to any of the other techniques. However, when interposition is performed, autologous tissue interposition seems to be preferable. (2) Trapeziectomy with ligament reconstruction or trapeziectomy with ligament reconstruction and tendon interposition (LRTI) is not superior to any of the other techniques. However long-term benefits could not be assessed as follow-up in the studies with a higher level of evidence was relatively short (maximally 12 months). In addition, trapeziectomy with LRTI seems associated with a higher complication rate. (3) Because the studies on thumb carpometacarpal (CMC) arthrodesis were of poor methodological quality and had inconsistent outcomes, we are not able to conclude whether CMC arthrodesis is superior to any other technique. Therefore, high-level randomized trials comparing CMC arthrodesis with other procedures are needed. Nevertheless, findings in the newly included studies did show that nonunion rates in the literature are on average 8% to 21% and complications and revision surgeries are more frequent following CMC arthrodesis. (4) A study on joint replacement showed that total joint prostheses might have better short-term results compared to trapeziectomy with LRTI but high-level randomized trials comparing total joint prosthesis with other procedures are needed. In addition, there is no evidence that the Artelon spacer is superior to trapeziectomy with LRTI.

We conclude that, at this time, no surgical procedure is proven to be superior to another. However, based on good results of CMC arthrodesis and total joint prostheses, we postulate that there could be differences between the various surgical procedures. Therefore randomized clinical trials of CMC arthrodesis and total joint prostheses compared to trapeziectomy with long follow-up (>1 y) are warranted.

In **Chapter 3** a prospective cohort study (pilot study) is reported in which we analyzed preoperative and postoperative objective and subjective outcomes after Weilby interposition tendoplasty (LRTI technique without requiring bone tunnel creation).

Nineteen patients (20 thumbs) with primary thumb carpometacarpal (CMC) osteoarthritis were treated with Weilby interposition tendoplasty. For subjective assessment, the Disabilities

of the Arm, Shoulder, and Hand (DASH) questionnaire was used to evaluate preoperative and postoperative outcomes at 0, 3, 6, and 12 months. Furthermore, patients completed a specific personal questionnaire at 12 months of follow-up.

Objective assessments included active range of motion (ROM) and strength measurements and were also performed preoperatively and at 3, 6, and 12 months after surgery. All complications were registered. Results showed that the DASH score significantly improved over time, and 17 of 19 patients were satisfied with the procedure. The active ROM measurements showed that CMC joint palmar abduction and opposition were significantly improved at 12 months. The 3-point pinch and overall grip strength were also significantly improved at 12 months.

In conclusion, the Weilby procedure is a reliable alternative to treat primary thumb CMC osteoarthritis without requiring bone tunnel creation. It achieves pain relief, stability, mobility, and strength. The objective and subjective outcomes of this study compare favorably with those of earlier reports of the Weilby procedure and are similar to the published results of the more commonly performed Burton-Pellegrini technique (LRTI technique with a bone tunnel at the base of the first metacarpal).

In **Chapter 4** we compared the outcomes of trapeziectomy with LRTI (Weilby arthroplasty) and thumb carpometacarpal (CMC) arthrodesis (plate and screws) in women with stage II and III osteoarthritis of the first CMC joint in a randomized trial.

Twenty-three patients in the LRTI group and 20 patients in the arthrodesis group were enrolled in this study. Since we found significantly more moderate and severe complications following arthrodesis compared to trapeziectomy with LRTI (71% vs 29%, $p = .016$), the study was prematurely terminated before the sample size necessary to validly compare the two groups was reached. The higher complication rate for arthrodesis led to an increase in revision surgery (2/17). In addition, significantly more patients in the LRTI group (86%) would consider the same surgery again under the same circumstances as compared to the arthrodesis group (53%) ($p = .025$). In both groups, PRWHE and DASH scores significantly improved over time, but the changes were not significantly different between groups.

Because patients after trapeziectomy with LRTI have fewer moderate and severe complications after trapeziectomy with LRTI and are more likely to consider surgery again under the same circumstances than those who undergo arthrodesis, we do not recommend routine use of arthrodesis with plate and screws in the treatment of women with stage II and III osteoarthritis of the first CMC joint.

In **Chapter 5** we compared the outcomes of trapeziectomy and total joint prosthesis (cemented Guepar prosthesis) in women with primary OA at the first carpometacarpal (CMC) joint in a RCT.

Twenty-six patients underwent a trapeziectomy and 29 patients received a total joint arthroplasty. Although in both groups the PRWHE scores significantly improved over time, there was no significant difference between both groups. Three months after surgery the group receiving a total joint arthroplasty showed significantly greater improvement in key- and three-point pinch and in IP extension compared to the trapeziectomy group. One year after surgery the total joint arthroplasty group showed a significantly greater improvement on DASH and key-pinch force compared to the trapeziectomy group. Furthermore, no significant difference in complications between both groups was observed.

Although differences were small, this study suggests a tendency that patients after total joint arthroplasty have better functional outcomes 1 year after surgery compared to patients treated with trapeziectomy. However, long-term results are warranted to evaluate subjective and objective outcomes and implant failure rates over the years.

While several ligament reconstructions have been described to treat osteoarthritis (OA) at the base of the thumb, they were never directly compared in a randomized clinical trial. In **Chapter 6** we described a RCT comparing the Burton-Pellegrini arthroplasty (LRTI technique with a bone tunnel at the base of the first metacarpal) and the Weilby arthroplasty (LRTI technique that preserves the structural integrity of the base of the first metacarpal) in women with stage IV OA.

Forty patients in the Burton-Pellegrini group and 39 patients in the Weilby group were enrolled in this study. Our main findings were that at 3 months PRWHE-pain and PRWHE-total were significantly more improved in the Burton-Pellegrini group compared to the Weilby group. At 12 months, however, no significant differences were found for all PRWHE and DASH scores between both groups. In addition, we observed no significant differences between groups in strength, patient satisfaction, and complication rates.

We conclude that the Burton-Pellegrini technique has better function and less pain 3-months after surgery than the Weilby group, indicating a faster recovery. However, 12-months after surgery, functional outcome is similar. Because of the better early recovery, the present study suggests that the Burton-Pellegrini technique should be preferred.

In **Chapter 7** (general discussion) an update of our systematic review published in 2011 (reviewing literature up to December 2009; Chapter 2) on the surgical treatment of symptomatic

OA at the base of the thumb is described. A total of 45 articles fulfilled the inclusion criteria and the results of these studies up to December 2012 were combined with the results of the 3 RCT's described in Chapters 4, 5, and 6. Based on the findings in these studies, the research questions, as outlined in the introduction section, were answered and treatment recommendations and future perspectives were provided.

In this Chapter, we conclude that, based on the present evidence, patients with symptomatic OA only at the first CMC joint are best treated with trapeziectomy, because trapeziectomy has fewer complications compared to trapeziectomy with LRTI or trapeziectomy with a non-autologous interposition. Thumb CMC arthrodesis should not be routinely used because of the high complication rate caused by delayed and non-union, regardless the use of a bone graft. Additionally, total joint prosthesis should only be performed in a trial setting.

If patients have clinical symptoms at both the first CMC and STT joint, we postulate that trapeziectomy with an additional LRTI (Burton Pellegrini technique) is the best treatment option.

Future research should concentrate on whether trapeziectomy with an additional LRTI, in patients with symptomatic OA at the first CMC and STT joint, is a valuable treatment option. In addition, we conclude that the improved quality of the total joint prostheses over the years compared to trapeziectomy should be studied with a long term follow-up in patients with symptomatic OA only at the first CMC joint. Furthermore, we believe it is crucial when evaluating complications after surgery that researchers differentiate between clinically important complications (e.g. delaying patients' recovery, like revision surgery or CRPS I) and clinically less important complications (e.g. minor adverse events not delaying patients' recovery, like sensibility disturbance). Significant difference in clinically relevant complications causing delayed recovery should determine which surgical technique is used. Additionally, researchers should search for new more sensitive outcome measures.

SAMENVATTING

Artrose aan de duimbasis kan leiden tot aanzienlijke beperkingen. In **hoofdstuk 2** wordt een systematisch review beschreven van de literatuur tot en met december 2009, waarin de 8 meest gebruikte chirurgische technieken worden geanalyseerd. Een grondig literatuuronderzoek werd uitgevoerd met behulp van vooraf bepaalde criteria. In totaal voldeden 35 artikelen aan de inclusiecriteria, waarvan er 9 niet werden behandeld in eerdere systematische reviews.

Systematische evaluatie toonde aan dat: (1) er geen bewijs is dat trapeziectomie of trapeziectomie met peesinterpositie superieur is aan één van de andere technieken. Wanneer een interpositie wordt uitgevoerd, heeft autoloog weefsel de voorkeur. (2) Trapeziectomie met ligamentreconstructie of trapeziectomie met ligamentreconstructie en peesinterpositie (LRTI) is niet superieur aan één van de andere technieken. Echter, omdat de follow-up in de studies met een hoger niveau van bewijs relatief kort was (maximaal 12 maanden), kunnen eventuele lange-termijnvoordelen niet worden beoordeeld. Daarnaast lijkt trapeziectomie met LRTI geassocieerd te zijn met een hoger percentage complicaties. (3) Omdat de studies over carpometacarpale (CMC) artrodese van de duim van matige methodologische kwaliteit zijn en inconsistente resultaten tonen, zijn we niet in staat om te concluderen of CMC artrodese superieur is aan andere technieken. Daarom zijn gerandomiseerde studies van hoog niveau nodig waarin CMC artrodese wordt vergeleken met andere procedures. Desalniettemin tonen de bevindingen in de nieuw geïnccludeerde studies dat nonunion percentages in de literatuur gemiddeld tussen de 8% en 21% zijn en dat complicaties en revisie-operaties vaker worden gezien na CMC artrodese. (4) Uit een studie over gewrichtsvervangende procedures bleek dat de totale gewrichtsprothese betere resultaten kan hebben op korte termijn in vergelijking met trapeziectomie met LRTI, maar gerandomiseerde studies van hoog niveau waarin totale gewrichtsprothese wordt vergeleken met andere procedures zijn nodig om dit te bevestigen. Bovendien is er geen bewijs dat de Artelon spacer superieur is aan trapeziectomie met LRTI.

Samenvattend kunnen we concluderen dat er op dit moment geen chirurgische procedure superieur is gebleken. Op basis van goede resultaten van CMC artrodese en de totale gewrichtsprothese, verwachten we dat verschillen in uitkomsten tussen de verschillende chirurgische procedures mogelijk zijn. Daarom zijn gerandomiseerde studies noodzakelijk waarin CMC artrodese en totale gewrichtsprothese worden vergeleken met trapeziectomie met een lange follow-up (> 1 jaar).

In **hoofdstuk 3** wordt een prospectieve cohortstudie (pilotstudie) gerapporteerd waarin pre- en postoperatieve objectieve en subjectieve resultaten worden geanalyseerd na een Weilby interpositie-artroplastiek (LRTI-techniek, zonder bottunnel aan de basis van metacarpale I).

Negentien patiënten (20 duimen) met primaire carpometacarpale artrose van de duim werden behandeld met een Weilby interpositie-artroplastiek. Als subjectieve uitkomstenmaat werd de DASH vragenlijst gebruikt om de pre- en postoperatieve resultaten te evalueren op 0, 3, 6 en 12 maanden. Daarnaast kregen de patiënten een specifieke persoonlijke vragenlijst op 12 maanden follow-up.

Objectieve uitkomstmaten zoals actieve 'range of motion' (ROM) en krachtmetingen werden preoperatief, op 3, 6 en 12 maanden na de operatie uitgevoerd. Alle complicaties werden geregistreerd. Resultaten toonden aan dat de DASH-score aanzienlijk verbeterde na de operatie, en 17 van de 19 patiënten waren tevreden over de procedure. De actieve ROM-metingen toonden aan dat na 12 maanden de carpometacarpale palmaire abductie en oppositie sterk waren verbeterd. De 3-puntsgreep en algehele knijpkracht, waren ook significant verbeterd na 12 maanden.

Kortom, de Weilby-procedure is een betrouwbaar alternatief in de behandeling van primaire carpometacarpale artrose van de duim, zonder het gebruik van een bottunnel aan de basis van metacarpale I. Het zorgt voor pijnverlichting, stabiliteit, mobiliteit en kracht. De objectieve en subjectieve resultaten van dit onderzoek zijn beter in vergelijking met eerdere studies over de Weilby-procedure en zijn vergelijkbaar met de gepubliceerde resultaten van de meer algemeen uitgevoerde Burton-Pellegrini-techniek (LRTI-techniek, met het gebruik van een bottunnel aan de basis van metacarpale I).

In **hoofdstuk 4** vergelijken we de resultaten van trapeziectomie met LRTI (Weilby artroplastiek) en carpometacarpale artrodese (met plaat en schroeven) bij vrouwen met graad II en III artrose in een gerandomiseerde studie.

Drieëntwintig patiënten in de LRTI-groep en 20 patiënten in de artrodese-groep namen deel aan dit onderzoek. Omdat we significant meer matige en ernstige complicaties vonden na artrodese in vergelijking met trapeziectomie met LRTI (71% versus 29%, $p = .016$), werd de studie vroegtijdig beëindigd, voordat het aantal geïncludeerde patiënten bereikt was dat noodzakelijk was om de twee groepen rechtmatig te vergelijken. Het hogere complicatiepercentage na artrodese, leidde tot een toename van het aantal heroperaties (2/17). Bovendien kozen significant meer patiënten in de LRTI-groep (86%) voor dezelfde operatie onder dezelfde omstandigheden, ten opzichte van de artrodese-groep (53%) ($p = .025$). In beide groepen verbeterde de PRWHE- en DASH-scores aanzienlijk na de operatie, maar de hoeveelheid verbetering verschilde niet significant tussen de groepen.

Omdat patiënten na trapeziectomie met LRTI minder matige en ernstige complicaties hebben en meer voornemens zijn de operatie opnieuw te overwegen onder dezelfde omstandigheden dan degenen die artrodese ondergaan, raden we routinematig gebruik van de artrodese met

plaat en schroeven in de behandeling van vrouwen met graad II en III carpometacarpale artrose van de duim af.

In **hoofdstuk 5** vergelijken we de resultaten van trapeziectomie en totale gewrichtsprothese (gecementeerde Guepar-prothese) bij vrouwen met primaire artrose in het carpometacarpale gewricht van de duim in een gerandomiseerde studie.

Zesentwintig patiënten ondergingen een trapeziectomie en 29 patiënten kregen een totale gewrichtsprothese. Hoewel in beide groepen de PRWHE-scores postoperatief sterk verbeterden, was er geen significant verschil tussen beide groepen. Drie maanden na de operatie toonde de groep met een totale gewrichtsprothese een significant grotere verbetering in de sleutel- en driepuntsgreep en in IP-extensie, ten opzichte van de trapeziectomiegroep. Eén jaar na de operatie toonde de groep met een totale gewrichtsprothese een significant grotere verbetering op de DASH en sleutelgreepknijpkracht in vergelijking met de groep die behandeld is met een trapeziectomie. Daarnaast werd er geen significant verschil gevonden in complicaties tussen de groepen.

Hoewel de verschillen klein zijn, suggereert deze studie dat er een tendens is dat patiënten na een totale gewrichtsprothese een beter functioneel resultaat hebben 1 jaar na de operatie in vergelijking met patiënten behandeld met een trapeziectomie. Echter, langere-termijnresultaten zijn nodig om subjectieve en objectieve uitkomsten en het implantaat complicatiepercentage te evalueren over de jaren.

Terwijl verschillende ligamentreconstructies zijn beschreven in de behandeling van artrose aan de duimbasis, zijn ze nooit rechtstreeks vergeleken in een gerandomiseerde studie. In **hoofdstuk 6** beschrijven we een gerandomiseerde studie waarin de Burton-Pellegrini-artroplastiek (LRTI-techniek met een bottunnel aan de basis van metacarpale I) en de Weilby-artroplastiek (LRTI-techniek zonder bottunnel aan de basis metacarpale I), bij vrouwen met graad IV duimbasisartrose wordt vergeleken. Veertig patiënten in de Burton-Pellegrini-groep en 39 patiënten in de Weilby-groep namen deel aan dit onderzoek. Onze bevindingen waren dat na 3 maanden de PRWHE-pijn- en PRWHE-totaalscores significant meer verbeterden in Burton-Pellegrini-groep, in vergelijking met de Weilby-groep. Na 12 maanden werden er echter geen significante verschillen meer gevonden tussen beide groepen voor alle PRWHE- en DASH-scores. Daarnaast zagen we ook geen significante verschillen tussen de groepen met betrekking tot kracht, patiënttevredenheid en complicaties.

Op basis van bovenstaande concluderen we dat de Burton-Pellegrini-techniek een betere functie en minder pijn geeft, 3 maanden na de operatie, ten opzichte van de Weilby-techniek. Dit wijst op een sneller herstel. Echter, 12 maanden na de operatie is het functionele resultaat

vergelijkbaar. Vanwege het betere en snellere herstel, suggereert de huidige studie dat de Burton-Pellegrini-techniek de voorkeur verdient.

In **hoofdstuk 7** (algemene discussie) wordt een update van onze systematische review – gepubliceerd in 2011 – gegeven (behandeling van de literatuur tot en met december 2009; hoofdstuk 2) over de chirurgische behandeling van symptomatische artrose aan de basis van de duim. Een totaal van 45 artikelen voldeed aan de inclusiecriteria. De bevindingen in deze studies, gepubliceerd tot en met december 2012, werden gecombineerd met de resultaten van de 3 gerandomiseerde studies beschreven in **hoofdstuk 4, 5 en 6**. Op basis van de bevindingen in deze studies werden de onderzoeksvragen, zoals beschreven in de introductie (**hoofdstuk 1**), beantwoord en behandelingsaanbevelingen en toekomstperspectieven verstrekt.

In dit hoofdstuk concluderen we dat, op basis van de huidige kennis, patiënten met symptomatische artrose van alleen het carpometacarpale (CMC) gewricht van de duim het beste kunnen worden behandeld met een trapeziectomie, omdat trapeziectomie minder complicaties geeft in vergelijking met een trapeziectomie met LRTI of trapeziectomie met een niet autologe interpositie. Het wordt niet aanbevolen CMC artrodese routinematig toe te passen, dit vanwege het hoge percentage complicaties als gevolg van delayed- en nonunion, ongeacht het gebruik van een bottransplantaat. Daarnaast moet het gebruik van een totale gewrichtsprothese alleen plaatsvinden in studieverband.


Als patiënten klinische symptomen hebben op zowel het eerste CMC en het scapho-trapezio-trapeziodale (STT) gewricht, postuleren we dat trapeziectomie met een extra LRTI (Burton-Pellegrini-techniek) de beste behandelingsoptie is.

Toekomstig onderzoek zal zich daarom wel moeten richten op de vraag of trapeziectomie met een aanvullende LRTI, bij patiënten met symptomatische artrose in het eerste CMC en STT gewricht, inderdaad een waardevolle behandelingsoptie is.

Verder concluderen we dat de verbeterde kwaliteit van de totale gewrichtsprothese in de afgelopen jaren moet worden vergeleken met de trapeziectomieprocedure met een lange follow-up bij patiënten met symptomatische artrose in alleen het CMC gewricht van de duim. Bovendien zijn wij van mening dat het van cruciaal belang is dat bij het evalueren van complicaties na operatie, de onderzoekers onderscheid maken tussen klinisch belangrijke complicaties (bijvoorbeeld complicaties die leiden tot een vertraagd patiëntenherstel, zoals heroperatie of CRPS I) en klinisch minder relevante complicaties (bijvoorbeeld milde complicaties die geen vertraagde patiëntenherstel geven, zoals milde sensibiliteitsafwijkingen). Significant verschil in klinisch relevante complicaties die vertraagd herstel veroorzaken, moet bepalen welke chirurgische techniek wordt gebruikt. Bovendien moeten onderzoekers naar nieuwe gevoeliger uitkomstmaten zoeken.



Appendix



**Dankwoord
Curriculum vitae
List of publications
PhD portfolio**

DANKWOORD

Alvorens enkele mensen te noemen die van essentieel belang zijn geweest bij het tot stand komen van mijn promotie, wil ik graag iedereen dankzeggen die betrokken is geweest bij mijn onderzoek. Hierbij spreek ik mijn speciale waardering uit voor de handtherapeuten die de vele metingen verricht hebben, voor de verpleegkundigen op de afdeling, die met grote inzet voor de geopereerde patiënten hebben gezorgd en natuurlijk voor de secretaresses die een groot deel van de planning en het nabellen van de patiënten voor hun rekening namen. Heel veel dank!

Prof. dr. S.E.R. Hovius, beste Prof,

Dank dat ik onder uw vleugels mocht promoveren, uw Rotterdamse ‘onderzoeksmachine’ en bijbehorende begeleiding is, zeker voor plastisch chirurgische begrippen, uniek in Nederland. Ik ben u dankbaar dat ik daar gebruik van kon maken. Uw scherpe blik en energieke werkhouding zijn zeer aanstekelijk en hebben een grote bijdrage geleverd aan de totstandkoming van dit proefschrift.

Dr. R.W. Selles, beste Ruud,

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Prof. T.R.C. Davis, FRCS,

Dear Professor Davis, it has been a great honor that you participated as an opponent in the defense of my thesis. Your publications on this subject are still leading articles and were inspiring to me. Your work has been, and still is, revolutionary and an example to us all.

Drs. R. Feitz, beste Reinier,

Ondanks je drukke agenda wist je toch altijd tijd te maken naar mijn stukken te kijken en ze te voorzien van een kritische noot. Ik bewonder hoe je zakelijk inzicht combineert met plastisch chirurg zijn, zonder ook de wetenschap uit het oog te verliezen. Hartelijk dank voor je bereidheid zitting te nemen in mijn promotiecommissie. Ik kijk uit naar onze samenwerking tijdens mijn aanstaande fellowship.

Prof. dr. J.M.W. Hazes,

Geachte professor Hazes, hartelijk dank voor uw bereidheid zitting te nemen in mijn promotiecommissie.

Dr. P. Houpt, beste Peter,

Tijdens mijn opleidingstijd in Zwolle heb ik enorm veel van je geleerd. Je pragmatiek, kennis en snelheid zijn om te benijden. Daarnaast is het ongelooflijke plezier, waarmee jij nog steeds opereert, bewonderenswaardig. Hartelijk dank voor je bereidheid zitting te nemen in mijn promotiecommissie.

Prof. dr. H.J. Stam,

Geachte professor, veel dank voor uw bereidheid zitting te nemen in de leescommissie en uw positieve reacties na de beoordeling van mijn proefschrift.

Prof. dr. F. Stockmans,

Geachte professor, het is voor mij een grote eer dat u bereid was zitting te nemen in de leescommissie. Uw expertise op het gebied van het CMC gewricht van de duim is groot en ik denk dat we over de potentie van de huidige generatie totale gewrichtsprotheses hetzelfde denken.

Prof. dr. J.A.N. Verhaar,

Geachte professor, veel dank voor uw bereidheid zitting te nemen in de kleine commissie en dat u de tijd hebt genomen om mijn proefschrift te toetsen als secretaris van de leescommissie.

Dr. T.M. Moojen, beste Thybout,

Jouw lijfspeuken zijn: 'Succes is een keuze', 'je krijgt wat je verdient' en 'failure is not an option'. Ik sluit mij hier graag bij aan en bewonder je gedrevenheid, zakelijke inzicht en doortastendheid. Ondanks je drukke schema kon je altijd tijd vinden om met een schuin oog naar mijn stukken te kijken. Ik kijk uit naar onze samenwerking tijdens mijn fellowship.

Dr. H. Slijper, beste Harm,

Met name de beginperiode van het PhD-traject hebben we veel samengewerkt. Je gevoel voor humor, onderzoekservaring en werkzaamheden rond datamanagement zijn bewonderenswaardig. Veel dank voor je bijdrage aan dit proefschrift.

Maatschap Zwolle,

De afgelopen 3 jaar opleiding zijn voorbij gevlogen. De Zwolse opleiding tot plastisch chirurg was op mijn lijf geschreven. Zelfstandigheid, kennis van zaken en opereren tot de blaren op je vingers staan, kortom één van de betere, dan wel de beste, opleiding van Nederland. Dank voor alles en zeker ook voor de ruimte die ik kreeg om soms een dag aan mijn proefschrift te mogen schrijven.

Assistentengroep Zwolle,

De opleiding valt of staat bij een betrouwbare, gezellige assistenten groep, die wat voor elkaar

over heeft. Ik wil jullie daar hartelijk voor danken. Ik zal de vele (nachtelijke) WhatsApp'jes, etentjes en skireisjes zeker missen!

Dr. W.B.W.H. Melenhorst, beste Wynand,

Over heel veel zaken denken we hetzelfde, het is daarom niet verwonderlijk dat we veel met elkaar zijn opgetrokken tijdens de opleiding. Door je creatieve ondernemersgeest is het prachtig om met je te bomen over de toekomst. Ik hoop dan ook dat onze paden in de toekomst elkaar nog vaak zullen kruisen. Dank dat je mijn paranimf wil zijn.

Drs. T.R. de Jong, beste Tjeerd,

Je levensovertuiging in combinatie met de plastische chirurgie is bijzonder. Daarnaast kan ik me geen betrouwbaardere collega voorstellen en daarom was en is het heel prettig met jou samen te werken. Ik wil je graag bedanken dat je mij als paranimf wil bijstaan.

Drs. S. Brink, beste Sander,

Vanaf het allereerste begin hebben we samengewerkt om meer duidelijkheid te krijgen in de chirurgische behandeling van duimbasis artrose. Jouw zienswijze vanuit het oogpunt van de bewegingswetenschap en die van mij vanuit het oogpunt van de geneeskunde is een goede combinatie gebleken. Ik heb de samenwerking altijd als zeer prettig ervaren, veel dank daarvoor.

Vrienden,

Het ei is gelegd! Dus nu voor mij geen excuses meer om af te haken. Dank voor jullie support de afgelopen jaren.

Familie Remmers, lieve Miriam en Henri,

Dank voor jullie enorme gastvrijheid de afgelopen jaren. De heerlijke reizen, etentjes, skitrips en ga zo maar door. Niets lijkt jullie te gek. Veel dank voor de support voor het afdrukken van het profeschrift. Maar het meest wil ik jullie natuurlijk danken voor Anouck...

Joep Vermeulen, lieve broer,

Dank voor je ongelooflijke ondersteuning de afgelopen jaren. De attente berichtjes, vele telefoontjes, kaarten en harten onder de riem tijdens de laatste fase van het onderzoek, ze waren onnavolgbaar en onbetaalbaar. Heel veel dank.

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totstandkoming van dit proefschrift. Pap, dank voor al je adviezen. Gevraagd of ongevraagd, ze waren altijd waardevol.

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Perth, here we come!

CURRICULUM VITAE

Guus Maarten Vermeulen was born on February 26th 1979 in Woerden, the Netherlands. He started medical school at the University of Utrecht in 1997 and passed his doctoral examination in September 2003. After two years of internships he passed his medical exam with honor in November 2005. During medical school, his interest in plastic and reconstructive surgery was strengthened by his first research project at the Department of Plastic Surgery, University Medical Center Utrecht under supervision of Dr. A.H. Schuurman. Between 2006 and 2008 he worked as a resident at the Department of Plastic, Reconstructive and Hand Surgery, Diaconessenhuis Utrecht, and started his PhD program at Erasmus Medical Center Rotterdam on primary osteoarthritis of the first CMC joint under supervision of Prof. dr. S.E.R. Hovius and Dr. R.W. Selles. He combined the PhD program with his plastic surgery training and finished his basic general surgery at the Department of General Surgery, Tergooiziekenhuizen Hilversum in 2010 (Dr. J.P. Eerenberg). He is currently continuing his plastic surgery training as a resident at the Department of Plastic, Reconstructive and Hand Surgery, Isala Klinieken Zwolle (Drs. M.A. Tellier). His plastic surgery training will be finished in January 2014. Because of his experience with osteoarthritis at the base of the thumb, he was asked in 2012 as a committee member responsible for the Dutch medical directive for the treatment of osteoarthritis of the trapeziometacarpal joint. This committee with 7 members will publish the medical directive entitled “Conservative and Surgical Treatment of Primary Osteoarthritis at the Base of the Thumb” in 2014.

LIST OF PUBLICATIONS

Publications for this thesis

- 2009 Ligament reconstruction arthroplasty for primary thumb carpometacarpal osteoarthritis (Weilby technique): A prospective cohort study. Vermeulen GM, Brink SM, Sluiter J, Elias SG, Hovius SE, Moojen TM. *J Hand Surg Am*. 2009 Oct;34(8):1393–401. Epub 2009 Sep 6.
- 2011 Evidenced based surgical treatment of trapeziometacarpal osteoarthritis. Vermeulen GM, Slijper H, Selles RW. Chapter course book Eurohand congress FESSH 2011.
- 2011 Surgical management of primary thumb carpometacarpal osteoarthritis: A systematic review. Vermeulen GM, Slijper H, Feitz R, Hovius SE, Moojen TM, Selles RW. *J Hand Surg Am*. 2011 Jan;36(1):157–69. Review.
- 2013 Trapeziometacarpal arthrodesis or trapeziectomy with ligament reconstruction in primary trapeziometacarpal osteoarthritis: A randomized controlled trial. Vermeulen GM, Brink SM, Slijper H, Feitz R, Moojen TM, Hovius SER, Selles RW. Accepted in *J Bone Joint Surg Am*.
- 2013 Total joint prosthesis or trapeziectomy in primary trapeziometacarpal osteoarthritis: A randomized controlled trial. Brink SM, Vermeulen GM, Houpt P, Emmelot CG. Submitted.
- 2013 LRTI with or without bone tunnel creation at the base of the first metacarpal bone in primary osteoarthritis at the base of the thumb: A randomized controlled trial. Vermeulen GM, Spekreijse KR, Slijper H, Feitz R, Moojen TM, Hovius SER, Selles RW. Submitted.

Other publications

- 2009 Carpal boss: effect of wedge excision depth on third carpometacarpal joint stability. Vermeulen GM, de With MC, Bleys RL, Schuurman AH. *J Hand Surg Am*. 2009 Jan;34(1):7–13.
- 2008 Isolated dislocation of the scaphoid with associated carpal dissociation. Scholtes VPW, Vermeulen GM, Sonneveld DJA, Clevers GJ, Moojen TM (Scholtes and Vermeulen contributed equally to this manuscript). *Ned Tijdschr Traum* 2008; Okt; 5.



PHD PORTFOLIO

Summary of PhD training and teaching activities

Name PhD student: Guus M. Vermeulen
 Erasmus MC, University Medical Center
 Departement: Plastic, Reconstructive and Hand Surgery
 PhD period: September 2008 – January 2014
 Promotor: Prof. dr. S.E.R. Hovius
 Supervisor: Dr. R.W. Selles

PhD training and teaching activities	Year	Workload (ECTS)
Research skills		
Methodology: Evidence-Based Surgery in Clinical Practice (AMC)	2010	2
In-depth courses		
Esser Master Class: New Frontiers in arthroscopic wrist surgery	2008	1
Several fresh frozen cadaver dissection courses with the Dr Nicolaes Tulp Foundation in Facial Aesthetic Surgery, Hand Flaps & Wrist Surgery, and Breast Reconstruction Surgery, UMC Utrecht, The Netherlands. During these 5 courses surgical training on fresh frozen cadavers with an international faculty was performed. The training was focused on hand and wrist problems.	2008–2013	10
Microsurgery course Northwick Park Hospital London, UK	2011	3
Radiation protection course 4A/M Zwolle, The Netherlands	2012	2
Presentations		
Presentation at the annual meeting of the Dutch Society for Hand Surgery (NVvH), Lelystad, The Netherlands, Primary osteoarthritis of the first CMC joint: a systematic review.	2010	2
Keynote speaker: Eurohand Congress FESSH 2011 Oslo, Norway: Evidenced based surgical treatment of trapeziometacarpal osteoarthritis.	2011	4
Presentation at the American Association for Hand Surgery (AAHS) Annual Meeting January 2012 in Las Vegas, Nevada, Poster: Trapeziometacarpal Arthrodesis Compared to Trapeziectomy with LRTI and Total Joint Prosthesis Compared to Trapeziectomy in the Treatment of Trapeziometacarpal Osteoarthritis: Two Randomized Clinical Trials.	2012	3

PhD training and teaching activities	Year	Workload (ECTS)
Presentation at the Eurohand congress FESSH 2012 Antwerp, Belgium: Arthrodesis or Trapeziectomy with Ligament Reconstruction in Primary Trapeziometacarpal Osteoarthritis: A Randomized Controlled Trial.	2012	3
Keynote speaker: Esser course 2013 Erasmus MC, Rotterdam, The Netherlands, Evidence based surgical treatment of the first CMC joint.	2013	4
International conferences		
FESSH, Poznan, Poland	2009	1
Teaching		
Physical examination of the hand and wrist: 5 th and 6 th year students	2009–2012	4
Suturing course for medical students	2011–2013	2
Other		
Committee member responsible for the Dutch medical directive for the surgical treatment of osteoarthritis of the trapeziometacarpal joint, including GRADE assessment of literature. This committee with 7 members will write the medical directive entitled: Conservative and Surgical Treatment of Primary Osteoarthritis at the Base of the Thumb in a period of 1.5 years.	2012–present	10

