



RAINE TIIHONEN

Bioabsorbable Poly-L/D-lactide 96/4 (PLDLA)  
Implant in Hand and Forefoot Joint  
in Chronic Inflammatory Arthritis



ACADEMIC DISSERTATION

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## ACADEMIC DISSERTATION

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To Marja, Emmi, Juho and Kaapo



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# ABSTRACT

Rheumatoid arthritis (RA) and also other inflammatory joint diseases cause pain, joint swelling, deformity, and severely impair quality of life. In RA, the small joints of the hands, wrists and forefeet are often involved. Arthroplasty has had considerable success in the replacement of larger joints, such as the hip and knee, but in small joints such as the metacarpophalangeal (MCP) the results have been variable. The use of silicone implants was first reported in 1966 and is still the gold standard for reconstruction of MCP joints in RA patients. However, the outcomes tend to deteriorate in long-term follow-up as regards joint stiffening and recurrence of deformity, as well frequent occurrence of silicone synovitis, osteolysis, and fracture of the implants. The novel bioreplaceable poly-L/D-lactide 96/4 (PLDLA) joint interposition implant is a new concept for small joint arthroplasty.

The purposes of the studies included in this dissertation were: 1. to evaluate the short-term biocompatibility and clinical performance of the PLDLA implant in the lesser MTP (metatarsophalangeal) joints. To compare the novel PLDLA implant interposition arthroplasties with conventional metatarsal resection arthroplasty in lesser MTP joints; 2. to compare the clinical and radiological outcomes of RA patients receiving PLDLA implant and the silastic Swanson implant in MCP primary arthroplasty; 3. to compare the PLDLA implant interposition arthroplasty with the tendon interposition arthroplasty in TMC (trapeziometacarpal) joint; 4. to determine the long-term clinical outcome and incorporation of the grafted bone of an PLDLA interposition arthroplasty combined with bone packing in silicone implant revisions.

This dissertation is based on four studies: In the forefoot (Study I) 35 patients were randomized to either PLDLA interposition arthroplasty group (16 patients) or to conventional metatarsal head resection group (19 patients) with a follow-up time of one year. Study II was a randomized clinical trial, the PLDLA implant arthroplasty (27 hands, 84 joints) outcome was compared to silicone Swanson arthroplasty (26 hands, 91 joints) with a median follow-up of 24 months. Study III was a clinical prospective study comparing PLDLA implant arthroplasty (n=17) with that of tendon interposition (n=12) of TMC joint destruction in arthritic patients with a follow-up of two years. Study IV evaluated the outcome of revision MCP arthroplasty using PLDLA interposition implants and bone packing in 15 patients (36 joints) with failed MCP arthroplasties with a mean follow-up of seven years.

At one-year follow-up, comparison between PLDLA interposition arthroplasty and conventional metatarsal head resection did not reveal any statistically significant differences in AOFAS score, pain or function VAS. However, there was no increase in complications or postoperative ossifications in the PLDLA group (Study I). In Study II the improvement in

clinical assessments was comparable in the PLDLA and Swanson groups. However, palmar dislocation was observed in 44/84 (52 %) PLDLA joints and in 10/91 (11%) in the Swanson at mean 24-months follow-up. In the clinical prospective TMC joint (Study III) the outcome (pain or function scores, functional tests or ROM) obtained using PLDLA implant compared to tendon interposition were statistically similar at two-year follow-up, but the surgical procedure was simpler to perform. In Study IV PLDLA interposition arthroplasty combined with bone packing provided adequate pain relief, but the functional results were generally poor. Radiographic analysis showed complete incorporation of the grafted bone to the diaphyseal portion of the host metacarpal and phalangeal bones in 30 of the 36 bones.

In this dissertation the outcome of the novel PLDLA implant in the treatment of rheumatoid TMC, MCP joints in primary cases and lesser MTP joints was comparable overall with that of the gold standard method. However, further studies with larger patient series and longer follow-ups are needed before this method can be generally recommended.



# LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by the Roman numerals I–IV.

- I Tiihonen R, Skyttä ET, Ikävalko M, Kaarela K, Belt E (2010). Comparison of bioreplaceable interposition arthroplasty with metatarsal head resection of the rheumatoid forefoot. *Foot Ank Int* 31(6):505–510.
- II Honkanen PB, Tiihonen R, Skyttä ET, Ikävalko M, Lehto MU, Konttinen YT (2010). Bioreconstructive poly-L/D-lactide implant compared with Swanson prosthesis in metacarpophalangeal joint arthroplasty in rheumatoid patients: a randomized clinical trial. *J Hand Surg Eur* 35(9):746–753.
- III Tiihonen R, Skyttä ET, Kaarela K, Ikävalko M, Belt EA (2012). Reconstruction of the Trapeziometacarpal Joint in Inflammatory Joint Disease Using Autologous Tendon or Poly-L/D-Lactic Acid Implant Interposition. A Prospective Randomized Trial. *J Plast Surg Hand Surg* 46:113–119.
- IV Tiihonen R, Honkanen PB, Ikävalko M, Belt EA, Skyttä ET (2012). The mean seven years' results of the use of poly-L/D-lactic acid (PLDLA) interposition implant and bone packing in revision metacarpophalangeal arthroplasty: a prospective cohort study. *Scand J Surg* 101(4):265–270.

Study II was also presented in the doctoral dissertation by Pirjo Honkanen (2012). Metacarpophalangeal arthroplasty and partial wrist fusion as a surgical treatment in rheumatoid hand disease. *Acta Universitatis Tamperensis* 1698.



# ABBREVIATIONS

ADL	activities of daily living
ANOVA	analysis of variance
BD	boutonnière deformity
CI	confidence interval (95%)
DLPLG	Poly(DL-lactide- <i>co</i> -glycolide)
DLPLA	Poly(DL-lactide)
DMARD	disease-modifying antirheumatic drug
DRUJ	distal radioulnar joint
ECR	extensor carpi radialis (tendon)
EHL	extensor hallucis longus (tendon)
FCR	flexor carpi radialis (tendon)
FIN-RACo	Finnish Rheumatoid Arthritis Combination Therapy
IL	interleukin
IP	interphalangeal (joint)
LDLPLA	Poly(DL-lactide- <i>co</i> -L-lactide)
LPLA	Poly(L-lactide)
LPLA-HA	Poly(L-lactide) with hydroxylapatite
LPLG	Poly(L-lactide- <i>co</i> -glycolide)
MCP	metacarpophalangeal (joint)
MTP	metatarsophalangeal (joint)
NSAID	non-steroidal anti-inflammatory drug
PDO	Poly(dioxanone)
PDS	polydioxanone
PGA	Polyglycolide
PGA-TMC	Poly(glycolide- <i>co</i> -trimethylene carbonate)
PIP	proximal interphalangeal (joint)
PLDLA	96L/4D poly-L/D-lactide copolymer implant
RA	rheumatoid arthritis
ROM	range of motion
SD	standard deviation
SND	swan neck deformity
TMC	trapeziometacarpal (joint)
TNF	tumour necrosis factor



# 1 INTRODUCTION

Rheumatoid arthritis (RA) and also other inflammatory joint diseases affect the small joints in hands and feet. Typical deformities in metacarpophalangeal (MCP) joints are volar subluxation and ulnar deviation (Ellison et al., 1971; Wilson, 1986). In long-term RA the thumbs are deformed in two thirds of patients (Terrano et al., 1990; Toledano et al., 1992). The boutonnière deformity (BD) characterizes 50–70% of involved thumbs. The trapezio-metacarpal (TMC) joint is affected in one third of rheumatoid patients (Wilson, 1986; Terrano et al., 1990).

MCP joint arthroplasty using a silicone implant has been the gold standard in advanced stages of RA. In follow-up studies after silicone arthroplasty of the MCP joints, silicone synovitis, osteolysis, and fracture of the implants frequently occur (Wilson et al., 1993; Parkkila et al., 2006a; Goldfarb and Stern, 2003). Revision MCP arthroplasty after silicone implants is challenging because of severe bone loss and soft tissue deficiencies (Burgess et al., 2007). Tendon interposition arthroplasty is commonly used for the surgical management of arthritis of the TMC joint (Burton and Pellegrini, 1986; Terrano et al., 1995). Arthrodesis of this joint is rarely indicated in RA, as the distal joints of the thumb are usually abnormal and may require fusion at a later date (Nalebuff 1984, Terrono et al., 1990). Various types of TMC joint replacement arthroplasties, both hemiarthroplasties and total arthroplasties, have been described (Swanson, 1972b; de la Caffinière and Aucouturier, 1979; Braun, 1985; Cooney et al., 1987; Glickel et al., 1992; De Smet et al., 2004), but the long-term results have been unsatisfactory when using implant arthroplasty (Rozenal, 2007).

The prevalence of forefoot deformities in adults with chronic rheumatoid arthritis has been reported to be as high as 80% to 90% (Vainio, 1956; Vainio, 1975; Fleming et al., 1976). Erosive changes occurred early in lesser metatarsophalangeal (MTP) joints, and their destruction was more severe than in other joints in RA (Belt et al., 1998c). Arthrodesis of the hallux metatarsophalangeal (MTP I) joint and resection arthroplasty of the lesser MTP joints have been considered the standard of care in rheumatoid forefoot reconstruction (Coughlin, 2000). The clinical outcomes varied a lot between studies: pain relief ranged from 40% to 95%, with persistent metatarsalgia as high as 36% and calluses under the lesser MTP area may occur in up to 70% of cases (Henry and Waugh, 1975; McGarvey and Johnson, 1998; Vandeputte et al., 1999; Kadambande et al., 2007).

The known weaknesses of the current silastic MCP joint arthroplasties used in the surgical treatment of destroyed MCP joints have led to a search for new materials. At the beginning of 1994 a fibrous cushion made of commercially available biodegradable fibers (Vicryl® and Ethisorb®) was studied by a group of researchers at Tampere University Hospital. The

biodegradable cushion was intended to act like the tendon in Vainio arthroplasty (Vainio, 1989) and the aim was to find a material that could serve as a scaffold for the collagenous proliferation of connective tissue or fibrocartilage. However, the resorption time on the material was too short, which led to the premature collapse of joint space (Lehtimäki et al., 1998). New implants were developed using a well-known poly-L/D-lactide copolymer with L/D-monomer ratio 96/4 (PLDLA) in collaboration between the Institute of Biomaterials at Tampere University of Technology and Tampere University Hospital. The porous PLDLA scaffold provides a temporary support to guide soft tissue ingrowth of fibrous tissue, allowing a gradual replacement of the implant with fibrous tissue providing a flexible and durable pseudarthrosis. In the joints of minipig the PLDLA implants were almost completely degraded at three years and had been replaced by longitudinally organized dense connective tissue (Waris et al., 2008).

The first prospective, non-randomized studies of the PLDLA interposition implant were used with promising results in primary and revision arthroplasties of MCP joints (Honkanen et al., 2003; Ikävalko et al., 2007; Honkanen et al. 2009). These promising results encouraged researchers to continue the study with randomized series in hand (MCP and TMC) and lesser MTP joints. This dissertation evaluates the outcomes of the PLDLA implant in these small joints.

## 2 REVIEW OF LITERATURE

### 2.1 Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory disease characterized by progressive damage of the synovial-lined joints and variable extra-articular manifestations. Tendon and bursal involvements are frequent and often clinically dominant in early disease. RA can affect any joint, but it is usually found in MCP, proximal interphalangeal (PIP), and MTP joints, as well as in the wrists and knees. Articular and periarticular manifestations include joint swelling and tenderness to palpation, with morning stiffness and severe motion impairment in the involved joints (Grassi et al., 1998). The most common extra-articular manifestations comprise subcutaneous rheumatic nodules, vasculitic skin lesions, secondary Sjögren's syndrome, pericarditis, pleuritis, pulmonary interstitial fibrosis, mononeuritis multiplex, amyloidosis, and Felty's syndrome (Turesson et al., 2002).

The prevalence of RA in Finland is about 0.8%, and the incidence 39/100000 of the adult population. Of the patients 70% are women (Kaipiainen-Seppänen et al., 1996; Aho et al., 1998).

The etiology of RA remains unknown. Many possibilities have been investigated, including occupational, geographical, metabolic, nutritional, genetic, and psychosocial factors (Alamanos and Drosos, 2005). The current consensus is that RA is a multifactorial disease and due to an interaction between environmental and genetic factors. Other factors involved include ethnicity, the role of hormones (Hazes and Van Zeben, 1991), and smoking (Sagg et al., 1997).

The course of the disease may vary widely from mild to aggressive forms. The management of RA rests on several principles. Drug treatment, which comprises disease-modifying antirheumatic drugs (DMARDs), but also non-steroidal anti-inflammatory drugs (NSAID) and glucocorticoids, as well as non-pharmacological measures, such as physical, occupational and psychological therapeutic approaches may in combination lead to therapeutic success (Smolen et al., 2010). Modern treatment strategy of RA is early aggressive anti-rheumatic therapy. The ultimate goal for treatment is to achieve drug-free remission.

Multiple trials have shown that combinations of DMARDs are more effective than monotherapy (Möttönen et al., 1999; O'Dell et al., 2002). In the Finnish Rheumatoid Arthritis Combination Therapy (FIN-RACo) trial on patients with early RA (Möttönen et al., 1999), initial combination therapy with sulfasalazine, methotrexate, hydrochloroquine and prednisolone was compared with monotherapy according to the "sawtooth" principle (Fries, 1990), starting with sulfasalazine. In the FIN-RACo study, at two years, 37% of the

patients in the combination-DMARD group and 18% in the single-DMARD group had achieved remission ( $P < 0.009$ ) (Möttönen et al., 1999). At five years, the corresponding percentages were 28% and 22% ( $P$  not significant) (Korpela et al., 2004). Patients in the combination-DMARD group had significantly less radiological damage at two, five, and 11 years of follow-up, even though the DMARD treatment after the initial two years became unrestricted (Korpela et al., 2004; Rantalaiho et al., 2010).

Biological therapy refers to the use of medication that is customized to specifically target an immune or genetic factor mediating disease (Staren et al., 1989). Currently, biologicals indicated to treat RA are available against several pro-inflammatory cytokines (IL-1, TNF $\alpha$  and IL-6) and against B-cells and activation of T-cells. Biologicals against the pro-inflammatory cytokine Tumor Necrosis Factor (TNF $\alpha$ )-blockers were the first biologicals introduced for use in clinical practice. TNF blockers have been shown to be able to control disease activity effectively and to reduce joint destruction, particularly when given in combination with methotrexate (Maini, 1998; Weinblatt et al., 2003; Edwards, 2004). However, because of the powerful immune suppression by these biologicals there is an increased risk of infections during treatment, especially severe lung, skin, soft tissue, and bone infections (Dixon et al., 2006), and reactivation of latent tuberculosis (Maini et al., 1999; Doran, 2002). Approved biological agents in Finland (2012) are presented in Table 1.

Table 1.  
Approved biological medications in Finland (2012).

Agent	Target	Structure
Adalimumab	TNF- $\alpha$	Human monoclonal antibody
Certolizumab pegol	TNF- $\alpha$	Pegylated humanized Fab fragment of an anti-TNF- $\alpha$ monoclonal antibody
Etanercept	TNF- $\alpha$	TNF- $\alpha$ receptor-Fc fusion
Golimumab	TNF- $\alpha$	Human monoclonal antibody
Infliximab	TNF- $\alpha$	Chimeric monoclonal antibody
Tocilizumab	Interleukin-6 receptor	Humanized monoclonal antibody
Anakinra	Interleukin-1	Interleukin-1 receptor antagonist
Rituximab	CD20	Chimeric monoclonal antibody
Abatacept	CD80 and CD86	CTLA4-Ig fusion protein



### 2.1.1 Spondylarthropathies and juvenile idiopathic arthritis

The spondyloarthropathies include ankylosing spondylitis, reactive arthritis (including Reiter's syndrome), psoriatic arthritis, inflammatory bowel disease-associated spondyloarthropathy, and undifferentiated spondyloarthropathy (Dougados, 1999). These diseases are linked by their association with the human leukocyte antigen HLA-B27 gene and by the presence of enthesitis as the basic pathologic lesion (Reveille and Arnett, 2005). As a group, the prevalence of spondyloarthropathies is estimated to be similar to that of RA in Europe (Akkoc 2008).

Juvenile idiopathic arthritis is a broad term that describes a clinically heterogeneous group of arthritides of unknown cause, which begin before 16 years of age. In Finland, the incidence of juvenile idiopathic arthritis has been reported to vary between 15 and 23 per 100000 (Kaipiainen-Seppänen and Savolainen, 2001).

## 2.2 The forefoot

### 2.2.1 Pathophysiology of rheumatoid forefoot

The prevalence of forefoot deformities in adults with chronic RA has been reported to be as high as 80% to 90% (Vainio, 1956; Vainio, 1975; Fleming et al., 1976). According to Belt et al. (1998c) erosive changes occurred early in lesser MTP joints, and their destruction was more severe than in other joints in RA. RA affects the foot in two ways. First, synovial hypertrophy and hyperplasia lead to stretching of capsular restraints causing ligament laxity, secondary muscle imbalance, and resultant joint subluxation and dislocation (Calabro, 1962; Gold and Basset, 1982). The second mechanism is the activation of the inflammatory cascade, which causes an enzymatic destruction of cartilage, periarticular tissues, and normal supportive structure (Spiegel and Spiegel, 1982).

As the capsule and ligaments are destroyed in the lesser MTP joints, the proximal phalanx is gradually dorsiflexed, with flexion at the proximal interphalangeal joint (Coughlin, 1984). Dislocation of the lesser MTP joints causes distal migration of the fat pad. This places the metatarsals heads in a subcutaneous position without any soft-tissue cushion during weight bearing (Amuso et al., 1971). This leads to painful callosities under the metatarsal heads and over the dorsal aspect of PIP joints in toes. The function of the lesser MTP joints is controlled by the surrounding extrinsic and intrinsic muscles. With dislocation of the lesser MTP joints, the digital flexor tendons are displaced into the metatarsal spaces and act as functional extensors instead of flexors at the lesser MTP joints. This imbalance between the intrinsic and the extrinsic muscles of the foot eventually leads to hammer, mallet, or claw toe deformities (Coughlin, 1984; Burra and Katchis, 1998).

Hallux valgus is the most common deformity of the great toe (Vainio, 1956; Spiegel and Spiegel, 1982; Mann and Thompson, 1984). Subluxation and dislocation of the lesser MTP joints removes an important lateral stabilizer to the great toe, and with the loss of medial soft-tissue support secondary to synovitis, the hallux drifts laterally into a valgus posi-

tion (Figure 1). With the progression of RA the articular cartilage is destroyed and subchondral bone is resorbed (Burra and Katchis, 1998). The hallux valgus deformity increases, impairing the weight-bearing function of the first ray. A greater proportion of weight is then transferred to the lesser MTP heads, with increases callus formation (Coughlin, 1984). The extensor hallucis tendon (EHL) is displaced into the first web space and acts more as an adductor than an extensor, thus increasing the valgus deformity (Sculco et al., 1992).

Figure 1.  
Typical deformities in RA, including hallux valgus with subluxation and erosive changes at the lesser MTP joints.



### 2.2.2 *Surgical treatment of rheumatoid forefoot*

Nonoperative treatment modalities include modifications to footwear, accommodative orthotic insoles, padding devices, corticosteroid injections, and physical therapy. Surgical treatment is indicated when nonoperative measures fail to relieve symptoms. The primary goal of surgery is relief of pain caused by joint synovitis, arthritic destruction, or deformity. Metatarsalgia can be alleviated by correcting toe deformities, thus relieving focal skin pressure, hyperkeratosis, or ulceration (Jeng and Campbell, 2008). Achieving a plantigrade position of the toes can also improve the fit of footwear and thus ambulation.

In spite of a variety of surgical options fusion of the MTP I joint with lesser MTP joint resection arthroplasty remains the gold standard (Coughlin, 2000; Jeng and Campbell, 2008). Recent attention has been directed to preservation of the lesser metatarsal heads with procedures such as Weil's osteotomy (Barouk and Barouk, 2007) or the Stainsby procedure (Briggs and Stainsby, 2001). Weil's osteotomy is a technique for shortening a lesser metatarsal. A near-horizontal cut is made through the head and neck. The Stainsby procedure is a salvage technique for the fixed subluxed or dislocated lesser toe with a fixed hammer or claw deformity. The key part of the operation is the release and reposition of the plantar plate under the metatarsal head, which automatically draws the plantar fat pad back to the correct position. Most of the proximal phalanx is resected, which makes the toe shorter but allows easy correction and stabilization. At present joint preserving forefoot operations have limited evidence-based support but they may ultimately offer an effective surgical alternative in combination with newer disease modifying drugs.

### 2.2.3 *Lesser metatarsophalangeal heads resection*

A multitude of surgical procedures, ranging from amputation of the toes (Flint and Sweetnam, 1960) to excision of the metatarsal heads and proximal phalanges have been advocated in the treatment of rheumatoid forefoot. In 1912, Hoffmann (Hoffmann, 1912) published research on the reconstruction of the rheumatoid forefoot. Many modifications to his technique have been described; however, the basic principle remains the same: removal of all the prominent metatarsal heads (Figure 2). In 1932 Gocht and Key proposed resection of the bases of the proximal phalanges through a dorsal incision (Gocht and Key, 1932). Fowler used the technique, followed by smoothing of the plantar surfaces of the metatarsal heads and elliptical excision of the plantar skin and callosities (Fowler, 1959). Clayton resected all metatarsal heads and the bases of the proximal phalanges (Clayton, 1960). Kates et al. introduced a new type of arthroplasty, a combination of the procedures described by Hoffmann and Fowler (Kates et al., 1967). This involves the removal of the metatarsal heads through a plantar incision with excision of callosities.

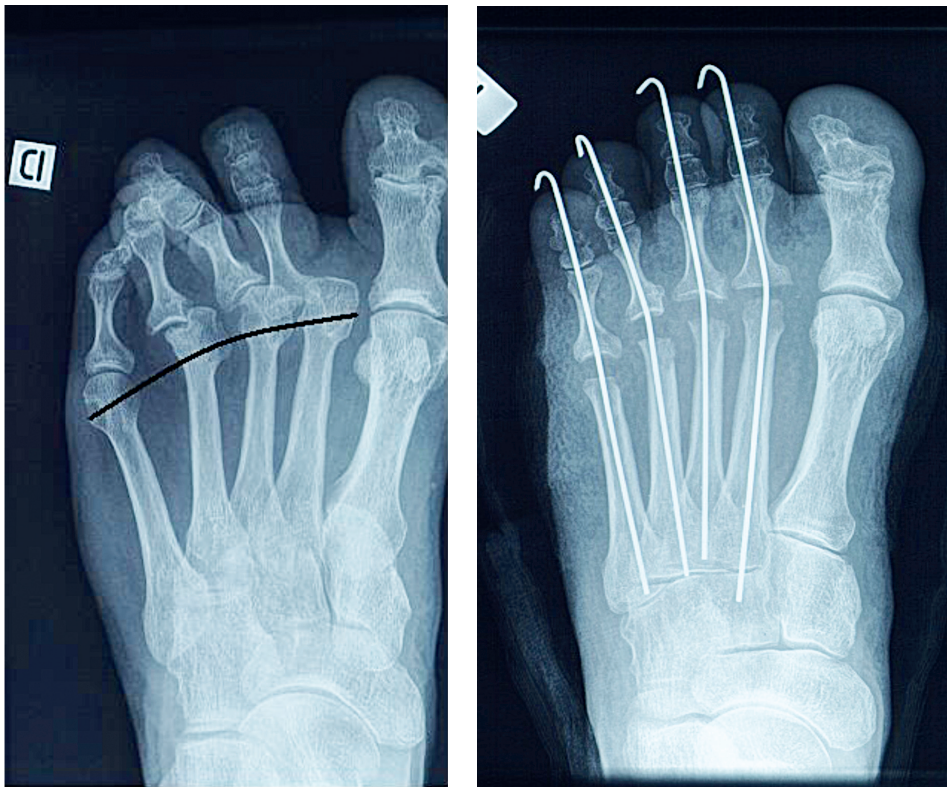
Dorsal, plantar or combined approaches to the lesser MTP joints using either transverse or longitudinal incisions have been described. The combined approach originally described by Fowler (Fowler, 1959) is no longer deemed necessary. The plantar incision is felt to allow direct access to the dislocated lesser MTP joints and excision of excess plantar fat pad and

skin (Kates et al., 1967). Disadvantages include an increased risk of keratotic scar formation and wound-healing complications. The reported prevalence of wound problems associated with the use of a plantar approach was reported to be eight percent (6 out of 74 feet) (van der Heijden et al., 1992), 13 percent (10 out of 77 feet) (Faithful and Savill, 1971), and 39 percent (22 out of 57 feet) in the study by Barton (Barton, 1973). Dorsal incisions are felt to provide good lesser MTP access while avoiding a scar on the plantar surface in patients with risk factors for wound healing problems (Molloy and Myerson, 2007).

Resection of the lesser MTP joints has been considered the standard of care in rheumatoid forefoot reconstruction. Numerous reports have endorsed the use of resection arthroplasty of the lesser MTP joints (Clayton, 1960; Kates et al., 1967; Mann and Thompson, 1984; Mann and Schakel, 1995; Hämmäläinen and Raunio, 1997; McGarvey and Johnson, 1998; Coughlin, 2000). Pain relief ranged from 40% to 95%, with persistent metatarsalgia as high as 36% and callosities under the lesser MTP area may occur in up to 70% of cases (Henry and Waugh, 1975; McGarvey and Johnson, 1998; Vandeputte et al., 1999; Kadambande et al., 2007). In early descriptions, the toes were not fixed in position (Clayton, 1960;

Figure 2.

The resection line of the lesser metatarsals is drawn from the distalmost aspect of the second metatarsal to the distalmost aspect of the fifth metatarsal. Preoperative X-ray (left) and postoperative X-ray after lesser MTP joints resection (right).



McGarvey and Johnson K, 1988). In contemporary reports, longitudinal Kirschner wires are utilized to stabilize the lesser MTP arthroplasty sites to minimize the risk of recurrent deformity (Bitzan et al., 1997; Coughlin, 2000; Gröndal et al., 2005; Gröndal, 2006).

The flexion contracture of the proximal interphalangeal (PIP) joint (digitus malleus) of the lesser toes is common in patients with RA. Flexible lesser toe deformities can be corrected with soft-tissue rebalancing (extensor tendon lengthening and/or plantar plate release) with or without closed osteoclasis (Clayton, 1960; Tillman, 1997; Kadambande et al., 2007). In most cases, authors prefer simple closed manipulation (or osteoclasis) of the contracted PIP joints. Rigid deformities require joint resection arthroplasty or arthrodesis. Results after both are reportedly good, independent of technique (Lehman and Smith, 1995; Coughlin et al., 2000; O'Kane and Kilmartin, 2005). Regardless of the chosen technique Kirshner wire stabilization should be employed for 3–6 weeks, driving the wires into the metatarsal shafts when the metatarsal heads have been resected.

#### 2.2.4 *First metatarsophalangeal joint*

Hallux valgus is the most common deformity of the rheumatoid forefoot. Methods for the treatment of a symptomatic hallux valgus deformity have included resection of the first metatarsal head (the Mayo resection), resection of the base of the proximal phalanx (Keller procedure) and arthrodesis of the MTP I joint (first metatarsophalangeal joint) (Amuso et al., 1971; Barton, 1973; Craxford et al., 1982; Lehman and Smith, 1995; Coughlin, 2000). Patients' satisfaction after resection varies widely, with 51% to 93% good-excellent results (Lipscomb et al., 1972; Vahvanen, 1980; Raunio et al., 1987; Dereymaker et al., 1997; McGarvey and Johnson, 1998; Vandeputti et al., 1999). The major complaints have been recurrence of hallux valgus, metatarsalgia and plantar callosities in sometimes up to 53%, 36% and 61% respectively (Vahvanen, 1980; Hämäläinen and Raunio, 1997; McGarvey and Johnson, 1998). In these studies the Keller type of resection was used. Fuhrmann and Anders conducted a retrospective study on 188 patients (254 feet) with RA and compared the late results between Mayo and Keller resection after 7.9 years (Fuhrmann and Anders, 2001). More than 60% of the Keller group and 30% of the Mayo group were suffering from persistent metatarsalgia due to increased forefoot pressure as well as experiencing pain around the great toe. Plantar callosities, recurrent hallux valgus deformity, lack of plantar flexion and weakened push-off were more frequent after Keller's procedure.

Direct comparison of arthrodesis and resection arthroplasty (Mayo) of the MTP I joint has been made. Two prospective, randomized comparisons demonstrated equal rates of pain relief, satisfaction, and relief of lesser metatarsalgia (Gröndal et al., 2005; Gröndal et al., 2006). Clinical outcomes measured with the Foot Function Index were also similar. Due to the small numbers of patients and lack of formal power analyses, it remains difficult to determine if outcomes after resection arthroplasty truly equal those after arthrodesis. Numerous retrospective and nonrandomized series have been reported (Henry and Waugh, 1975; Hämäläinen and Raunio, 1997; Mulcahy et al., 2003). While different fusion techniques and outcome measures were used, arthrodesis tended to yield better results in terms

of pain relief, cosmetic appearance, shoe-fitting, maintenance of alignment, and restoration of weight bearing under the hallux. Clinical outcomes following MTP I arthrodesis and lesser MTP resection arthroplasties have resulted in pain relief in 88% to 97% (Beauchamp et al., 1984; Mann and Thompson, 1984; Mann and Schakel, 1995; Coughlin, 2000; Kadambande et al., 2007). In these studies patient satisfaction has ranged from 16% to 95% complete satisfaction and 11% to 63% partial satisfaction; 36% to 100% of patients noted improvement in footwear fitting.

Appropriate positioning of an arthrodesis of the MTP I joint is crucial to its success, with the recommended position described as 10 degrees to 15 degrees of valgus, 20 degrees to 30 degrees of dorsiflexion relative to the first metatarsal shaft, and neutral rotation (Beauchamp et al., 1984; Mann and Thompson, 1984; Hämäläinen and Raunio, 1997; Coughlin, 2000; Kadambande et al., 2007). Fixation in early series consisted of Steinman pins (Mann and Schakel, 1995; Hämäläinen and Raunio, 1997). Nowadays more contemporary techniques incorporate crossed lag screw(s) with or without a dorsal plate construct or a large diameter axial screw (Coughlin, 2000; Kadambande et al., 2007; Jeng and Campbell, 2008). The incidence of nonunion in the setting of MTP I arthrodesis for RA ranges from 0% to 26% (Mann and Thompson, 1984; Mann and Schakel, 1995; Vandeputte et al., 1999; Coughlin, 2000; Gröndal et al., 2005; Kadambande et al., 2007). The incidence of radiographic hallux interphalangeal (IP) arthritis following MTP I fusion may be as high as 60%, but many of these patients are asymptomatic (Mann and Thompson, 1984; Mann and Schakel, 1995; Coughlin, 2000). MTP I fusion also improves the first-second intermetatarsal angle (IMA1-2), with a mean change of four degrees to six degrees (Mann and Katcherian, 1989; Cronin et al., 2006).

Arthroplasty of the MTP I has been proposed as an alternative to resection arthroplasty or arthrodesis for the rheumatoid patient. Numerous implant types have been described: hinged double-stemmed silicone implants (Granberry et al., 1991; Cracchiolo et al., 1992; Moeckel et al., 1992; Clayton et al., 1997), silicone implants with titanium grommets (Sebold and Cracchiolo, 1996), and metallic hemiarthroplasty resurfacing implants (Townley and Taranow, 1994). In a retrospective series pain relief in these series was roughly 67%, with significant reduction compared to preoperative levels (Granberry et al., 1991; Cracchiolo et al., 1992; Moeckel et al., 1992). Satisfaction rates are more disparate, with these studies indicating satisfaction of 49% to 84%, and partial satisfaction (with reservations) of 13% to 37%. Recurrent deformity or contracture ranged from 24% to 50%. Rahman and Fagg reported synovitis occurring in up to 72% of cases in their series and on the basis of their findings suggested that the procedure should be abandoned (Rahmann and Fagg, 1993).

### *2.2.5 Forefoot preserving surgery*

Several techniques for lesser MTP joint preservation in rheumatoid forefoot reconstruction have been reported in the literature and mostly involved distal osteotomies of the distal metatarsals. Syndactylization procedure includes the removal of a skin wedge devoid of subcutaneous tissue between the digits, including heloma if present, and suturing the skin edges

on the adjacent digits together. Saltzman et al. analyzed the use of partial lesser toe phalangectomy and syndactylization in order to preserve less severely affected lesser MTP joints in RA patients an average of eight years postoperatively (Saltzman et al., 1993). Syndactylization procedure included the removal of a skin wedge devoid of subcutaneous tissue between the digits, and suturing the skin edges on the adjacent digits together. In this study 64% of patients had persistent metatarsalgia and 82% had deterioration of clinical results with time. The conclusion was that the indications for this procedure are limited.

In a retrospective series of 15 feet in eight patients with rheumatoid forefoot problems (Thordarson et al., 2002), 13/15 feet were operated on in an attempt to preserve the MTP I joint while performing a resectional arthroplasty on the lesser MTP joints. Eight feet underwent a distal Chevron osteotomy to realign the great toe. Two feet underwent an IP fusion as only the IP joint had evidence of erosive changes, and one foot underwent a combination of a Chevron osteotomy and a proximal phalangeal osteotomy (Akin procedure). During follow-up 11/15 feet developed progressive valgus deformity or synovitis within two years. The authors concluded that patients with rheumatoid forefoot disease may on occasion have a well-preserved MTP I joint with minimal or no deformity and no active inflammation, with severe lesser toe involvement. Most of these feet will fail in surgery if the procedure does not also involve fusion of the MTP I joint.

The initial results after oblique osteotomies of metatarsal heads were promising (Helal, 1975). Helal and Greiss presented results of 508 feet in 310 patients after telescoping osteotomy of the lesser metatarsals for metatarsalgia with a mean of 4.3 years. Of these patients 22% were diagnosed rheumatoid arthritis. In this procedure, using a narrow-gauge oscillating saw the metatarsal was divided, starting proximally on the dorsum and proceeding distally and plantar ward at an angle of 45°. An excessive dorsal spike was trimmed off with a bone nibbler and an osteotomy was slid between the bone and the plantar soft-tissue to free the head which was then displaced dorsally and proximally. At the final review 274 (88.4%) of the patients had no pain at all and had resumed their normal range of activities (Helal and Greiss, 1984). Hanyu used a similar type of osteotomy producing shortening (Hanyu et al., 1997). On average six years after surgery, 39 (83%) patients were satisfied with the outcome after surgery. However, recurrence of deformity of the toes (44%) and calluses (12%) was reported and the technique is not widely used.

Weil's osteotomy is designed to allow shortening without plantar flexion of the metatarsal heads. An osteotomy is made parallel to the weight bearing surface, then sliding the metatarsal head proximally, thus providing axial decompression. This reduces the plantar pressure by reducing the joint and the plantar plate (Barouk, 1996). In a preliminary study with more than two years of follow-up, Barouk and Barouk reported excellent correction of the hallux valgus deformity in the rheumatoid forefoot with a scarf osteotomy in 92% of cases with no need for MTP I joint arthrodesis. In this study 86% of the lesser metatarsal heads were preserved using Weil's osteotomies (Barouk and Barouk, 2007). In a retrospective study on 17 patients (26 feet) Weil's osteotomies were used for preserving lesser MTP in combination with MTP I arthrodesis (Bolland et al., 2008). Patients rated the result in 88% of cases as excellent or good with 76% improvement in pain, 74% improvement in function, and 70% improvement in footwear fit. There was a 12% rate of recurrent metatarsalgia and

or calluses. Bhavikatti et al. retrospectively reviewed 49 patients with rheumatoid forefoot deformities who underwent 66 joint preserving procedures with Scarf osteotomy of the first metatarsal and Weil's shortening osteotomy of the lesser metatarsals with a mean follow-up of 51 months (Bhavikatti et al., 2012). In this study the mean AOFAS score improved from 40 preoperatively to 89 at final follow-up. Subjectively patients reported their outcome as excellent in 49 feet (74%), good in nine feet, fair in seven feet and poor in one foot. Five feet had residual stiffness and 11 residual pains.

The use of a modified Hohmann method for hallux valgus and telescoping osteotomy for lesser toe deformities on 47 RA patients yielded a 78% satisfaction rate and pain improvement. However, there were several complications, such as painful callosity, which was recurrent in seven feet, and delayed wound healing was observed in two out of the 90 feet (Nagashima et al., 2007). Highlander and colleagues reviewed the complications after 1131 Weil's osteotomies (Highlander et al., 2011). The most commonly reported complication of Weil's osteotomy was floating toe, reported in 233 (36%). Recurrence of malposition was reported in 15% of the cases. Transferred metatarsalgia was reported in 7% of the cases, whereas delayed union, non-union, and malunion were collectively reported in 3% of the cases.

## 2.3 Rheumatoid changes in hand

RA, as it affects the hand, is a disease of the synovium lining the joints and sheaths of the tendon. The proliferating synovium destroys the articular surfaces of the joint, impedes with the gliding mechanism of the tendons and weakens the supporting ligaments of the joints, causing severe impairment of hand function (Apfelberg, 1978). Extensor tenosynovitis in untreated hands attach to and invade the extensor tendons, and even cause tendon ruptures (Albernethy and Dennyson, 1969). Flexor tenosynovitis can cause weakness of grip and symptoms of a carpal tunnel syndrome in the wrist area. In the palm area the tenosynovial involvement and nodule may block finger function (Nalebuff, 1969; Gray and Gottlieb, 1977).

### 2.3.1 *Wrist and metacarpophalangeal joints*

The wrist is the most commonly affected joint in RA hand. In the course of RA the wrist becomes involved in as many as 95% of cases, and 39% of the wrists of patients have been fused or show severe erosive changes in radiographs by 15 years after diagnosis (Belt et al., 1998b). Synovitis in the wrist joint weakens the ligamentous support and the distal radioulnar joint (DRUJ). Collapse of the radial column of the carpals results in a relative lengthening of the distal ulna in relation to the distal radius. The typical caput ulna appearance, in which the ulna head dislocates dorsally, results in DRUJ incongruity and impaction of the distal ulna on the carpus (Chung and Pushman, 2011).



The scapholunate ligament is prone to weakening from the synovitis, which leads to flexion of the scaphoid and collapse of the radial column (Taleisnik and Ruby, 1998). Stretching of the wrist ulnar collateral ligament attenuates the ulnar column support. These two events ultimately lead to the typical carpal supination pattern. It has been observed that the carpus may sublux in an ulnar direction along the inclined radius (Figure 3). The consequence of carpal supination is the collapse of the radial wrist, which contributes to the radial deviation of the metacarpals and accentuates the ulnar deforming forces of the fingers at the MCP joints (Wilson, 1986). The wrist joint may also sublux in an anterior direction, which causes difficulties in wrist extension.

Figure 3.  
Typical RA changes in X-ray. The carpus is subluxated in an ulnar direction along the radius. The metacarpals are deviated in the radial direction and the MCP joints are deviated in an ulnar drift. In thumb shows boutonniere deformity. MCP II has been treated with Swanson arthroplasty, PIP III and PIP V are fused.



Typical deformities in MCP joints are volar subluxation and ulnar deviation (Ellison et al., 1971; Wilson, 1986). Chronic synovitis at the MCP joints disrupts the ligamentous support and the radial stress on the fingers with pinch drives the fingers in the ulnar direction. Destruction of cartilage in the joint, destruction of the attachment of the radial collateral ligaments and distension of the ligaments exacerbate the malposition. The extensor tendons tend to subluxate ulnarly and contracture of the interosseus muscles prevents extension. Contracture of the intrinsic muscles contributes to volar displacement (Stirrat, 1996).

### 2.3.2 Thumb deformities

In long-term RA the thumbs are deformed in two thirds of patients (Terrano et al., 1990; Toledano et al., 1992). The boutonnière deformity (BD) characterizes 50–70% of involved thumbs (Wilson, 1986; Terrano et al., 1990). BD the MCP I joint becomes flexed and the interphalangeal joint extended. The cause of this deformity is synovitis in the MCP I joint, giving rise to subluxation of the joint and tendon imbalance leading to BD (Belt et al., 1996). The TMC joint is affected in one third of rheumatoid patients. Synovitis is the cause of cartilage and bone resorption and joint capsule distension. The joint becomes subluxated radially and the first metacarpal collapses into flexion, abduction and supination. Swan neck deformity (SND) with MCP I joint hyperextension and interphalangeal joint flexion is also common (Belt et al., 1996; Belt et al., 1998a). In 1968, Nalebuff presented a classification of thumb deformities in RA (Nalebuff, 1968). The original Nalebuff classification has since been extended to include three additional patterns of thumb involvement (Terrano et al., 1995). RA thumb deformities are presented in Table 2.

Table 2.  
Rheumatoid Thumb Deformities

Type	TMC Joint	MP Joint	IP Joint
I (Boutonnière)	Not involved	Flexed	Hyperextended
II (Uncommon)	TMC flexed and adducted	Flexed	Hyperextended
III (Swan neck)	TMC subluxed, flexed, and adducted	Hyperextended	Flexed
IV (Gamekeeper's)	TMC not subluxed, flexed, or adducted	Radially deviated, ulnar collateral ligament unstable	Not involved
V	May or may not be involved	Hyperextended, volar plate unstable	Not involved
VI (Arthritis mutilans)	Bone loss at any level	Bone loss at any level	Bone loss at any level

## 2.4 Surgical treatment of the rheumatoid hand

Collaboration between surgeons, occupational therapists and rheumatologists is of paramount importance in the successful management of surgical hand problems in RA. The indications for surgery in RA are relief of pain, improvement or preservation of function, correction of deformity, and cosmesis. Surgical procedures include nerve decompression,

synovectomy, tenosynovectomy, tendon surgery, arthroplasty, and arthrodesis. The results of arthroplasty depend on appropriate function and balance in the soft tissues, which may be sub-optimal in rheumatoid disease (Chung and Pushman, 2011). Arthrodesis is successful in alleviating pain but causes loss of movement in the joints.

Understanding the priority of treatment is also critical in optimizing outcome, particularly when multiple joints are damaged. In general the deformities in the proximal joints are corrected before distal articulations. Nerve decompression and impediments due to tendon ruptures are indications for urgent surgical treatment. The wrist malalignment has to be treated before MCP arthroplasties (Stanley and Norris, 1988; Burke, 2011). Before hand and wrist reconstruction, the need for lower extremity surgery of the weight-bearing joints should be assessed. Stabilizing and mobilizing operations have to be performed at different sessions to facilitate postoperative rehabilitation (Wilson, 1986; Boco, 1992).

## 2.4.1 Metacarpophalangeal joints

### 2.4.1.1 Evolving MCP joint surgery

A variety of surgical techniques has been developed in MCP joint surgery. Arthrodesis of the finger MCP joint is not performed because the arc of motion of the fingers is initiated at the MCP joint. Resection arthroplasties of MCP joints were used without and with interposition of soft-tissues (Riordan and Fowler, 1989). In Vainio arthroplasty an extensor tendon is interpositioned between the proximal phalanx and the resected metacarpal head and sutured to the volar plate (Vainio et al., 1967). Vainio reported functional results similar to those obtained with Swanson arthroplasty, but Swanson arthroplasty gave better stability and correction of subluxation (Vainio, 1989). Tupper described volar plate arthroplasty (Tupper, 1989), in which the volar plate is released proximally brought over the metacarpal head excision, and sutured dorsally as an interposition material. This method resulted in reported pain relief at rest, but improvement of hand function was less satisfactory as regards both grip and pinch strength (Gotze and Jensen, 2000).

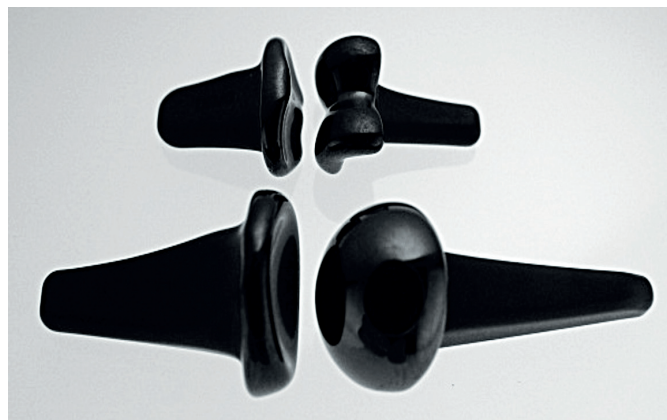
Three basic MCP joint prosthetic designs have been developed; hinged total prostheses, flexible interposition implants and unconstrained total prostheses. The earliest developed implants were all hinge designs composed of two or three metal components. The first MCP joint prosthesis proposed was designed by Brannon and Klein in 1953 (Brannon and Klein, 1959). The implant consisted of two components joined together by a hinge joint, locked by a half threaded rivet screw. The Flatt prosthesis was developed in 1961 with three extra low carbon vacuum melt stainless steel components (Flatt, 1961). These first hinge prostheses were followed by various types of cemented or non-cemented constrained implants, e.g. Griffit-Nicolle, Scultz, St Georg-Buchholtz and Steffee, with metal and polymeric components (Beevers and Seedhom, 1995; Linscheid, 2000). The results of the first and second generation prostheses were compromised and a high incidence of complications was reported including loosening, implant breakage, recurrence of deformity, progressive loss of mobility, bone erosion, deposition of debris and perforation through the cortex. In addition

some ceramic implants were developed, the first being the KY Alumina ceramic prosthesis, followed by the Minami alumina ceramic implant (Minami et al., 1998). The problem with these implants was limited functionality. The average range of motion was only 36.5 degrees. None of these implants are currently used.

Third generation implants are so-called “total” implants, comprising several components. These include the Kessler (1974), Hagert (1986), Beckenbaugh (1983) and Ludborg (1993) implants all made from different materials (Beevers and Seedhom, 1995). These implants are not suitable for patients with severe RA, including bone erosions and considerable deformity as ligaments and muscles are needed to ensure the stability of the implant. Third generation implants have been reported to be associated with bone loss, recurrence of ulnar drift and decreasing hand function (Beevers and Seedhom, 1995; Linscheid, 2000).

Pyrolytic carbon is a synthetically produced biocompatible material with an elastic modulus similar to that of cortical bone (Cook et al., 1981). Pyrolytic carbon implants have been used in many joints e.g. MCP, PIP, TMC, MTP I, mainly in osteoarthritic patients (Figure 4). The preliminary evaluation of articulating pyrolytic carbon-on-pyrolytic carbon metacarpophalangeal joint implants in primates revealed no evidence of wear or wear debris, no evidence of an inflammatory reaction, and excellent bone-implant incorporation (Cook et al., 1983). Parker et al. reviewed 142 consecutive MCP arthroplasties performed with pyrolytic carbon joint replacements, with an average follow-up of 17 months (Parker et al., 2007). The outcomes of patients treated for osteoarthritis were generally excellent, but outcomes in the RA group were less optimal, and the authors stressed that patients with a good bonestock, and well maintained and preserved supporting tissues are the optimal candidates for unconstrained joint replacement. The pyrolytic carbon MCP joint implant is not appropriate for RA because ligament laxity and deforming forces make recurrent joint subluxation likely (Chung and Pushman, 2011).

Figure 4.  
Pyrolytic carbon implants. Below is a PIP joint implant and under MCP joint.

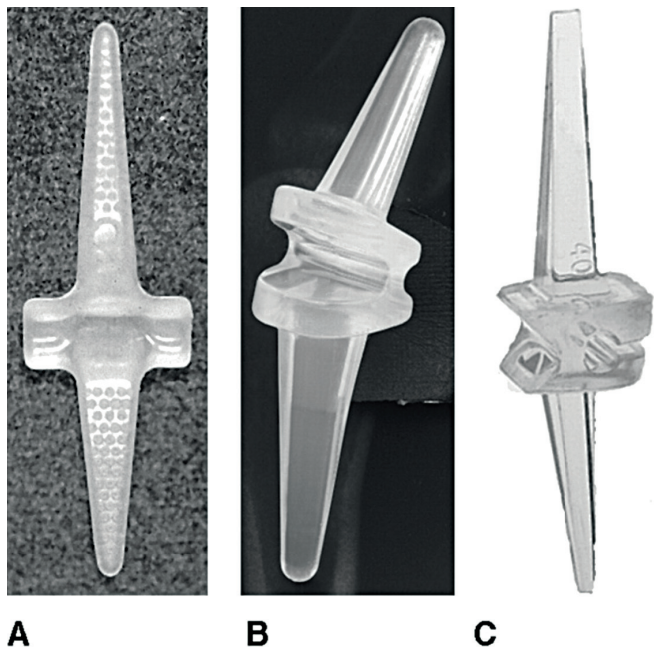


#### 2.4.1.2 Primary MCP silicone arthroplasty

Silicone arthroplasty is still the gold standard for MCP primary arthroplasties. The first silicone spacer was described by Swanson in 1968 (Swanson, 1968). The silicone implant acted as a spacer following resection arthroplasty, providing stability and allowing early motion while the soft-tissue envelope healed. Stability is provided by the developing capsule, which in turn protects the implant from fracture. Swanson termed this process “encapsulation” (Swanson, 1997). The formation of a functional and stable fibrous capsule requires the initiation of early motion using postoperative orthosis (Goldfarb and Dovan, 2006). The modifications of the Swanson implant such as Sutter and Neuflex were developed to improve the biomechanism (Figure 5). The Sutter implant (Avanta), introduced in 1987, is made of the same material, polysiloxane elastomer (Silastic), but the axis of rotation is located further in a palmar direction to improve MCP extension. The hinge is rectangular, whereas that in the Swanson model is u-shaped, and where the stems of the Swanson implant meet the hinge with a gentle curve, the Sutter stems do so at a sharp angle, and this area may be susceptible to fractures (Joyce et al., 2003). In a Neuflex implant, introduced in 1988, is preflexed to 30 ° to facilitate flexion and has a palmar hinge location to improve biomechanism and diminish peak stresses. One randomized follow-up study reported better flexion in patients provided with a Neuflex implant than with the Swanson model, but the subjective evaluation of function was better in the Swanson group (Escott et al., 2010). A prospective and randomized study showed no significant difference between the Swanson and Sutter (Avanta) implants (Parkkila et al., 2005a). Sutter and Neuflex implants yielded similar results in one year follow up in a randomized series (Pettersson et al., 2006).

Figure 5.  
Different types of  
silicone rubber MCP  
joint implants.

- A: Swanson implant,
- B: Neuflex implant,
- C: Sutter implant.



Several studies have shown that MCP arthroplasties using a silicone implant provide good pain relief, slightly improve the arc of motion and correct the deformity (Swanson, 1972a; Schmidt et al., 1999; Chung et al., 2000; Goldfarb and Stern, 2003; Escott et al., 2010). The reported active ROM values after silicone MCP arthroplasty are usually 30–50°. The immediate post-operative ulnar deviation is usually corrected to less than 5°. However, the outcomes tend to deteriorate with long-term follow-up as regards joint stiffening and recurrence of deformity (Chung et al., 2000; Goldfarb and Stern, 2003).

In follow-up studies after silicone arthroplasty of the MCP joints, silicone synovitis, osteolysis, and fracture of the implants have frequently been reported to occur (Wilson et al., 1993; Goldfarb and Stern, 2003; Parkkila et al., 2005b). Silicone synovitis is caused by repeated rubbing of the implant against bony or sharp surfaces leading to silicone wear particles inducing an immune response, causing release of multinucleated giant cells and synovial hypertrophy (Lanzetta et al., 1994). Characteristic radiological changes including the development of cysts in adjacent bones may occur without symptoms, whereas others will encounter pain, joint stiffness, loss of motion and swelling of soft tissue (Khoo et al., 2004). The incidence of osteolysis changes after silicone MCP arthroplasty varies widely across studies. One radiological study reported osteolysis around 89% of the implants (Schmidt et al., 1999). Another study evaluated the incidence and degree of osteolysis operated on with Sutter implants (Parkkila et al., 2006b). After a mean of 5.7 years osteolytic changes were present in 142 (50%) of the metacarpal and 152 (54%) of the phalangeal bones. Cortical invasion was recorded in 100 (35%) of the metacarpal and 103 (37%) of the proximal phalangeal bones. The cortex was perforated in 14 (5%) of both bones. Osteolytic changes were related to fractures of implants and to the dominant hand, but not to pain.

The breakage of Swanson implants reported in the literature varies considerably and fracture rates have been reported anywhere from 0–82%. Goldfarb and Stern evaluated 208 arthroplasties an average of 14 years postoperatively, and reported that 63% were broken, with an additional 22% deformed. However, the reported ROM and hand function measures were similar with respect both to intact and broken implants (Goldfarb and Stern, 2003). Kay et al. reported the highest fracture rate of 82% in Swanson prostheses followed up for five years (Kay et al., 1978). Bass et al. reported a high implant fracture incidence with Sutter silicone MCP arthroplasty after an average of 27 months of follow-up (Bass et al., 1996). 20% of the implants were shown to be definitely fractured. At the final follow-up examination, the average ulnar drift in intact implants was 11 degrees and in the fractured implants 23 degrees. However, there was no correlation between implant fracture and patient satisfaction. Tägil et al. reported a fracture rate of 36% with Avanta prosthesis compared to 11% with Swanson implants at five year follow-up (Tägil et al., 2009). Parkkila and colleagues compared 89 Swanson implants to 126 Sutter (Avanta) implants (Parkkila et al., 2006a). During a period of 48 months the survival of Swanson and Sutter prostheses did not differ significantly. However, the fracture rate was high in both groups: 26 (34%) in the Swanson and 25 (26%) in the Sutter group. Recurrent ulnar deviation was related to silicone implant breakage.

### 2.4.1.3 Revision MCP silicone arthroplasty

There are a few series concerning revision MCP arthroplasties (Table 3) (Ferlic et al., 1975; Beckenbaugh et al., 1976; Wilson et al., 1993; Kirschenbaum et al., 1993; Hansraj et al., 1997; Trail et al., 2004). In these studies, reported implant fracture rates varied from 7% to 66%. The broken implants were only one reason to revision surgery, other causes included deformity, stiffness, malalignment and silicone synovitis. There is no consensus about the indications for revision surgery, and it is generally accepted that a prosthesis fracture is not an indication for revision without other symptoms. Trail et al. reported the largest number of revisions, revising 76 out of 1336 joints, 39 with fractured stems. With a revision rate of 3%, they concluded that radiographic implant failure does not require revision surgery (Trail et al., 2004). Burgess et al. reported results of 20 hands in 18 patients (62 implants) with revision silicone MCP arthroplasties between 1986 and 2005 and a mean five year follow-up period (Burgess et al., 2007). Of these implants 76% were fractured. Revision silicone arthroplasty achieved pain relief, the but objective results were generally poor. There was no significant change in the flexion range (preoperative 16° to 50°, postoperative 20° to 54°) and a slight improvement in ulnar drift (preoperative 24°, postoperative 13°). In addition, there was a high implant fracture rate (34%) in the revisions, suggesting that the soft tissues were unable to support the forces at the joint, and leading to excessive demand and stress on the implant. The use of a silicone implant in revision MCP arthroplasty was limited by poor survival.

Table 3.  
Revision rates after silicone implant arthroplasty.

Study	Implant	Total number of implants	Follow-up time	Fracture rate	Revision rate	ROM preop.	ROM postop.
Ferlic (1975)	Swanson	162	38 mnths	9%	1.8%		
Beckenbaugh (1976)	Swanson/ Niebauer	186/16	32 mnths	26.2/ 38.2%	2.4%		10–48
Wilson (1993)	Swanson	375	9.5 yrs	17%	3%		21–50
Kirschenbaum (1993)	Swanson	144	102 mnths	10%	2%		16–59
Hansraj (1997)	Swanson	170	5.2 yrs	7%	6.4%	38	27
Trail (2004)	Swanson	1336	17 yrs	66%	5.7%		

## 2.4.2 Rheumatoid thumb

BD is the most common rheumatoid thumb deformity (Nalebuff, 1968). Surgical treatment includes MCP I synovectomy and increasing the extensor force (EPL rerouting) for early correctable deformities (Toledano et al., 1992). Failure rates of EPL rerouting technique are reportedly high, however, with deformity recurring in up to 64% of cases (Terrono et al., 1990). Capsulodesis/sesamoidesis is used for MCP I hyperextension deformities with good flexion, and ligament reconstruction is used for lateral deformities as needed (Rozenal, 2007). MCP I arthroplasties have also been reported in patients with severe destruction of the articular surfaces with preserved ligamentous stability (Swanson and Herndon, 1977; Terrono et al., 1990). A common indication for MCP I arthroplasty is a patient with a BD. Swanson and Herndon reported from good to excellent results in 42 out of 44 thumbs at follow-up of 2 to 6.5 years (Swanson and Herndon, 1977). MCP I arthroplasty is best for the low-demand patient with involved adjacent joints. It has a higher incidence of IP deformity and weaker pinch when compared to MCP I fusion (Terrono et al., 1990).

MCP I fusion is the most reliable treatment for rheumatoid thumb and is recommended for hyperextended deformity and for flexion deformities with good IP and TMC function. The ideal arthrodesis position of MCP I joint is 15° of flexion (Nalebuff, 1984). IP Joint arthrodesis is recommended for patients in whom the joint is grossly unstable with or without intact extrinsic tendons (Terrono et al., 1990)

Tendon interposition arthroplasty is commonly used for the surgical management of arthritis of the TMC joint (Burton and Pellegrini, 1986). Arthrodesis of this joint is rarely indicated in RA, as the distal joints of the thumb are usually abnormal and may require fusion at a later date (Nalebuff 1984, Terrono et al. 1990). Multiple techniques have been described, ranging from simple trapezium excision to techniques of tendon interpositional arthroplasty using extensor carpi radialis, flexor carpi radialis, palmaris longus, or abductor pollicis longus tendons. However, most of the clinical studies to date have been performed on patients with osteoarthritis. The long-term results of these procedures are grossly equivalent and boast up to 95% excellent long-term results (Dell et al. 1978, Burton and Pellegrini 1986, Tomaino et al. 1995, Weilby 1998).

Various types of TMC joint replacement arthroplasty, both hemiarthroplasties and total arthroplasties, have been described (Swanson, 1972b; de la Caffinière and Aucouturier, 1979; Braun, 1985; Cooney et al., 1987; Glickel et al., 1992; De Smet et al., 2004), but the long-term results have been unsatisfactory when using implant arthroplasty (Rozenal, 2007). Most series also concerned osteoarthritic patients. Silicone implant arthroplasty is associated with multiple long-term complications, including silicone synovitis and implant subluxation (Swanson et al., 1981). Smith (Smith et al., 1985) and Peimer (Peimer et al., 1986) both described silicone synovitis secondary to particulate debris. Further studies showed a 74% incidence of metacarpal cysts as well as a 56% incidence of scaphoid involvement (Creighton et al., 1991). The Niebauer silicone design, with polyethylene mesh allowing for bony ingrowth has provided good short-term results (Adams et al., 1990). At nine year follow-up, however, studies have shown a high incidence of subluxation (Sotereanos et al., 1993). The first reported total arthroplasty was by de la Caffinière (de la Caffinière and



Aucouturier, 1979). Skyttä et al. evaluated the outcome of the de la Caffinière prosthesis in patients with inflammatory arthritis in 57 thumbs (Skyttä et al., 2005). The implant survival rate based on revision operation was 87% at 10 years. August et al. reported significantly poorer results: 24% of prostheses were revised and 24% needed revision due to cup loosening and a further 19% prostheses were seen with lucent cement lines around the cup (August, 1984). de Smet *et al.* analyzed a series of 43 patients in whom they implanted a de la Caffinière prosthesis. They reported good and excellent results as far as pain, function, and overall satisfaction were concerned. However, 44% of these implants eventually loosened and this was more pronounced in the dominant hands of younger patients (de Smet et al., 2004).

The synthetic allograft Artelon (Artimplant AB, Sweden) has been used in the TMC joint for the treatment of osteoarthritis. Artelon Spacer is synthesized of a degradable polyurethaneurea and it takes approximately six years before the material is hydrolyzed. Jörheim et al. compared the short-term efficacy of the Artelon implant with that of total trapezectomy and abductor pollicis longus tendon suspension interposition arthroplasty in TMC osteoarthritis (Jörheim et al. 2009). Two Artelon patients underwent revision surgery and the short-term outcomes were not superior in this study. There are also case reports of the Artelon spacer causing a foreign body reaction (Choung and Tan, 2008, Giuffrida et al., 2009). Kokkalis et al. reported the outcomes after suspension and interposition arthroplasty using an acellular dermal allograft (GraftJacket; Wright Medical Technology, Inc., Arlington, TN) for TMC osteoarthritis (Kokkalis et al. 2009). Eighty-nine patients (100 thumbs) were followed up for a minimum of 12 months (average 30 months). Patients' pain levels were significantly reduced. No patient experienced a foreign body reaction or suffered from an infection.

## 2.5 Bioabsorbable materials

In the late 1960s, animal studies reporting the use of bioabsorbable polymers began to appear in the literature. In 1966, Kulkarni and coauthors published a report on the biocompatibility of Poly(L-lactide) (LPLA) in animals (Kulkarni et al., 1966). The polymer was implanted in powder form in both guinea pigs and rats. It was found that the polymer was nontoxic, non-tissue reactive, and degraded slowly. In 1971, the results were presented using LPLA plates and screws to fix mandibular fractures (Kulkarni et al., 1971). In the same year, Cutright and colleagues presented their work on using LPLA suture to fix mandibular fractures (Cutright et al., 1971). Both studies demonstrated that the material did not cause detrimental inflammatory or foreign body reactions, although the material had not completely degraded by the end of the study. The world's first orthopedic patient treated with biodegradable rods was an ankle fracture patient treated in Helsinki, Finland in 1984 (Rokkanen et al., 1985).

Bioabsorbable implants are used today, for example in trauma (Rokkanen et al., 2000), orthopedic (Waris et al., 2004), urologic (Kotsar et al., 2010) and craniomaxillofacial surgery (Ashammakhi et al., 2001). Bioabsorbable implants have been applied for the controlled release of different drugs and proteins (Tiainen et al., 2002; Niemelä et al., 2006; Kotsar et al., 2009) and also manufactured in the form of pins, screws, plates, rods, tacks, and suture

anchors, and are most often manufactured from PLLA, PGA, PDO, or a copolymer of PLA or PGA. Polydioxanone (PDS) is a polymer consisting of p-dioxanone monomers. PDS has been used as a suture material, for bone fixation and as a dural patch (as a copolymer with PLA, commercially available as Ethisorb® Dura Patch). Bioabsorbable implants offer potential advantages over metallic implants, such as gradual stress transfer to the healing bone, permitting more complete remodeling, and decreasing the necessity for hardware removal (Hanafusa et al., 1995; Blasier et al., 1997). According to a Cochrane Review (Jainandusing et al., 2009), no significant difference between the bioresorbable and other implants could be demonstrated with respect to functional outcome, infections, and other complications. Reoperation rates were lower in some patient groups treated with bioresorbable implants. The authors' conclusion was that in a selected group of compliant patients with simple fractures, the use of bioresorbable fixation devices may indeed be advantageous. In addition to the obvious advantage for the patients, the use of biodegradable implants instead of metallic hardware has been shown to reduce the overall costs, e.g. in ankle fracture cases by more than 20% (Böstman, 1996; Juutilainen et al., 1997).

The initial biomechanical properties of self-reinforced bioabsorbable plates, screws and pins are comparable to currently-employed metal fixation methods in small tubular bones (Waris et al., 2002; Waris et al., 2003). Bioabsorbable fixation devices, however, have lower mechanical strength and torsional stability compared to metallic ones (Daniels et al., 1990; Waris et al., 2002; Waris et al., 2003), which makes them best suited for application in small fragment fractures, small joint arthrodeses, and osteotomies, as well as for the fixation of ligamentous structures in shoulder and knee surgery (Rokkanen et al., 1985; Hirvensalo et al., 1991; Pihlajamäki et al., 1992; Buchotz et al., 1994; Athanasiou et al., 1998; Maitra et al., 1998; Gogolewski, 2000; Rokkanen et al., 2000).

### *2.5.1 Polyglycolide (PGA), polylactide (PLA) and their co-polymers*

The first bioabsorbable synthetic polymer was made from (polyglycolic acid) PGA and belongs to the group of poly ( $\alpha$ -hydroxyacids). PGA is a fairly strong material with sufficient strength retention rate for most fractures, but since it is hydrophilic, from a biocompatibility point of view it degrades too quickly. The mechanical strength of PGA is lost in 4 to 7 weeks (Vasenius et al., 1990) and the polymer is completely gone at 6–12 months (Törmälä et al., 1987; Vainionpää et al., 1987). Because of their rapid degradation the pure PGA implants are no longer used in bone osteosynthesis. PGA implants have been reported to cause sinus formation because of excessively rapid degradation (Böstman et al., 1990).

Polylactide acid (PLA) is a hydrophobic, semicrystalline polymer. PLA is composed of repeating units of lactic acid, which has two stereoisomeric forms, L- and D isomers. L-isomer is found at variable levels in human tissues, for example as a result of anaerobic glucose metabolism, but the D-isomer is detected only at extremely low levels. The L-isomer has higher mechanical strength and degrades more slowly, and thus increasing the proportion of L-isomer, serves also to increase the mechanical strength (Nakamura et al., 1989; Törmälä et al., 1998). Poly-L-lactic acid (PLLA) containing bioabsorbable fixation devices have been

widely used in orthopedic fixation implants. Compared to other bioabsorbable materials, such as PGA or PDS, PLLA has a considerably long degradation time of 2–6 years (Williams, 1982; Vert et al., 1992; Vert et al., 1994; Suuronen et al., 1998). The polymerization product of PLA and PGA is copolymer, these  $\alpha$ -hydroxyacids called polylactide-glycolide (PLGA). The first commercially available copolymer was Vicryl®, the ratio of PLA/PGA was 92/8 (Gilding and Reed, 1979). PLGA implants have also been studied and used especially in pediatric surgery (Ashammakhi and Rokkanen, 1995; Törmälä and Rokkanen, 2001).

The rapid degradation of pure PGA and the slow degradation of pure PLLA implants eventually led to the utilization of co-polymers containing both L- and D-isomers, also called poly-L/D-lactic acid (or PLDLA or P(L/DL)LA). The proportion of L/D may vary i.e. 70/30 or 96/4, depending on the application requirements (Törmälä et al., 1998). Their strength and degradation rate depend on the relative amount of L- and D-monomers in the polymer chain. For example, the P(L/DL)LA 70/30 pins started to decrease significantly after 18 weeks in vitro, losing all strength within 48 weeks (Törmälä et al., 1998). The impact strength of PLA copolymers can be significantly improved by blending with biodegradable rubbers, e.g. trimethylene carbonate (Tams et al., 1995; Leonhardt et al., 2008; Losken et al., 2008).

In RA patients, bioabsorbable polymers (such as PLLA) with long degradation characteristics are preferred (Rokkanen et al., 2000). Self-reinforced poly-L-lactide SR-PLLA screws and pins provided stable fixation for 53 arthrodeses (18 wrist, 18 hand, 6 talocrural and 11 subtalar-calcaneocuboid-talonavicular joint) in patients with RA. There were three superficial infections and two nonunions (both talocrural arthrodesis) (Juutilainen and Päätiälä, 1997). A long-term evaluation (average 5.4 years), of 21 wrist fusions in 18 patients with RA was also favorable, except for one case of non-union (Voutilainen et al., 2001). In another series of 18 RA patients, 24 wrist fusions were stabilized with 3.2 mm SR-PLLA pins, with satisfactory outcomes in 21 instances (Voutilainen et al., 2002). In one study resection arthroplasty of the lesser MTP joints with poly-L-lactic acid (PLLA) thread pins or Kirschner wires was performed at random in the reconstruction of the 87 rheumatoid forefeet (62 patients) with a grommet-protected silicone-rubber implant insertion of the MTP I joint (Tanaka et al., 2004). Recurrent dorsal subluxation of the lesser MTP joints was visible on radiographs in three of the 46 feet with PLLA pins, and recurrent dorsal subluxation of the lesser MTP joints was visible in four of the 41 feet with Kirschner wires. Three patients with Kirschner wires had wire-track infection, and one patient had a severe circulation disturbance of the corrected lesser toes necessitating wire removal.

### 2.5.2 Degradation and biocompatibility

The biodegradation of PLA, PGA and their co-polymers is mainly initiated by hydrolysis of the polymer chain backbone and to a lesser extent by enzymatic activity (Nakamura et al., 1989). Degradation times depend on multiple factors, such as polymer crystallinity, molecular weight, thermal history, porosity, monomer concentration, geometry and the location of the implant (Gopferich, 1996). In the first phase water

penetrates the implant, and the polymer chains are broken down through hydrolysis. In this phase, the molecular weight drops first, followed by mechanical strength loss, and finally by a loss of mass. The actual mass loss of the implant occurs due to release of soluble degradation products, phagocytosis by macrophages and histiocytes, intracellular degradation, and finally, metabolic elimination through the citric acid (Krebs) cycle to carbon dioxide (CO<sub>2</sub>) and water, and the metabolic end products are expelled from the body via respiration and urine. Degradation is faster *in vivo* than *in vitro*, likewise in well vascularized cancellous bone than in subcutaneous tissue (Vasenius et al., 1990).

All biodegradable implants induce a subclinical but microscopically recognizable non-specific foreign body type of tissue response (Rokkanen et al., 2000). Microscopic examination reveals a transient, non-specific inflammatory reaction during the biodegradation process characterized by an invasion of macrophages, foreign-body giant cells, and neutrophilic leukocytes. Macrophages and foreign-body giant cells take part in the process of elimination of the polymeric debris (Päivärinta et al., 1993). Ideally, the degradation should not occur too quickly, yet fast enough to provide clinical benefit, it should be possible to tailor the degradation rate to be indication-specific, and the degradation process should be a controlled, steady process with no obvious degradation peaks. The tissue reaction risk is highest when the gross geometry of the implant is lost (i.e., when the actual mass loss of the implant occurs). Accordingly, the risk of symptomatic tissue reactions is high if the implant is very large and/or made of a material that degrades in an uncontrolled or sudden manner (Böstman and Pihlajamäki, 2000a; Böstman and Pihlajamäki, 2000b).

Synthetic bioabsorbable polymers are generally well tolerated by living tissues and inflammatory response to this is rare. However, in orthopedic and trauma applications it has been reported that in a few situations fluid accumulation and/or sinus formation associated with local pain, redness and swelling may occur at the site of implantation (Pelto-Vasenius et al., 1995; Böstman and Pihlajamäki, 2000a). These reported adverse tissue reactions are mainly related to the use of the older generation of bioabsorbable implants made of pure PGA. Those containing impurities such as aromatic quinone dye, implants with large surface area such as screws, and implant sites with low vascularity such as the scaphoid were all found to be related to a higher incidence of adverse tissue response (Böstman and Pihlajamäki, 2000a). Clinical and experimental experience has shown that sterilized, amorphous, copolymeric SR-P(L/DL)LA 70/30 and SR-PLGA 80/20 devices have good degradation characteristics as regards fixation of small-fragment fractures and there is only a very low risk of adverse reactions (Suuronen et al., 1999; Ashammakhi et al., 2001; Ashammakhi et al., 2003).

### 2.5.3 *Bioabsorbable poly-L/D-lactide 96/4 (PLDLA)*

PLA 96/4 is a polymer of L- and D-lactid acid (L/D ratio 96/4). This copolymer has been studied in several experimental and with cells *in vitro*. Like other polylactides, the material is totally bioabsorbable and degradation takes place by hydrolytic scission of the ester bonds in the polymer. Subsequent degradation of material will proceed when the material is absorbed

by inflammatory cells, mainly macrophages and foreign-body giant cells. The molecules and particles of the material are absorbed and used in cellular metabolism in the citric acid cycle (Törmälä et al., 1992). Absorption rate varies with the type of implant.

Typical histological findings are mild tissue reactions. Rods made of PLDLA placed intramuscularly in rats caused minimal and well-tolerated reactions with a follow-up period of six months (Isotalo et al., 1999). PLDLA stents have been studied in rabbit renal aorta, with a minimal tissue response in a follow-up of 24 months. The stent hydrolyzation started after 9–12 months and the material was not visible at 24 months (Hietala et al., 2001). PLDLA discs placed subcutaneously caused mild local tissue reactions during a follow-up of 52 weeks (Bergsma et al., 1995). Intramedullary fixation with PLDLA rods in rabbits caused a local very mild foreign body type reaction in a follow-up from three weeks to three years, and the material had almost totally disappeared after three years (Saikku-Bäckström et al., 2001). Knitted stents made of PLDLA maintained 50% of compression stiffness for 26 weeks (Nuutinen et al., 2002). Intramedullar fixation with large PLDLA nails evoked a mild reaction in medullar cavity at 6 – 18 months, but by three years, the implant had almost totally degraded (Saikku-Bäckström et al., 2004). Studies on the muscle pouch already after the first week in vivo showed a rapid muscle and connective tissue in-growth to the mesh structure with a positive effect on the tensile strength of the implant (Kellomäki et al., 2000). In rat subcutis, connective tissue ingrowth into the PLDLA implants occurred within three weeks of implantation. Histological examination showed that PLDLA implants provided a structurally supporting element for 48 weeks (Länsman et al., 2006). Melt-spun PLDLA filaments used for the implants retain 50% of their strength for at least 13 weeks in in vitro laboratory tests (Paatola et al., 2000). This makes it possible to retain the shape and size of the PLDLA implants in situ long enough for tissue in-growth.

Biodegradable PLDLA interposition arthroplasty or Swanson silicone arthroplasty was used on 11 minipigs the fifth metacarpophalangeal joints (Waris et al., 2008). This experimental small joint arthroplasty model showed that the PLDLA interposition arthroplasty could be successfully used to engineer fibrous tissue joints in situ. At three years, the PLDLA implant had almost completely degraded and the site of the scaffold had mostly been replaced with acellular dense connective tissue, characterized by abundant dense compacted collagen and a paucity of cells. The PLDLA implant degradation induced no significant osteolysis or cortical erosion in the adjacent bones.

The first preliminary study on the formation of living, functional joint in situ of a synthetic bioabsorbable PLDLA interposition arthroplasty was presented in 2003 (Honkanen et al., 2003). In a prospective study, 23 RA patients (80 joints) were operated on using PLDLA implants. Previous silicone arthroplasty had been performed for 6 (40%) patients and thus in 18 (33%) joints. Fifteen patients (54 joints) were monitored for at least one year. Pain alleviation was well achieved. ROM improved slightly. The average ulnar deviation was preoperatively 26 degrees, and at follow-up it was 6 degrees. Volar subluxation was noticeable in 56% of joints preoperatively and in 6% at one-year follow-up. Honkanen et al. assessed the same 23 patient cohort at an average of 59 months after surgery (Honkanen et al. 2009). Volar subluxation was seen in 11% of joints, the mean ulnar deviation was 5 degrees. Implant resorption induced no significant osteolysis in the medium term and the

restoration of the structure and function of the hand was maintained after implant resorption. There were no infections and none of the implants had to be revised. Ikävalko and colleagues used PLDLA interposition implant and bone packing after failed silicone implant arthroplasties and severe osteolysis (Ikävalko et al., 2007). Volar subluxation recurred in 33 out of 52 (63%) joint at one-year follow-up. Honkanen et al. reported only 6% recurrence of volar subluxation at one-year follow-up (Honkanen et al., 2003). Roentgenograms showed complete incorporation of grafted bone into the diaphyseal portion of the host metacarpal and phalangeal bones in 48/52 joints. However, the periarticular part of the graft was regularly absorbed (Ikävalko et al., 2007).

### 3 PURPOSE OF THE STUDY

The purpose of the present study was to evaluate the clinical performance and safety of bioreplaceable PLLDLA interposition arthroplasty of small joints in chronic inflammatory arthritis patients. The specific objectives were:

- I To evaluate the short-term biocompatibility and clinical performance of the PLLDLA implant in the lesser MTP joints. To compare the novel PLLDLA implant interposition arthroplasties with conventional metatarsal resection arthroplasty in lesser MTP joints
- II To compare the clinical and radiological outcomes of RA patients receiving PLLDLA implant and the silastic Swanson implant in MCP primary arthroplasty
- III To compare the PLLDLA implant interposition arthroplasty with the tendon interposition arthroplasty in TMC joint
- IV To determine the long-term clinical outcome and incorporation of the grafted bone of an PLLDLA interposition arthroplasty combined with bone packing in silicone implant revisions

## 4 PATIENTS AND METHODS

### 4.1 Patients

This dissertation includes four different patient groups. In Studies I and III–IV patients were operated on at the Rheumatism Foundation Hospital in Heinola, Finland during the period 2001–2007. Study II was carried out at two centers, the Rheumatism Foundation Hospital and Tampere University Hospital. All patients were informed about the study and provided written informed consent. Studies I–IV were approved by the Päijät-Häme Central Hospital District Ethics Committee, Lahti, Finland and Study II also by the Ethics Committee of the Tampere University Hospital and Pirkanmaa Hospital District.

#### 4.1.1 Study I

In the first study patients were recruited for a prospective, randomized clinical study. During the period 2004–2007 a total of 36 patients (31 women and 5 men, 18 left and 18 right feet) with RA refractory to conservative treatment were recruited. One patient in the PLDLA implant group, who had only two MTP joints resected, was excluded from the analysis. PLDLA interposition arthroplasty group included 16 patients and conventional metatarsal head resection group included 19 patients. The average age of the patients at the time of surgery was 59 years (range 47 to 74 years). The average duration of disease at the time of surgery was 17 years (range 3 to 40 years). The outcomes of 35 patients (140 joints) were evaluated at a three months and one-year follow-ups.

#### 4.1.2 Study II

This randomized parallel group trial was carried out at two centers, Tampere University Hospital, in Finland and the Rheumatism Foundation Hospital in Heinola, Finland. The inclusion criterion was rheumatoid MCP arthritis interfering with activities of daily living (ADL). Ulnar drift and/or palmar subluxation were present in all operated MCP joints. All revision operations were excluded. Randomization was performed by random digit table and allocation concealment by sealed sequentially numbered envelopes. Patients were randomized to either the PLDLA implant or the silastic Swanson arthroplasty groups. The outcomes of primary operations on 52 patients (53 hands, 175 joints) at a mean follow-



up of 2 years (minimum 1 year) were presented. The PLDLA group consisted of 27 hands (84 joints) with a median follow-up of 23 months (range 17–26 months) and the Swanson group of 26 hands (91 joints) with a median follow-up of 24 months (range 21–26 months). The number of MCP joints operated on was 23, 22, 19 and 20 in the index, middle, ring and little fingers respectively, and in the Swanson group 25, 25, 21 and 20. The operated hand was dominant in 18/27 cases in the PLDLA group and in 16/26 cases in the Swanson group. The diagnosis of arthritis had been made a mean of 27 (range 3–61) years before surgery in the PLDLA group and 24 (12–43) years before surgery in the Swanson group. The majority of the ipsilateral wrists (18 in both groups) were totally or partially fused at the time of MCP joint arthroplasty. Fifteen of the remaining 17 wrists had arthritic changes on radiographs but the carpus was well aligned. Outcomes of patients were evaluated at three-month, one-year and two-year follow-up.

#### 4.1.3 Study III

The third prospective study included 35 patients with symptomatic arthritis of the TMC joint. Patients were randomized to undergo either tendon interposition (flexor carpi radialis or extensor carpi radialis) or PLDLA implant interposition arthroplasty. During data analysis other than RA or inflammatory arthritis patients were excluded (6 osteoarthrosis patients), leaving 29 thumbs in 29 patients (27 women and 2 men) in the study. The PLDLA interposition group comprised 17 and the tendon group 12 patients. Mean age at the time of surgery was 58 (31–73) years in the PLDLA group and 54 (30–76) years in the tendon group. The diagnosis of arthritis had been made a mean of 22 years before surgery in both groups. Mean TMC joint Larsen grade was 3.0 in the PLDLA interposition group and 4.2 in the tendon group. Preoperatively seven thumbs were diagnosed BD in the PLDLA group and 6 thumbs in the tendon group. One SND was diagnosed in both groups. Among the operated hands, 4/17 of the wrists in the PLDLA group and 4/12 in the control group were partially or totally fused earlier. In addition, 5/17 of the MCP I and 2/17 of thumb IP joints in the PLDLA group and 5/12 and 2/12 in the control group had been fused earlier or at the latest by the time of the TMC surgery. Outcomes of study patients were evaluated at a three-month, one-year and two-year follow-up.

#### 4.1.4 Study IV

The fourth non-randomized study was composed of 15 patients (15 hands and 36 joints) who between 2001 and 2003 underwent revision MCP arthroplasty using PLDLA interposition arthroplasty and morcelized allograft or autograft bone packing in patients with failed MCP arthroplasties and severe osteolysis. Ten patients had rheumatoid factor positive RA, three had juvenile idiopathic arthritis, one had psoriatic arthropathy and one had rheumatoid factor negative chronic polyarthritis. The results were evaluated at a mean follow-up of seven years (range 5–10 years). The one-year results were published earlier (Ikävalko et al., 2007), and were not included in this dissertation.

## 4.2 Methods

### 4.2.1 *Clinical examination*

In Studies I–IV pain and function were assessed using 100 millimetre visual analogue scales (VAS, 0–100) with 0 mm being “no pain” or “no functional impairment” and 100 mm being “worst possible pain” or “all functions impaired” respectively. In Study I the clinical signs and symptoms were measured according to the American Orthopedic Foot Association scoring system (AOFAS) (Kitaoka et al. 1994). The function was also determined by gait with four response options: “normal”, “slight limp”, “severe limp” and “unable to walk”.

In Studies II–IV measurements were recorded by an occupational therapist. The grip strength was measured with a Jamar dynamometer (Preston, Jackson, MI, USA) and tip and key pinch were measured with a pinch grip meter. The best value of three consecutive measurements was recorded. In Study II active TMC joint radial and palmar abductions were measured. The clinical examination also included evaluation of range of motion in the MCP I and IP I joints. In Studies III and IV active extension and flexion of the MCP II–V joints were measured from the dorsal surface using a goniometry. Ulnar deviation was measured dorsally using a goniometry with the fingers in maximal active extension.

In Studies II–IV tip pinch grip was assessed for each finger with a wooden bead of 10 mm diameter: the patient was asked to pick up the bead from the table using tip pinch in each finger in turn. A therapist conducted simulated ADL tests, such as ability to handle a knife and fork (precision grip) and a jug with capacity of 0.5 litres (cylinder and transverse volar grip). In the precision grip assessment the patient used a knife and fork to cut a piece of resistant exercise putty (Rolyan A497-280, diameter 7.5 cm). In the cylinder grip test the patient was asked to decant 1 dl water from a jug to a glass (diameter 6–7 cm), and decanting the water back to the jug was assessed as a transverse palmar grip. These functional grips were graded as normal, adapted or not able, “adapted” meaning that the patient was able to perform the task but not in the manner requested. A timed Box and Block test was used to evaluate the dexterity of the hand (Desrosiers et al., 1994). The Box and Block test result indicates the number of cubes transposed per 60 seconds. Patient satisfaction was assessed using a scale indicating excellent, good, satisfactory or poor outcome.

### 4.2.2 *Radiological assessment*

In Study I postoperative radiographs were taken on the first or second postoperative day, at the three-month and at one-year follow-up. The image material for this study consisted of weight-bearing AP and lateral foot radiographs, 24 x 30cm, obtained at a focus-film distance of 1.15 m. All radiographs were obtained with a consistent technique: the patients were standing on both feet with the medial aspects of the feet parallel and with their knees fully extended. Radiographs were assessed according to the Larsen grades (Figure 6) from 0 to 5 (Larsen et al., 1977). However, in the presence of subluxation or dislocation the joint was assessed as grade 5.

Figure 6.  
Larsen grades in the lesser  
metatarsophalangeal joints.

- 0 = Intact bony outlines and normal joint space;
- 1 = Erosion less than 1 mm in diameter or joint space narrowing;
- 2 = One or several small erosions, diameter more than 1 mm;
- 3 = Marked erosions;
- 4 = Severe erosions, where there is usually no joint space left, and the original bony outlines are partly preserved; and
- 5 = Mutilating changes, where the original bony outlines have been destroyed.



In Studies II–V radiological evaluation was made from standardized anteroposterior and lateral X-rays of the hand. In Study II preoperative radiographic destruction of the TMC joint was classified in RA patients using the modified Larsen method (Belt et al., 1999). Other inflammatory arthritis patients were reviewed to enable staging of the disease process at the TMC joint and also other areas of the hand. Postoperative radiographs were performed on the first or second postoperative day and at postoperative follow-up. Bony changes, especially osteolysis with respect to PLDLA implant joints were evaluated.

In Study III arthritis of the MCP and wrist joints was graded using the Larsen scale before PLDLA or Swanson arthroplasties (Larsen et al., 1977). In the follow-ups implant fractures and cortical bone perforations were evaluated from radiographs. In Studies II and IV palmar subluxation of the MCP joints was measured from standardized supine oblique radiographs with the fingers at maximal active extension, and graded as 0 = no subluxation, 1 = subluxation less than 50% of metacarpus thickness, 2 = subluxation more than 50% of metacarpus thickness, 3 = complete dislocation.

In Study IV radiographs were assessed visually for the incorporation of the bone grafts and the radiographic osteolysis changes were assigned for the metacarpal and the proximal

phalangeal bones to four grades depending on the radiological cortical bone changes (Parkkila et al., 2006b): Grade I: Osteolysis varying from a single clear line adjacent to the stem of the prosthesis to a larger, clear area which did not involve the bone cortex. Grade II: Osteolysis affecting the bone cortex to a maximum of one half of its thickness. Grade III: Osteolysis affecting the cortex to more than one half of its thickness but not perforating it. Grade IV: Osteolysis perforating the cortex.

### 4.2.3 Implants

#### 4.2.3.1 The bioabsorbable PLDLA implant

The bioabsorbable PLDLA implant consisted of a porous, fibrous spacer (scaffold), which enables on- and in-growth of tissue. The highly porous scaffold was made of L and D lactic acid copolymers with L,D-monomer ratio 96 to 4 (Purac Biochem b.v., Gorinchem, The Netherlands). Raw PLDLA polymer was melt-spun to 4-ply multifilament using Gimac microextruder (Gimac, Castronno, Italy). The four-ply filament was knitted into a tubular jersey (Textilmaschinenfabrik Harry Lucas, Neumunster, Germany). The knitted tube was rolled into a cylindrical scaffold and heat-treated above the glass transition temperature in the molds. The implant had open porosity throughout the structure, because porosity is formed by mesh loops and by layers of the mesh. The study implants were manufactured at the Institute of Biomaterials, Tampere University of Technology, Finland. Implants with diameters of 12, 14, 16, 18 mm and thickness of 4.5 mm (range 4.3–4.7 mm) were used in these studies. The implants were packed separately and were sterilized with gamma irradiation (nominal dose 25kGy).

#### 4.2.3.2 The silicone Swanson implant

The Swanson silicone finger joint implant (Wright Medical Technology, Inc., Arlington, Tennessee, USA) of size was appropriate to meet the anatomical requirements (Figure 7).

Figure 7.  
The PLDLA interposition implant and the silicone Swanson implant (right).



## 4.3 Surgical technique and post-operative care

### 4.3.1 Forefoot

The procedure was done under tourniquet, and the PLDLA interposition arthroplasty group was routinely given a single dose antibiotic prophylaxis of cefuroxime 3000 mg. If needed, the great toe arthrodesis was done through a slightly curved medial longitudinal approach. The capsule was incised with a straight medial incision and was released subperiostally by sharp dissection from the basal portion of the proximal phalanx. After the synovectomy, the articular surface of the phalanx and metatarsal head were resected with an oscillating saw. Arthrodesis was fixed with two or more Kirschner wires. Osteophytes were removed. The joint capsule was tightened medially. A single transverse dorsal incision was used to excise metatarsal heads from the second to the fifth. Exposure of the joints was done between extensor tendons. The contracted capsule and collateral ligaments were released. In severe deformities extensor tendon lengthenings were done. The second and third metatarsal stumps were osteomized at about equal length, and no stump projected beyond a gently curving line of resection ending at the fifth metatarsal. The interphalangeal joints were corrected by manipulation. In the study group, PLDLA implant (thickness 4 mm, diameter 12 or 14 mm), provided by Tampere University of Technology, Finland, was inserted into the joint space and fixed with a Kirschner wire from the tip of the toe to the metatarsal bone. In the control group, the lesser toes were fixed in the same way. Extensor tendons were adapted with resorbable sutures and skin closure with unresorbable sutures.

Bedrest was prescribed for one to two days with the feet elevated followed by weight bearing in a surgical sandal. Sutures were removed after two weeks and the lesser metatarsal pins after three weeks and proper mobilization was encouraged. In the patients with MTP I arthrodesis a support under the heel was used for six to eight weeks. Patients were evaluated in the clinic at six weeks, three months and one-year postoperatively. Postoperative radiographs were taken on the first or second postoperative day, at the three month and one-year follow-ups.

### 4.3.2 Primary MCP joint arthroplasty

The surgical technique followed the guidelines recommended by Swanson (1972) for silicone MCP joint arthroplasty, but the intramedullary preparation was unnecessary for the stemless PLDLA implants. The release of the volar plate was performed and ulnar intrinsic muscle contractures were released when required. The abductor digiti mini of the fifth finger was always dissected. After metacarpal head excision the PLDLA implant was fixed to the metacarpal bone with long-lasting absorbable monofilament suture (polydioxanone, PDS II, 2/0 USP, Ethicon, Norderstedt, Germany). The size of the PLDLA implant was chosen so that it completely covered the metacarpal bone. Soft tissue balancing was performed when required in a similar way in both groups (Figure 9). The surgical technique

has been described in more detail elsewhere (Honkanen et al., 2003). In the Swanson group the medullar canals were reamed to accommodate the largest appropriate-sized implant. The adequacy of the soft tissue balance was checked with trial implants. The permanent implants were inserted and balancing of the collateral ligaments was performed.

The rehabilitation scheme was identical in both groups, supervised and guided by an occupational therapist. The operated MCP joints were first immobilized in a bulky dressing for 2–3 days, then up to 7–10 days after surgery supported in a static palmar splint. Active and passive ROM exercises were assisted with low-profile dynamic dorsal splinting starting 7–10 days postoperatively and continuing for up to 12 weeks after surgery. The palmar resting splint was used at night up to 12 weeks. Light activities of daily living, such as eating and personal hygiene, were allowed immediately after application of the dynamic splint.

### 4.3.3 Trapeziometacarpal joint

The operation was performed under tourniquet control through a dorsoradial longitudinal incision. A single dose of antibiotic prophylaxis, cefuroxime 3000 mg, was routinely given. Branches of superficial radial nerve and the deep branch of the radial artery were preserved. The capsule was released and opened dorsoradially. Approximately 4–6 mm of the bone was resected from the metacarpal base, perpendicular to its longitudinal axis, allowing full abduction with the interposition. Synovectomy was performed and all osteophytes were revised. The cartilage surface of the trapezium was resected using a courette or an oscillating saw. PLDLA implants (thickness 4 mm, diameter 12 or 14 mm), were provided by Tampere University of Technology, Finland. The PLDLA implant was inserted into the joint space and fixed with absorbable sutures through bone holes to the resected surface of the trapezium. The thumb was placed in suitable position (in sufficient abduction) and a Kirschner wire was inserted to stabilize the first ray. The capsule was carefully reconstructed. In the tendon interposition group the flexor carpi radialis (FCR) was favored because of the size and strength of the tendon. In cases without wrist fusion half of the tendon was used. If the FCR tendon was not available, extensor carpi radialis (ECR) could also be used. The tendon graft was prepared and trimmed using a separate incision. Proximally the tendon was released from the muscle while retaining the tendon's distal insertion intact. The tendon was tunneled into the resected space and a knot was sutured to fill the space. Resections were performed similarly as in the technique for PLDLA interposition arthroplasty. A part of the tendon could be used to reinforce the dorsoradial capsule. A Kirschner wire was used to stabilize the joint in the same way as with the PLDLA interposition arthroplasty.

In both groups, a temporary cast was used for immobilization for two to three days. After that the cast was replaced with an individually fitted plastic splint for three to four weeks. The external Kirschner wire was removed after three weeks and a range of motion exercises was allowed to begin after four to six weeks using a special training splint.

#### 4.3.4 Revision MCP joint arthroplasty

The procedure was done under tourniquet, and to the implant group was routinely given single dose antibiotic prophylaxis of cefuroxime 3000 mg. The joint was approached by a longitudinal incision adjacent to the extensor tendon. The old prostheses were removed. Scar and granulation tissue were removed from inside the metacarpal and phalangeal bones. Release of the volar capsule under the metacarpal bone and release of the volar plate were performed. Significant cortical bone perforations and periarticular cortical defects were recorded, and the status of the previous implant was assessed. Allograft bone (fresh frozen femoral heads or tibial/femoral cuts of non-rheumatoid patients) was morcelized to 2–3 mm chips which were then packed inside the bones leaving the juxta-articular portion empty at this stage. Two to three microburr holes were drilled in the distal dorsal side of the metacarpal bones. A PLDLA implant (thickness 4 mm, diameter 12 or 14 mm) was inserted into the joint space and fixed with a 1–0 absorbable suture passing through the burr holes and attaching the volar plate adjacent to the base of the phalanx. At this stage the bone packing was completed up to the level of the bone ends. After bone packing the implant fixation suture was tightened and thereafter the collateral ligaments were tightened while balancing the finger alignment simultaneously (Figure 8). At the end, the extensor tendon was centralized. A suction drain was applied in revisions of all metacarpophalangeal joints, but not in cases with one or two revised metacarpophalangeal joints.

Figure 8.  
Schematic picture of revision MCP joint arthroplasty using of PLDLA implant and bone packing.

- A: The previous silicone implant has been removed.
- B: The medullary canal has been preliminarily packed with allograft bone chips.
- C: The fixing thread for PLDLA implant has been passed through bone holes and the implant has been inserted into the joint space. The hold sutures (not shown) for collateral ligament reconstruction are passed through bone holes.
- D: Bone packing has been completed and the sutures are tightened.

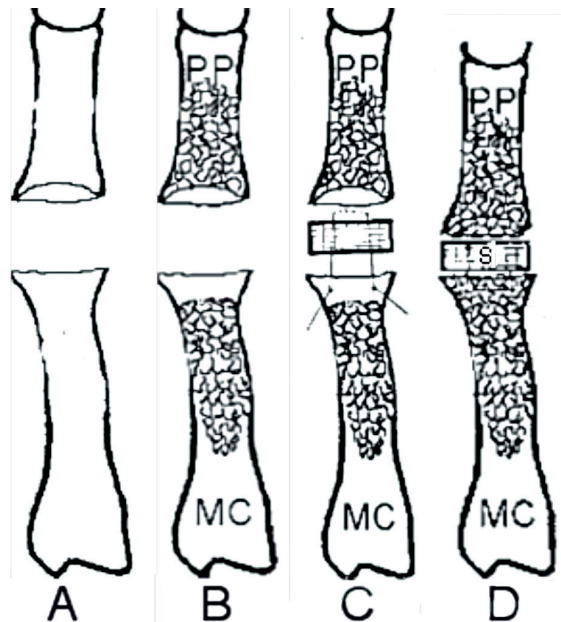


Figure 9.  
Dorsal dynamic splint in rehabilitation after MCP joint arthroplasty.



After the implantation of bioreplaceable finger joint prostheses a static splint was worn. A static splint was applied on the second or third postoperative day. Patients were discharged from hospital and returned to the ward at 10–14 days postoperatively in order to begin the ROM exercises after application of a dynamic splint (Figure 9). Splints were used for 3 months and the ROM exercises were supervised by an occupational therapist on the ward and thereafter by a physiotherapist in outpatient follow-up.

#### 4.4 Statistics

The most descriptive data are presented as mean and (SD) or range. Differences between groups were analyzed using independent samples T-test and using one-way ANOVA, and considered statistically significant if the p-values were less than 0.05 in a two-tailed test. The Mann-Whitney test was used to analyze differences between groups for parameters with a skewed distribution. Analysis between preoperative and postoperative non-parametric variables inside one group was made with the Wilcoxon test, whereas the paired Student's t-test was used for normally distributed variables in this setting. Differences between groups for normally distributed variables were analyzed with independent samples t-test. Classified categorical variables were analyzed using cross-tabulations with Fisher's exact test, when appropriate. SPSS 17.0 statistical software (SPSS Inc, Chicago, Illinois, U.S.A.) was used for the statistical analyses.



## 5 RESULTS

### 5.1 Outcome of PLDLA interposition implant in lesser MTP joints (Study I)

There were no statistical differences between the groups preoperatively in subjective ability to walk, in median AOFAS score, in median VAS score for pain or function. In the PLDLA interposition group, median preoperative lesser metatarsophalangeal Larsen grade was 3.6 (2.7–4.5) and in the control group 3.8 (3.0–4.6).

In both groups all the clinical parameters improved at one-year follow-up (Table 4). The only statistical difference found was in the function; VAS was significantly better in the control group three months after surgery ( $p=0.003$ ). The difference disappeared by 12 months. The other difference between the groups was that in the control group two patients (5 joints) had postoperative spontaneous ossification in the MTP II–III and MTP II–V joints, respectively (Figure 10).

Table 4.  
AOFAS score, pain and function preoperatively and at one-year follow-up.

	PLDLA interposition arthroplasty (n=16)	Metatarsal head resection arthroplasty (n=19)	p
Pain VAS‡ (95% CI)			
Preoperative	44.3 (29.1 – 59.4)	51.2 (37.5 – 65.0)	0.48
1 year postoperative	16.4 (5.0 – 27.8)	9.2 (0.3 – 18.0)	0.18
Function VAS‡ (95% CI)			
Preoperative	52.7 (38.1 – 67.3)	45.2 (28.4 – 62.0)	0.83
1 year postoperative	19.2 (3.5 – 34.8)	19.5 (4.6 – 34.3)	0.63
AOFAS score (95% CI)			
Preoperative	42.2 (34.8 – 49.7)	43.8 (37.9 – 49.7)	0.73
1 year postoperative	77.8 (69.2 – 86.4)	78.0 (71.9 – 84.2)	0.35

Figure 10.

X-ray one year after conventional metatarsal head resection. MTP II–IV joints are spontaneously fused.



Walking ability was improved in both groups at one year after PLDLA interposition arthroplasty or metatarsal head resection. Preoperatively normal walking ability was found in three patients in the PLDLA group and in four patients in the control group. One year after surgery, walking ability was normal in 10 patients in the study group and in 11 patients in the control group.

No reoperations were performed during follow-up. A superficial dorsal wound infection developed in one patient in each study group (5.7 %) and four superficial wound infections (17.4 %) and one delayed wound healing were recorded in MTP I after arthrodesis. All infections were cured with antibiotic therapy. Pseudarthrosis of the fused MTP I joints was recorded in 5/23 (21.7 %).

## 5.2 PLDLA compared to Swanson in primary MCP arthroplasty (Study II)

This randomized clinical study compared the PLDLA implant to the Swanson silicone implant in primary MCP arthroplasties. The clinical outcomes were comparable in both groups, except for better maintenance of palmar alignment in the Swanson group. At the final follow-up, palmar dislocation was observed in the PLDLA implant joints 44/84 (52 %) and 10/91 (11 %) in the Swanson group (Table 5). The recurrence of palmar subluxation was less than the height of the metacarpal bone in 38 out of 44 (86 %) joints in the PLDLA group. The active ROM improved equally in both groups despite a slight loss of flexion. The

Table 5.  
Palmar subluxation before surgery and at mean 24 months of follow-up in Swanson and PLDLA arthroplasty.

	Swanson							PLDLA										
	Preoperative			Follow-up				p-value <sup>a</sup>	Preoperative			Follow-up				p-value <sup>b</sup>	p-value <sup>c</sup>	p-value <sup>d</sup>
	A	B	C	A	B	C	A		B	C	A	B	C					
MCP II	4	17	4	21	4	0	<0.001	0	18	5	9	12	2	0.008	0.164	0.001		
MCP III	4	17	4	22	3	0	<0.001	2	16	4	7	13	2	0.038	0.578	<0.001		
MCP IV	8	8	5	19	2	0	0.001	3	12	4	13	5	1	0.001	0.368	0.079		
MCP V	6	7	7	19	1	0	0.001	4	10	6	11	8	1	0.003	0.862	0.004		

A=no palmar subluxation B=palmar subluxation C=luxation

<sup>a</sup> A comparison before vs. after Swanson arthroplasty

<sup>b</sup> A comparison before vs. after PLDLA arthroplasty

<sup>c</sup> A comparison of preoperative values between Swanson and PLDLA

<sup>d</sup> A comparison of follow-up values between Swanson and PLDLA

preoperative arc of motion was 51° and 41° for the Swanson and PLDLA implants respectively, and the corresponding postoperative arc of motion was 53° and 51°. Subjective outcome was excellent or good in 17 (65 %) patients in the Swanson group and in 20 (77 %) patients in the PLDLA group.

Correction of ulnar drift was statistically significant in both groups postoperatively. In the PLDLA group ulnar deviations were preoperatively vs postoperatively 13° vs 2°, 26° vs 8°, 32° vs 7° and 41° vs 10° in the MCP II, III, IV and V joints, and in the Swanson group 12° vs 3°, 21° vs 5°, 26° vs 5° and 34° vs 6°. There was no statistical difference pre- or postoperatively between the study groups. Pain relief was good in both groups. Median VAS score decreased from 37 to 5 in the Swanson group, and from 40 to 6 in the PLDLA group. The postoperative improvement was statistically significant in both groups but the difference between groups was not significant.

Power grip strength improved significantly in both Swanson (from 9.7 kg to 11.4 kg, p=0.01) and PLDLA groups (from 9.4 kg to 11.7 kg, p=0.016). No statistical significance was found between the groups. Now were there any statistically significant differences in postoperative functional grip assessments (Tip pinch, Precision grip, Cylinder grip, Transverse volar grip) between the groups. Box and Block dexterity test change was statistically significant in the PLDLA group (from 59 to 66, p=0.001), but not in the Swanson group (from 60 to 64, p=0.136).

Radiologically 12 (10%) Swanson implants were broken and perforation of the phalangeal cortex was noted in two fingers at final follow-up.

### 5.3 Trapeziometacarpal joint (Study III)

The clinical outcome of TMC joint interposition arthroplasty using PLDLA was comparable to that in tendon interposition arthroplasty. One year after the operation, the function VAS was significantly better in the PLDLA implant group ( $p=0.03$ ), but no difference was found at three-month or two-year follow-ups. The median pain VAS decreased from 41.6 preoperatively to 9.4 in the PLDLA group, and from 31.5 to 22 in the tendon interposition group with no statistically significant differences between the methods.

Comparison between the two groups revealed no statistically significant differences in the functional tests range of motion (Table 6). However, there was a tendency for better active range of motion in the PLDLA group at final follow-up. Actually, in the tendon interposition group TMC joint palmar abduction, MCP I flexion and IP I extension assessments deteriorated from preoperative values.

One year after surgery, median power grip strength and tip pinch strength were significantly improved in the PLDLA group from 15.6 kg to 19.3 kg ( $p=0.01$ ) and from 3.4 kg to 4.0 kg ( $P=0.008$ ). Two years after surgery, median power grip strength deteriorated 16.4 kg in the PLDLA group. In the tendon interposition group the power grip improved from 10.6 kg to 12.4 kg at two-year follow-up. However, there was no statistically significant difference between the groups. At two-year follow-up, the Box and Block test improved significantly in the PLDLA group (from 55 to 61,  $p=0.02$ ), whereas in the tendon group there was no change (65,  $p=0.94$ ). Like the Box and Block test, there were no significant differences between the study groups in pinch grip, jug lift, glass lift or knife and fork tests.

Table 6.

Operated thumb active range of motion (ROM) tests preoperatively and two years after PLDLA ( $n=17$ ) or tendon interposition arthroplasty ( $n=12$ ).

Active ROM	PLDLA			Tendon				
	Preoperative	2-year	$p_{1,b}$	Preoperative	2-year	$p_{2,b}$	$p_{3,b}$	$p_{4,b}$
TMC radial abduction <sup>a</sup>	42.2°	54.1°	0.26	40.4°	41.3°	0.91	0.77	0.40
TMC palmar abduction <sup>a</sup>	34.4°	37.7°	0.53	42.5°	31.3°	0.35	0.15	0.49
MCP I extension <sup>a</sup>	3.2°	11.7°	0.47	6.3°	11.3°	0.40	0.65	0.99
MCP I flexion <sup>a</sup>	39.1°	44.0°	0.81	30.4°	18.8°	0.30	0.23	0.051
IP I extension <sup>a</sup>	5.6°	5.6°	0.90	13.8°	5.0°	0.13	0.23	0.48
IP I flexion <sup>a</sup>	58.5°	57.8°	0.83	48.3°	58.8°	0.20	0.20	0.83

<sup>a</sup>mean active ROM <sup>b</sup> $p_1$  and  $p_2$ : comparison between preoperative and two-year results within group;  $p_3$  and  $p_4$ : comparison between preoperative and two-year results between groups.

There were no wound infections or other complications during follow-up. The PLDLA interposition arthroplasty group had no foreign body reaction or abnormal swelling. Radiologically only a minor osteolysis was detected in the bone structures around the PLDLA implant.

#### 5.4 Revision MCP arthroplasty with PLDLA and bone grafting (Study IV)

Revision MCP arthroplasty using PLDLA interposition implants and bone packing provided satisfactory pain relief. The mean pain VAS was 12.3 (0–53) at final follow-up. Five (33%) patients had no pain and 8 (53%) patients rated pain minimal (VAS less than 27). Incorporation of the grafted bone was complete in radiographic analysis to the diaphyseal portion of the host metacarpal and phalangeal bones in 30 of the 36 joints. However, a concave resorption occurred in all periarticular areas and was already apparent at one-year follow-up (Figure 11). This may have occurred as a result of insufficient blood supply or foreign body reaction caused by the PLDLA implant.

Functional results were generally poor. At average seven-year follow-up limited flexion was the most common clinical finding in active ROM examination (Table 7). Before revision surgery the average flexion was (MCP II, III, IV, V) 66°, 78°, 78°, 70° and postoperatively 55°, 57°, 53°, 45° at mean seven years follow-up. Statistically significant deterioration was seen in MCP II active flexion ( $P=0.03$ ).

Figure 11.  
X-ray seven years after PLDLA implant arthroplasty and bone packing. The bone grafts are integrated, but typical concave bone resorptions are seen in the operated MCP II–V joints.



Table 7.

Operated MCP joints active range of motion (ROM) before revision, at one-year and at mean seven-year follow-up using PLDLA implant and bone grafting.

Active ROM	Before revision (n=52 joints)	At 1 year (n=52 joints)	At mean 7 years (n=36 joints)	p <sup>b</sup>
Extension lag				
MCP II <sup>a</sup>	10° (0-30)	3° (0-10)	9° (0-30)	0.28
MCP III <sup>a</sup>	14° (0-30)	10° (0-30)	13° (-10-40)	0.69
MCP IV <sup>a</sup>	4° (-20-25)	9° (0-25)	14° (-5-45)	0.90
MCP V <sup>a</sup>	5° (0-10)	6° (0-15)	10° (-10-45)	0.94
Flexion				
MCP II <sup>a</sup>	66° (60-80)	56° (40-80)	55° (40-75)	0.03
MCP III <sup>a</sup>	78° (60-85)	61° (40-90)	57° (40-85)	0.23
MCP IV <sup>a</sup>	74° (60-85)	64° (40-90)	53° (30-75)	0.20
MCP V <sup>a</sup>	70° (50-85)	64° (50-90)	45° (-5-75)	0.51

<sup>a</sup>mean active ROM (range); negative value indicates hyperextension.

<sup>b</sup>oneway-ANOVA comparing ROM before revision, at 1 year and at 7 years after MCP revision.

The mean preoperative ulnar deviations were (MCP II, III, IV, V) 10°, 12°, 16°, 16°. At one-year follow-up the mean ulnar deviation was 5°, 6°, 10°, 13°. The correction of ulnar was well sustained and the mean ulnar deviations were in MCP II 4°, MCP III 10°, MCP IV 14° and MCP V 13° at final follow-up. Volar displacement of the proximal phalanges occurred in 24 out of the 36 joints (67 %). Complete dislocation was seen in seven joints. In one juvenile rheumatoid arthritis patient, all four revised MCP joints were completely dislocated at final follow-up (Figure 12). Recurrent volar displacement had already occurred in 33 out of the 52 joints (63 %) at one-year follow-up.

Subjective outcome was after PLDLA implant arthroplasty and bone packing was not good at mean seven-year follow-up. There was only one excellent outcome in a patient with a single-MCP revision at the final follow-up. Three patients considered the result to be good, all having undergone a single or MCP II revision. Six patients considered the outcome satisfactory and five patients considered the outcome poor.

Figure 12.  
At eighth-year follow-up. All four MCP joints were completely volarly dislocated.



## 6 DISCUSSION

### 6.1 PLDLA implant in lesser MTP joints

RA commonly affects the forefoot causing metatarsalgia, hallux valgus, and deformities of the lesser toes. The key factor in the reconstruction of a rheumatoid forefoot is the achievement of stable realignment of the first ray. Arthrodesis of the MTP I increases weight-bearing along the medial column of the foot, minimizes stress on the lesser MTP joints, and protects the relocated plantar fat pad (Coughlin, 2000). Optimal positioning of a fusion in MTP I is important and is quite difficult to achieve. Our study complications rate was high: four superficial wound infections in MTP I after arthrodesis (17.4 %), one delayed wound healing (4.3 %) and five pseudarthrosis (21.7 %) of the fused MTP I joints were recorded. In the literature, the incidence of nonunion in the setting of MTP I arthrodesis for RA ranges from 0% to 26% (Mann and Thompson, 1984; Mann and Schakel, 1995; Vandeputte et al., 1999; Coughlin, 2000; Gröndal et al., 2005; Kadambande et al., 2007). The good results are probably related to both the technique of preparation of the MTP I joint and the stability of internal fixation. Cannulated cupshaped reamers are useful to prepare the phalangeal and metatarsal surfaces for arthrodesis. The use of reamers will also prevent the shortening of the first ray, because the length of the first ray should be equal to or slightly (two to four millimeters) greater than that of the second ray (Coughlin, 2000). The optimal position of arthrodesis is performed with the MTP I joint in 15 to 20 degrees of valgus, 20 to 30 degrees of dorsiflexion (in relation to the first metatarsal shaft), and neutral rotation (Beauchamp et al., 1984; Mann and Thompson, 1984; Hämäläinen and Raunio, 1997; Coughlin, 2000; Kadambande et al., 2007). Nowadays it is recommended in fixation to use crossed lag screw(s) with or without a dorsal plate construct or a large diameter axial screw (Coughlin, 2000; Kadambande et al., 2007; Jeng and Campbell, 2008).

Various surgical procedures have been described to correct the lesser MTP joints of the rheumatoid patients. Several techniques for lesser MTP joint preservation in rheumatoid forefoot reconstruction have been reported in the literature and mostly involved distal osteotomies of the distal metatarsals. However, resection of the metatarsal heads is an established procedure for the management of rheumatic forefoot deformations. In this procedure, a recurrence of lateral deviation of the lesser toes and painful plantar keratosis remain a challenging problem for the treatment of these patients. Our hypothesis was that the use of a PLDLA interposition arthroplasty could improve the results of metatarsal head resections: it ensures the formation of fibrous tissue and preserves better the length of the rays and inhibits the bony healing between the resected bone ends. In our study, the follow-up time



was short and primary outcome did not differ from that of the original method. However, no ossification occurred in the implant group, which might improve the patient contentment in the long term. Also there was no increase in complications with respect to the novel method and no reoperations were done during the follow-up time.

## 6.2 PLDLA implant in primary and revision MCP arthroplasty

The typical destruction of MCP joints in RA results in palmar subluxation and ulnar drift (Ellison et al., 1971). Chronic synovitis at the MCP joints disrupts the ligamentous support and the radial stress on the fingers with pinch drives the fingers in the ulnar direction. Destruction of cartilage in the joint, destruction of the attachment of the radial collateral ligaments and distension of the ligaments exacerbate the malposition. A variety of surgical techniques have been developed in MCP joint surgery, but silicone arthroplasty is still the gold standard for MCP primary joint replacement. Although silicone arthroplasty causes unpredictable osteolysis, long-term studies have reported a recurrence of ulnar drift and loss of motion with time (Goldfarb and Stern, 2003; Trail et al., 2004; Parkkila et al., 2005b).

The bioresorbable interposition implant was developed to avoid the chronic foreign body evoked complications associated with silicone prosthesis. In Study II PLDLA interposition arthroplasty was compared to silicone Swanson arthroplasty in primary surgery at a mean follow-up of 2 years. The outcome improvement in clinical assessments was comparable in both groups, and no statistically significant differences were seen in final follow-up between the groups. However, subluxation or palmar dislocation was observed more frequently in the PLDLA group (44/84 joints, 52%) than in the Swanson group (10/91 joints, 11%). In revisions of failed silicone arthroplasty using PLDLA implants, palmar subluxation recurred in 33 out of 52 (63%) joints at one-year follow-up (Ikävalko et al., 2007). Honkanen et al. reported recurrent palmar subluxation in 21/54 (39%) joints at one-year and 53/80 (66%) joints at five-year follow-up after PLDLA implant interposition arthroplasty (Honkanen et al., 2003; 2009). The implications of recurrent palmar subluxation for the outcome of MCP arthroplasty are uncertain. One reason could be that the degradation of PLDLA implant is not optimal and the soft tissue support is not sufficient to support the MCP joint in palmar direction. The lower rate of subluxation in the Swanson group is probably due to the stems of the implant. Ulnar drift correction was achieved with a comparable outcome in both study groups.

Goldfarb and Stern reported at an average follow-up period of 14 years an implant fracture rate of 63% and that only 38% of patients were satisfied with hand function (Goldfarb and Stern, 2003). In our study 12 (10%) Swanson implants were broken in radiological analysis at mean two-year follow-up and perforation of the phalangeal cortex was noted in two fingers. The absence of implant fractures and intramedullary osteolysis were advantages of the PLDLA implant.

The outcome after revision MCP arthroplasty using PLDLA interposition implants and bone packing in patients with failed MCP arthroplasties and severe osteolysis provided satisfactory pain relief in most patients, but the functional results were generally poor. All these study patients had severe soft tissue deficiencies, including missing or only rudimentary collateral ligaments and the joint capsules and extensor mechanisms were stretched. The collateral ligaments were reconstructed through the bone holes with absorbable sutures. When the sutures were absorbed or cut through the bone there was no collateral support and palmar displacement occurred. If collateral ligaments and other soft tissue support are lost, none of the available implants or PLDLA interposition arthroplasty can stabilize the MCP joint.

In the literature there is no consensus about the indications for revision surgery, and it is generally accepted that a prosthesis fracture is not an indication for revision in the absence of other symptoms. Only a few series have addressed revision silicone MCP arthroplasties (Ferlic et al., 1975; Beckenbaugh et al., 1976; Wilson et al., 1993; Kirschenbaum et al., 1993; Hansraj et al., 1997; Trail et al., 2004; Burgess et al., 2007). In general, these studies have reported poor objective results, but pain relief in most patients. Re-revision rates have varied from 2.1% to 26.5%. In these studies no significant change was detected in the ROMs. In addition, there was a high implant fracture rate (34%). These studies, like ours, showed that the soft tissues are more critical to long-term stability and function than the implant.

### 6.3 PLDLA implant in trapeziometacarpal joint

Numerous techniques have been described in the literature to correct the affected TMC joint (Swanson, 1972b; de la Caffinière and Aucouturier, 1979; Braun, 1985; Cooney et al., 1987; Glickel et al., 1992; de Smet et al., 2004), but most of the studies concern osteoarthritis patients. Only a few studies address the reconstruction of rheumatoid TMC joint. Arthrodesis of the TMC joint is rarely indicated in RA, because the distal joints of the thumb are usually abnormal and may require subsequent fusion (Nalebuff 1984, Terrono et al. 1990). Tendon interposition arthroplasty is commonly used for the surgical management of arthritis of the TMC joint (Burton and Pellegrini, 1986). Tendon interposition arthroplasty is a reliable method for TMC reconstruction, but it can lead to imbalance of the wrist in patients with mobile radiocarpal joints. Sometimes tenosynovitis erupts due to the use of tendon (or half the tendon) transplants in the reconstruction.

In this thesis the clinical and subjective outcomes after PLDLA joint interposition arthroplasty were comparable to those of tendon interposition arthroplasty. The pain relief was good in both groups. One year after the operation, the function VAS was significantly better in the PLDLA implant group ( $p=0.03$ ), but no difference was found at three-months or two-year follow-up. There was a tendency for slightly superior active range of motion in the PLDLA group compared to the tendon group at final follow-up, but statistically no significant differences between groups were seen.

The Artelon (Artimplant AB, Sweden) is synthesized from a degradable polyurethaneurea for use in TMC joint osteoarthritis. The degradation process takes place by hydrolysis over approximately 6 years (Gretzer et al., 2003) with 50% of the initial mass of the Artelon material remaining permanently at the implant site. With respect to the pilot study, good pain relief and superior results in terms of pinch strength were reported compared to tendon arthroplasty for the treatment of TMC joint osteoarthritis (Nilsson et al. 2005). A larger randomized, controlled trial involved 109 patients (72 Artelon TMC spacer and 37 tendon interposition arthroplasty) followed up for one year (Nilsson et al., 2010). The Artelon TMC spacer showed no superior results compared to tendon interposition arthroplasty. Swelling and pain were more common in the Artelon group and 6 implants were removed because of such symptoms. Thereafter several studies were published concerning complications with the use of the Artelon spacer in TMC osteoarthritis comprising inflammation, osteolysis, and persistent pain (Choung and Tan, 2008; Giuffrida et al, 2009; Robinson and Muir 2011).

There were no wound infections or other complications during follow-up in our study. The PLDLA interposition arthroplasty group had no foreign body reaction or abnormal swelling. Radiologically only minor osteolysis was detected in the bone structures around the PLDLA implant.

Surgery with the PLDLA implant is tissue-preserving, as it conserves most of the trapezium and does not require tendon harvest. The surgical procedure is easier to perform than with the tendon interposition technique. In our small series the PLDLA implant interposition arthroplasty worked as well as tendon interposition at short-time follow-up. However, further studies with larger patient series and longer follow-ups are needed before this method can be widely recommended.

## 6.4 PLDLA implant interposition possibilities in the future

The experimental small joint arthroplasty model in minipigs showed that PLDLA interposition arthroplasty could be successfully used to engineer fibrous tissue joints in situ. The structure of the PLDLA implant was almost completely disintegrated and replaced by dense fibrous connective tissue at 3 years (Waris et al., 2008). No accumulations of lymphocytes, implying an immune-inflammatory process, were seen in in situ, clinical, histological or immunohistological studies on PLDLA implants (Sedrakyan et al., 2006; Waris et al. 2008). In this thesis the outcome of the novel PLDLA implant in the treatment of rheumatoid hand MCP joints and TMC joint or the lesser MTP joints was comparable overall with that of the standard operation in these joints. However, at an average 24 months follow-up, more palmar dislocation was observed in the PLDLA (52 %) group vs. Swanson (11 %) group. This was alarming, and must be closely evaluated in future.

Bioabsorbable joint interposition implants may be improved by developing the implant design. In future, one possibility to develop a bioabsorbable interposition implant will be by use of surface modification of the interposition implant, like bioactive molecules, growth factors, cytokine or seeded cells like chondrocytes (Sedrakyan et al., 2006).

Extending the use of bioresorbable implant to other joints of the hand and feet, like MTP I and IP I in the foot or PIP joints in the hand, is a debatable issue. The suitability of the implant in these joints cannot be taken for granted. Development in implant design and larger series are needed and additional scientific work is called for.

## 7 CONCLUSIONS

The biocompatibility of a PLDLA implant interposition arthroplasty was good in the lesser metatarsal head arthroplasties at one-year follow-up. The subjective and objective outcomes of PLDLA implant interposition arthroplasties were comparable to those of conventional lesser metatarsal head resection arthroplasties. No ossification, however, occurred in the implant group, which might improve the patient contentment (I).

The outcome of improvements in clinical assessments was comparable in the PLDLA and Swanson groups. At average 24 months of follow-up, more palmar dislocation was observed in the PLDLA (52 %) group vs. Swanson (11 %) group. This worried us and these hands must carefully be followed up for longer (II).

Bioabsorbable PLDLA interposition arthroplasty also works well as a tendon interposition in the TMC joint. Surgery with PLDLA implant is tissue preserving and the method does not require tendon harvest. No complications, such as foreign body reactions, were detected with the use of this novel PLDLA interposition method. However, the follow-up time was only two years and the study group 17 patients (III).

The outcome after revision MCP arthroplasty using PLDLA interposition implants and bone packing in patients with failed MCP arthroplasties and severe osteolysis provided satisfactory pain relief for most patients, but the functional results were generally poor. The main problem in revision MCP arthroplasty seems to be the loss of collateral ligaments and other soft tissues. Reconstruction is difficult or even impossible in many cases. The novel PLDLA interposition implant cannot stabilize the MCP joint in severe cases and malalignment will soon return (IV).

## 8 SUMMARY IN FINNISH

Nivelreuma ja muut tulehdukselliset nivelsairaudet aiheuttavat kipua, nivelten turvotusta ja virheasentoja huonontaan siten elämän laatua. Nivelreuma aiheuttaa usein vaurioita käden, ranteen ja etujalkaterän niveliin. Tekonivelleikkausten tulokset suurissa nivelissä, kuten lonkassa ja polvessa, ovat varsin hyviä reumapotilailla, mutta pikku nivelissä, kuten rystysnivelissä tulokset ovat vaihtelevia. Rystysnivelten silikoniproteeseista ensimmäinen julkaisu on vuodelta 1966. Silikoniproteesit ovat säilyttäneet asemansa reumapotilailla rystysnivelten leikkauksissa vuosikymmeniä. Silikoniproteeseilla tehtyjen rystysnivelleikkausten tulokset kuitenkin huononevat ajan kuluessa johtaen liikelaajuuksien huononemiseen, virheasentojen palautumiseen, silikonisynoviittiin, osteolyysiin sekä proteesien hajoamiseen. Bioresorboituva poly-L/D-lactide 96/4 (PLDLA) implantti on uusi vaihtoehto pienten nivelten rekonstruktioihin.

Väitöskirjatutkimuksen tarkoituksena oli: 1. Selvittää PLDLA implantin biosopivuutta ja kliinistä soveltuvuutta päkiänivelissä lyhyellä aikavälillä. Verrata PLDLA implantin tuloksia perinteiseen päkiänivelten resektiioleikkaukseen. 2. Verrata PLDLA implantin kliinisiä ja radiologisia tuloksia rystysnivelissä Swanson silikonitekonivelleikkauksiin reumapotilailla. 3. Verrata PLDLA implanttia peukalon trapetziometakarpaali (TMC) nivelessä jänneinterpositioleikkaukseen. 4. Selvittää pitkäaikaistuloksia käytettäessä PLDLA implanttia ja luusiirteitä silikoniproteesi uusintaleikkauksissa.

Väitöskirja koostuu neljästä osajulkaisusta: Päkiätutkimuksessa (I) 35 potilasta randomoitiin joko PLDLA (16 potilasta) tai perinteiseen päkiänivelten resektioryhmään (19 potilasta). Tutkimuksessa tulokset arvioitiin vuoden kohdalla leikkauksesta. Randoimoidussa kliinisessä tutkimuksessa (II) verrattiin PLDLA implanttia (27 kättä, 84 niveltä) Swanson silikoniproteesiin (26 kättä, 91 niveltä) keskimäärin 24 kk kuluttua leikkauksesta. Kliinisessä prospektiivisessä tutkimuksessa (III) verrattiin PLDLA implanttia (17 niveltä) perinteiseen jänneinterpositioon TMC nivelessä (12 niveltä) kahden vuoden kuluttua leikkauksesta. Viimeisessä osatyössä (IV) selvitettiin rystysnivelissä PLDLA implantin ja luupakkauksen menestymistä silikonitekonivel uusintaleikkauksissa keskimäärin 7 vuoden kuluttua leikkauksesta.

Vuoden kohdalla leikkauksesta ei todettu tilastollisesti merkitseviä eroja PLDLA implantti ja perinteisen päkiänivelten resektioryhmien välillä AOFAS, kipu VAS tai toiminnallisessa VAS tuloksissa. Komplikaatioiden määrässä ei ollut eroja ryhmien välillä, mutta PLDLA ryhmän potilailla ei todettu seurannassa päkiänivelten luutumisia (tutkimus 1). Tutkimuksessa II kliiniset tulokset paranivat sekä PLDLA että Swanson ryhmissä vastaa-

vanlaisesti. PLDLA ryhmässä kuitenkin todettiin palmaarista dislokaatiota 44/84 (52 %) nivelessä ja Swanson ryhmässä 10/91 (11 %) nivelessä keskimäärin 24 kk kuluttua leikkauksesta. Tutkimuksessa III kliinisissä tuloksissa (kipu ja toiminnalliset pisteet, toiminnalliset testit ja liikelajuudet) ei ollut tilastollisia eroja PLDLA ja jänneinterpositio ryhmien välillä. Kuitenkin teknisesti PLDLA implanttileikkaus todettiin helpommaksi toteuttaa kuin jänneinterpositio leikkaus. Tutkimuksessa IV PLDLA implanttia ja luunpakkausta käytettäessä saavutettiin hyväksyttävä kivun lievitys, mutta toiminnallisesti tulokset olivat yleisesti huonoja. Radiologisesti todettiin luusiirteiden inkorporaatio metakarpaaliluiden ja proksimaaliphalangien varsialueilla 30/36 tapauksessa.

Tässä väitöskirjassa esitetyt tulokset PLDLA implanttia käytettäessä ovat vertailukelpoisia perinteisiin leikkausmenetelmiin verrattuna päkiänivelissä, rystysnivelten primaari-leikkauksissa sekä peukalon TMC nivelen leikkauksessa. Jotta PLDLA implanttia voidaan kuitenkin suositella laajempaan käyttöön, tarvitaan laajempia potilassarjoja ja pidempää seuranta-aikaa.

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## 11 ORIGINAL PUBLICATIONS I–IV

- I Tiihonen R, Skyttä ET, Ikävalko M, Kaarela K, Belt E (2010). Comparison of bioreplaceable interposition arthroplasty with metatarsal head resection of the rheumatoid forefoot. *Foot Ank Int* 31(6):505–510.
- II Honkanen PB, Tiihonen R, Skyttä ET, Ikävalko M, Lehto MU, Konttinen YT (2010). Bioreconstructive poly-L/D-lactide implant compared with Swanson prosthesis in metacarpophalangeal joint arthroplasty in rheumatoid patients: a randomized clinical trial. *J Hand Surg Eur* 35(9):746–753.
- III Tiihonen R, Skyttä ET, Kaarela K, Ikävalko M, Belt EA (2012). Reconstruction of the Trapeziometacarpal Joint in Inflammatory Joint Disease Using Autologous Tendon or Poly-L/D-Lactic Acid Implant Interposition. A Prospective Randomized Trial. *J Plast Surg Hand Surg* 46:113–119.
- IV Tiihonen R, Honkanen PB, Ikävalko M, Belt EA, Skyttä ET (2012). The mean seven years' results of the use of poly-L/D-lactic acid (PLDLA) interposition implant and bone packing in revision metacarpophalangeal arthroplasty: a prospective cohort study. *Scand J Surg* 101(4):265–270.



## Comparison of Bioreplaceable Interposition Arthroplasty with Metatarsal Head Resection of the Rheumatoid Forefoot

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### ABSTRACT

**Background:** Interposition arthroplasty with bioreplaceable poly-L/D-lactic acid (PLDLA) implants has been studied in Finland with promising results in reconstruction of the rheumatoid hand. We evaluated this material in a series of patients with rheumatoid forefoot deformities. **Materials and Methods:** Thirty-five patients were randomized to either PLDLA metatarsophalangeal joint interposition arthroplasty group (16 patients) or to conventional metatarsal head resection group (19 patients). **Results:** At 3 months after surgery, the function VAS was significantly better in the control group ( $p = 0.003$ ). The difference disappeared by 12 months. Otherwise, comparison between the two groups did not reveal any statistically significant differences in the AOFAS scores or the pain VAS at 3 or 12 months. **Conclusion:** Early results after PLDLA interposition arthroplasty of metatarsophalangeal joints were not as promising as previously reported with rheumatoid metacarpophalangeal reconstruction.

### Level of Evidence: II, Prospective Randomized Trial

**Key Words:** Rheumatoid Arthritis; Forefoot; Interposition Arthroplasty; Poly-L/D-Lactid; Metatarsal Head Resection

### INTRODUCTION

A multitude of surgical procedures, ranging from amputation of the toes to excision of the metatarsal heads and proximal phalanges have been advocated in the treatment of rheumatoid forefoot. In 1912 Hoffmann published a significant work on the reconstruction of the rheumatoid forefoot.<sup>11</sup> Many modifications to his technique have been

described;<sup>3,6,15</sup> however, the basic principle is still the same: removal of all the prominent metatarsal heads.

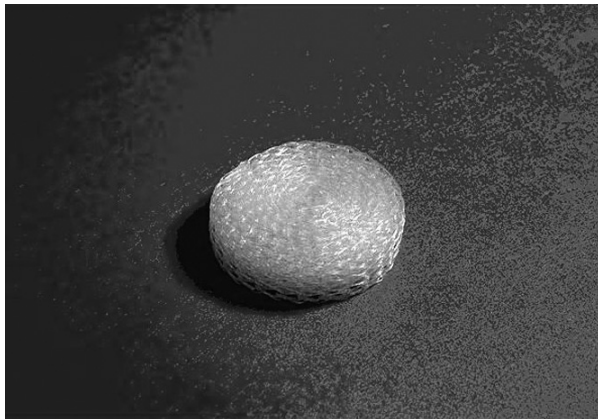
Many authors recommend fusion as a standard treatment for rheumatoid arthritis (RA) of the MTP joints.<sup>4,5,19,20,22</sup> The hallux retains a more reliable weightbearing position after an arthrodesis, and incidence of metatarsalgia and plantar callosities is decreased. However, postoperative gait analysis indicates that toe-off in the later part of the stance phase begins earlier than normal.<sup>10</sup>

In 1994 the concept of the bioreconstructive joint arthroplasty was developed by performing metacarpophalangeal joint revision arthroplasty using commercially available bioabsorbable Vicryl® and Ethisorb® fleeces folded into small, rectangular scaffolds.<sup>12</sup> The scaffold was intended to be a temporary support to be filled by the in-growing tissue of the host. The experiment was based on the so-called Vainio method, in which the extensor tendon is folded between the ends of the metacarpus and phalanx.<sup>22</sup> The resorption time of these bioabsorbable materials proved too short for sufficient fibrous tissue growth. The early results, however, were promising and a scaffold consisting of a porous bioabsorbable poly-L/D-lactic acid copolymer with an L:D monomer ratio of 96:4 (PLDLA) was developed in collaboration with Tampere University Hospital and Tampere Technical University in Finland.<sup>16</sup> The implant is pliable and the half-life of the tensile strength of PLDLA 96/4 filament is approximately 13 weeks (Figure 1).<sup>12</sup> It was designed to retain its shape long enough to allow the in-growth of host tissue and be replaced with fibrous tissue in approximately 2 to 3 years.

PLDLA scaffolds have been used with promising results in primary and revision arthroplasties of metacarpophalangeal joints<sup>12-14</sup> so we have applied the use of PLDLA implants to MTP joints. The primary hypothesis was that treatment with a bioreplaceable implant performs as well as the standard treatment during the short-term (1 year) followup in MTP joints. A secondary aim of this study was to evaluate long-term (up to 5 years) performance of the PLDLA implants. The hypothesis was that the investigational device would improve long-term results and better patient satisfaction. In

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**Fig. 1:** The PLDLA Implant.

this article we present the 1-year results of a prospective, randomized clinical study of the use of PLDLA implants in the MTP II-V joints.

## PATIENTS AND METHODS

### Patients

From November 2004 to March 2007, 36 patients (31 women and five men, 18 left and 18 right feet) with RA refractory to conservative treatment signed a written informed consent and were randomized into a study protocol to assess the results of lesser MTP joint surgery at our institute. One patient in PLDLA implant group who had only two MTP joints resected, was omitted from the analysis. The average age of patients at the time of surgery was 59 (range, 47 to 74) years. The average duration of disease at the time of surgery was 17 (range, 3 to 40) years. In 23 of the operated feet, first metatarsophalangeal joint (MTP I) arthrodesis was performed simultaneously. In two of the remaining 13 feet, the MTP I was successfully fused in an earlier operation and the rest of the first rays were asymptomatic and well aligned.

### Operative technique

The procedure was done under tourniquet, and the implant group was routinely given a single dose antibiotic prophylaxis of cefuroxime 3000 mg. If needed, the great toe arthrodesis was done through a slightly curved medial longitudinal approach. After the synovectomy, the articular surface of the phalanx and metatarsal head were resected with an oscillating saw (Figure 2). The arthrodesis was fixed with two or more Kirschner wires immediately, or in selected cases after correction of lateral toe deformities. A single transverse dorsal incision was used to excise the metatarsal heads from the second to the fifth. Exposure of the joints was done between extensor tendons. The contracted capsule and collateral ligaments were released. In severe deformities extensor tendon lengthenings were done. The second and third metatarsal shafts were osteomized at about equal

length, and no cut projected beyond a gently curving line of resection, which ended at the fifth metatarsal. The interphalangeal joints were corrected by manipulation. In the study group, PLDLA scaffold (thickness 4 mm, diameter 12 or 14 mm), provided by Tampere University of Technology, Finland, was inserted in the joint space and fixed with a Kirschner wire from the tip of the toe into the metatarsal bone. In the control group, the lesser toes were fixed in the same way. Extensor tendons when lengthened were reapproximated with resorbable sutures and skin closure with nonresorbable sutures.

### Postoperative Management

Bedrest was prescribed for 1 to 2 days with the feet elevated followed by weightbearing in a surgical sandal. Sutures were removed after 2 weeks and the lesser metatarsal pins after 3 weeks and mobilization was encouraged. In the patients with MTP I arthrodesis, a support under the heel was used for 6 to 8 weeks. Patients were evaluated in the clinic at 6 weeks, 3 months, and 1 year postoperatively. Postoperative radiographs were performed on the first or second postoperative day, at the 3-month and 1-year followups.

### Outcome measures

The clinical signs and symptoms were measured according to the American Orthopedic Foot Association scoring system (AOFAS).<sup>17</sup> In addition to AOFAS scores, pain and function were assessed using 100 mm visual analogue scales with 0 mm being “no pain” or “no functional impairment” and 100 mm being “worst possible pain” or “all functions impaired,” respectively. The function was also determined by gait ability with four multiple choices: “normal,” “slight limp,” “severe limp,” and “unable to walk.”

### Radiographs and radiographic score

Image material for this study consisted of weightbearing AP and lateral foot radiographs, 24 × 30 cm, obtained at a focus-film distance of 1.15 m. All radiographs were obtained with a consistent technique: the patients were standing on both legs with the medial aspect of the feet parallel and with their knees in full extension. Radiographs were assessed according to the Larsen grades from 0 to 5.<sup>18</sup> However, in the presence of subluxation or dislocation, the joint was assessed as grade 5.

### Ethical aspects

The study was approved by the Research Board of our institute. Patients gave their written informed consent after oral and written information. The study was conducted in accordance with the Helsinki Declaration.

### Statistical analysis

The descriptive data are presented as mean and 95% confidence interval. Differences between groups were analyzed using independent samples T-test, and considered statistically significant if the *p* values were less than 0.05 in a



**Fig. 2:** A 59-year-old woman with rheumatoid arthritis. Radiographs preoperatively (A), postoperatively after PLDLA implant operation (B), 3 months after (C), and 1 year after (D) PLDLA interposition arthroplasty of the metatarsophalangeal joints.

two-tailed test. We used SPSS 17.0 statistical software (SPSS Inc, Chicago, IL) for the statistical analyses.

## RESULTS

Before surgery, there were no differences between the groups in parameters (Table 1). Four of the MTP I joints had been fused earlier. Of the remaining 171 MTP joints, 51 had Larsen grade 3 or higher. The mean preoperative AOFAS

scores were 42.6 and 43.8 in the study and control groups, respectively. At 1-year followup, the mean AOFAS scores were 77.8 and 78.0. Complete results are presented in Table 2. Radiographically resected joint spaces were preserved without significant bone changes at all followups.

In both groups, all the clinical parameters improved (Table 2 and 3). At 3 months after surgery, the function VAS was significantly better in the control group ( $p = 0.003$ ). The difference disappeared by 12 months. Otherwise, comparison

**Table 1:** Preoperative Demographic, Clinical, and Radiographic Characteristics of 35 Patients with RA

	PLDLA interposition arthroplasty (n = 16)	Metatarsal head resection arthroplasty (n = 19)	<i>p</i>
Number of women	14	16	—
Mean age at the time of operation, years (range)	58.8 (47–74)	59.9 (49–73)	0.45
Mean duration of disease at the time of surgery, years	17.4	16.7	0.81
Operated foot, right / left	9 / 7	9 / 10	—
Number of feet with previous ipsilateral foot surgery†	5	4	—
Subjective ability to walk with the affected foot, number of patients			
Normal	3	4	—
Slight limp	12	14	—
Severe limp	1	1	—
Unable to walk	0	0	—
Mean preoperative pain VAS‡ (95% CI)	47.3 (33.8–60.7)	53.3 (41.6–65.1)	0.48
Mean preoperative function VAS‡ (95% CI)	53.7 (41.7–65.7)	51.8 (38.4–65.2)	0.83
Mean preoperative AOFAS score (95% CI)	42.6 (34.7–50.5)	43.8 (37.9–49.7)	0.79
Mean worst preoperative lesser metatarsophalangeal joint Larsen grade (95% CI)	3.6 (2.7–4.5)	3.8 (3.0–4.6)	0.11

†, Includes MTP I synovectomies, fusions, MTP II-V synovectomies and toe PIP joint resections arthroplasties. ‡, VAS 0 = “no pain” or “no functional impairment”; VAS 100 = “worst possible pain” or “all functions impaired”.

between the two groups did not reveal any statistically significant differences in the AOFAS scores or the pain VAS at 3 or 12 months. In the control group two patients had post-operatively spontaneous ossification in the MTP II-III and MTP II-V joints, respectively. Walking ability was improved in both groups (Table 3).

A superficial dorsal wound infection developed in two feet (one in both groups). MTP I superficial wound infections were recorded in four and one had delayed wound healing. All infections resolved with antibiotic therapy. Fibrous non-union of the fused MTP I joints was recorded in 5 of 23 (21.7 %). No reoperations were done during the followup period.

## DISCUSSION

Short-term followup of metatarsophalangeal PLDLA interposition arthroplasty for rheumatoid forefoot deformities revealed no significant differences when compared to the conventional metatarsal head resection in our randomized

study. At 12 months after surgery, both the study and the control group were similar with respect to complications and clinical results.

Rheumatoid arthritis involves commonly the forefoot, causing metatarsalgia, hallux valgus, and deformities of the lesser toes.<sup>5</sup> Resection of the metatarsal heads is an established procedure for the management of rheumatic forefoot deformities. However, a recurrence of lateral deviation of the lesser toes and painful plantar keratosis remain a challenging problem for the treatment of these patients. In the literature the good to excellent success rates vary from 51 % to 93 %.<sup>7,21,24</sup>

Resection of the metatarsal heads is a well known procedure that can be used to get the resection line slightly curved to avoid recurrence of callosities and problems with footwear. Resection arthroplasty may yield reasonable results with difficult rheumatoid feet, but should be performed only with consideration in minor foot problems.<sup>8</sup> It is important to avoid solitary resection of individual metatarsal heads.<sup>2</sup> Alternative procedures include metatarsal osteotomies with shortening of the metatarsals.<sup>1,9</sup> In this

**Table 2:** AOFAS score, Pain and Function Preoperatively, After 3 Months, and 1 Year

	PLDLA interposition arthroplasty (n = 16)	Metatarsal head resection arthroplasty (n = 19)	p
Pain VAS‡ (95% CI)			
Preoperative	44.3 (29.1–59.4)	51.2 (37.5–65.0)	0.48
3-months postoperative	25.0 (12.3–37.8)	22.5 (7.3–37.7)	0.46
1-year postoperative	16.4 (5.0–27.8)	9.2 (0.3–18.0)	0.18
Function VAS‡ (95% CI)			
Preoperative	52.7 (38.1–67.3)	45.2 (28.4–62.0)	0.83
3-months postoperative	37.9 (25.2–50.7)	14.8 (2.0–27.5)	0.003
1-year postoperative	19.2 (3.5–34.8)	19.5 (4.6–34.3)	0.63
AOFAS score (95% CI)			
Preoperative	42.2 (34.8–49.7)	43.8 (37.9–49.7)	0.73
3-months postoperative	74.7 (66.1–83.3)	79.1 (70.3–87.9)	0.58
1-year postoperative	77.8 (69.2–86.4)	78.0 (71.9–84.2)	0.35

‡, VAS 0 = “no pain” or “no functional impairment; VAS 100 = “worst possible pain” or “all functions impaired”.

**Table 3:** Walking Ability Preoperatively, 3 Months and 1 Year After PLDLA Interposition Arthroplasty or Metatarsal Head Resection Arthroplasty

Gait ability	PLDLA interposition arthroplasty (n = 16)	Metatarsal head resection arthroplasty (n = 19)
Preoperative		
Normal	3	4
Slight limp	12	14
Severe limp	1	1
3-months postoperative		
Normal	7	11
Slight limp	8	7
Severe limp	0	0
1-year postoperative		
Normal	10	11
Slight limp	5	5
Severe limp	0	0

series we had over 20% delayed union rate in MTP I fusion. Currently, we use screws or plates more frequently and have noted better outcomes.

Previous experimental studies have showed that the PLDLA scaffold could be successfully used to result in fibrous joint arthroplasties.<sup>12,13,14,25</sup> The scaffold is initially invaded by vascularized and cell-rich loose connective tissue. Later, the loose connective tissue inside the joint scaffold construct matures to dense fibrous connective tissue with an abundant collagen framework.<sup>25</sup> Preliminary clinical results have been reported concerning the use of a joint scaffold for the correction and reconstruction of the metacarpophalangeal joint in RA. The outcome has been favorable with

good pain relief, decrease in ulnar deviation and reasonable range of motion. Volar subluxation recurred in only 6% of cases.<sup>12</sup> The results were comparable with the use of silicone implants without the risk of implant fracture or any signs of periprosthetic osteolysis. The use of the joint scaffold enabled intramedullary bone packing.<sup>14</sup>

Originally the use of a joint scaffold was concentrated on the metacarpophalangeal joints. This design could be used in other small joint arthroplasties including the first carpometacarpal and proximal interphalangeal joints. It possibly could be used in the first metatarsophalangeal joint in correction of hallux valgus or hallux rigidus to enhance the outcome. Our hypothesis was that the use of

a PLDLA interposition implant could improve the results of metatarsal head resections since it facilitates the formation of fibrous tissue and better preserves the length of the rays and inhibits bony healing between the resected bone ends.

The primary outcome did not differ from that of the original method. This was disappointing and not expected. However, these are the only preliminary results of a minor series. We believe larger series with longer followup are needed. The implant is not yet commercially available but will be in European Union countries towards the end of 2010. The price of the implant has not been set but is expected to be approximately equivalent to the metacarpophalangeal arthroplasty silastic implants.

## CONCLUSION

This study did not show any evidence that the bioreplaceable interposition arthroplasty had any benefit over metatarsal resection alone. No ossification, however, occurred in the implant group, which might improve the outcome. There was no increase in complications with respect to the novel method.

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ORIGINAL ARTICLE

## Reconstruction of the trapeziometacarpal joint in inflammatory joint disease using interposition of autologous tendon or poly-L-D-lactic acid implants: A prospective clinical trial

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### Abstract

Interposition arthroplasty with bioreplaceable poly-L-D-lactic acid (PLDLA) implants has yielded promising results in reconstruction of rheumatoid hands. In this prospective clinical study we compared the PLDLA implant arthroplasty ( $n = 17$ ) with that of tendon interposition ( $n = 12$ ) for destruction of the trapeziometacarpal joint in arthritic patients. There was no significant difference between the two groups preoperatively. At one-year follow-up, the mean pain and function scores were 5 and 13 in the PLDLA group, and 19 and 43 in the tendon interposition group, respectively. At one-year follow-up the visual analogue scale (VAS) for function of the PLDLA group differed significantly from that of the tendon interposition group ( $p = 0.03$ ). This difference was not found at three months postoperatively, and disappeared again at two-year follow-up. Otherwise, no significant difference was found between the groups in the pain or function scores, functional tests, or range of movement. Bioreplaceable interposition arthroplasty works at least as well as tendon interposition. The operation is easier.

**Key Words:** *Trapeziometacarpal joint, poly-L/D-lactic acid (PLDLA) implant, tendon interposition, inflammatory joint disease*

### Introduction

Two thirds of patients with rheumatoid arthritis (RA) of long duration have involvement of the thumb with erosions and destruction of the trapeziometacarpal (TM) joint that cause deformities of the thumb, particularly swan-neck [1–5]. TM arthrodesis is rarely indicated in RA, as the distal joints of the thumb are often involved, and require fusion at a later date [3]. Implant arthroplasty of the TM joint has often resulted in failures as a result of wear and breakage of the implant, instability, osteolysis, and loosening, despite various designs and materials [6,7]. Currently, tendon interposition arthroplasty is the gold standard of surgical management of symptomatic end-stage arthritis of the TM joint [8,9].

A porous bioabsorbable poly-L-D-lactic acid (PLDLA) interposition implant (Figure 1) designed to retain its shape long enough to allow the ingrowth of host tissue and then gradually be replaced with fibrous tissue in about 2–3 years [10], has yielded promising results in both primary and revision arthroplasties of the metacarpophalangeal (MCP) joint [11–13]. The use of such an implant in interposition arthroplasty of the TM joint avoids the morbidity associated with harvest of tendons, particularly in cases with mobile radiocarpal joints. Various different sizes of implant assure sufficient interposition with cortical bone coverage to avoid bony contact with resected surfaces.

In this prospective clinical study we present our one-year and two-year results of the use of PLDLA

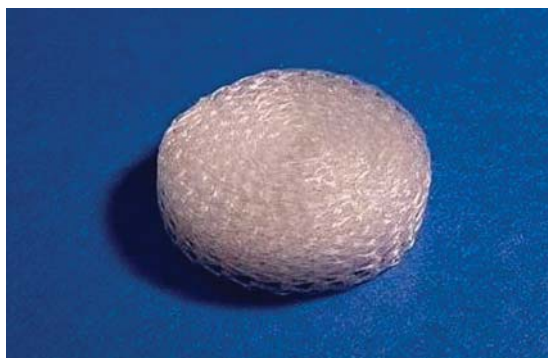


Figure 1. The PLDLA implant.

implants in TM joints. Our hypothesis was that treatment with bioreplaceable implant are at least as good as tendon interposition during the follow-up period.

### Patients and methods

Thirty-five patients with symptomatic end-stage inflammatory arthritis of the TM joint signed written informed consent and were randomised to undergo either tendon interposition or PLDLA implant interposition arthroplasty. The study was approved by the hospital district ethics committee. During data analysis, 6 patients were found not to have inflammatory arthritis and were excluded. Twenty-nine thumbs in 29 patients (27 women and 2 men) were included in this study (Table I).

### Surgical technique

The operation was done under tourniquet control through a dorsoradial longitudinal incision. A single dose of antibiotic prophylaxis, cefuroxime 3000 mg, was given routinely. Branches of the superficial radial nerve and the deep branch of the radial artery were preserved. The capsule was released and opened dorsoradially. Approximately 4–6 mm of the bone was resected from the metacarpal base, perpendicular to its longitudinal axis, allowing full abduction with the interposition. Synovectomy was done, and all osteophytes were revised. The cartilage surface of the trapezium was resected using a courette or an oscillating saw. PLDLA implants (thickness 4 mm, diameter 12 or 14 mm), were provided by Tampere University of Technology, Finland. The implant was inserted into the joint space and fixed with an absorbable suture through holes in the bone to the resected surface of trapezium. The thumb was placed in a suitable position (in sufficient abduction) and a Kirschner wire (K wire) was inserted to stabilise the first ray. The capsule was reconstructed carefully. In the tendon interposition group the flexor carpi radialis was favoured because of the size and strength of the tendon. In cases without wrist fusion half of the tendon was used. If the flexor carpi tendon was not available, the extensor carpi radialis could also be used. The tendon graft was prepared and trimmed through a separate incision. Proximally the tendon

Table I. Preoperative demographic, clinical, and radiographic characteristics of the 29 hands (29 patients). Data are number of patients except where otherwise stated.

	PLDLA interposition arthroplasty ( <i>n</i> = 17)	Tendon interposition arthroplasty ( <i>n</i> = 12)	<i>p</i> value
Women	17	10	-
Mean (range) age at the time of operation (years)	57.9 (31–73)	53.5 (30–76)	0.38
Diagnosis			
Rheumatoid arthritis	10	8	-
Other inflammatory arthritis	7	4	-
Mean duration of disease at the time of operation (years)	22.2	22.2	0.99
Operated hand, right/left	5/ 12	8/ 4	-
Operated hand, dominant/non-dominant	8/ 9	8/ 4	-
Thumb deformity			
None	7	5	-
Boutonnière	7	6	-
Swan neck	1	1	-
Mean preoperative pain VAS <sup>†</sup> (95% CI)	41.6 (28.8 to 54.4)	31.5 (15.5 to 47.5)	0.25
Mean preoperative function VAS <sup>†</sup> (95% CI)	51.0 (40.2 to 61.8)	63.0 (43.8 to 82.2)	0.21
Mean TM I Larsen grade <sup>‡</sup>	3.0	4.2	-

<sup>†</sup>VAS 0 = “no pain” or “no functional impairment”; VAS 100 = “worst possible pain” or “all functions impaired”. <sup>‡</sup>Larsen grading according to Belt et al. [14]. Only rheumatoid arthritis patients assessed with Larsen grade.

was released from the muscle while the tendon's distal insertion was kept intact. The tendon was tunneled into the resected space and a knot was tied to fill the space. Resections were similar with PLDLA interposition. A part of the tendon could be used to reinforce the dorsoradial capsule. A K wire was used to stabilise the joint in the same way as for PLDLA.

#### *Postoperative management*

In both groups, a temporary cast was used for immobilisation for 2–3 days. After that the cast was replaced with an individually-fitted plastic splint for 3–4 weeks. The external K wire was removed after 3 weeks and range of movement exercises were allowed to begin after 4–6 weeks using a special training splint.

#### *Clinical evaluation*

The patients were evaluated clinically at six weeks, three months, one year, and two years postoperatively. Pain and function were assessed using 100 mm visual analogue scales (VAS) with 0 mm being “no pain” or “no functional impairment” and 100 mm being “worst possible pain” or “all functions impaired”, respectively. Grip strength was measured with a Jamar dynamometer and the thumb tip and key pinch were measured with a pinch grip meter. Active radial and palmar abductions of the TM joint were measured. Clinical examination included also evaluation of range of movement in the first metacarpophalangeal (MCP I) and interphalangeal (IP) joints.

The function of the hand was evaluated by an occupational therapist. Pinch grip of the tip was assessed for each finger with a wooden bead 10 mm in diameter. The patient was asked to pick up the bead from the table using the tip of each finger in turn. A therapist did simulated ADL tests, such as ability to handle a knife and fork (precision grip) and a jug with capacity of 0.5 L (cylinder and transverse volar grip). In the precision grip assessment the patient used a knife and fork to cut a piece of resistive exercise putty (Rolyan A497-280, diameter 7.5 cm). In the cylinder grip test the patient was asked to decant 1 dl water from a jug to a glass (diameter 6–7 cm), and decanting the water back to the jug was assessed as a transverse palmar grip. These functional grips were graded as normal, adapted, or not able, the adapted meaning to be able to do the task but not in the requested way.

#### *Radiographic evaluation*

The preoperative radiographic destruction of the TM joint was classified in patients with RA using the

modified Larsen method [14]. Other patients with inflammatory arthritis were reviewed to enable staging of the disease at the TM joint and also other areas of the hand. Postoperative radiographs were taken on the first or second postoperative day, and at the three month, one-year, and two-year follow-ups. Joint space was measured in all patients and bony changes, particularly with respect to PLDLA implant joints, were evaluated.

#### *Statistical analyses*

The Mann-Whitney test was used to assess the significance of differences between groups for variables with a skewed distribution. Between preoperative and postoperative skewed variables in one group the Wilcoxon test was used, whereas the paired Student *t*-test was used for normally distributed variables in this setting. The significance of differences between groups for normally distributed variables was assessed using the independent samples *t* test. Differences in classified categorical variables were assessed by cross tables with Fisher's exact test, when appropriate. Results are given as the mean (range) unless otherwise indicated.

## **Results**

Before the operation, there were no significant differences between the groups (Table I). Among the operated hands, 4/17 of the wrists in the PLDLA group and 4/12 in the control group had been partially or totally fused earlier. In addition, 5/17 of the MCP I and 2/17 of thumb IP joints in the PLDLA group, and 5/12 and 2/12 in the control group, respectively, were fused earlier or at the time of the operation on the TM. The mean preoperative pain and function VAS scores were 42 and 51, and 32 and 63 in the study and control groups, respectively. At one-year follow-up, the mean scores were 5 and 13, and 19 and 43. Complete results are presented in Table II. Resected joint spaces were preserved radiographically without major bone changes at all follow-up visits.

In both groups, most of the clinical variables had improved (Tables II, III(a–c), IV) during the follow-up. One year after the operation, the function VAS was significantly better in the PLDLA group ( $p = 0.03$ ). This difference was not found at 3 months after the operation, and disappeared again by 2 years. Otherwise, comparison between the two groups did not reveal any significant differences in the pain or function scores, functional tests, or ROM.

During the follow-up time no wound infections developed and no reoperations were required.

Table II. Pain and function preoperatively, three months, one year, and two years postoperatively.

	PLDLA interposition arthroplasty ( <i>n</i> = 17)	Tendon interposition arthroplasty ( <i>n</i> = 12)	<i>p</i> value
Pain VAS <sup>‡</sup> (95% CI)			
Preoperative	41.6 (28.8 to 54.4)	31.5 (15.5 to 47.5)	0.25
3 months postoperative	10.9 (0 to 22.3)	13.2 (3.8 to 22.5)	0.10
1 year postoperative	4.7 (0 to 9.5)	18.7 (0 to 48.1)	0.36
2 years postoperative	9.4 (0 to 20.5)	22.0 (3.2 to 40.8)	0.14
Function VAS <sup>‡</sup> (95% CI)			
Preoperative	51.0 (40.2 to 61.8)	63.0 (43.8 to 82.2)	0.21
3 months postoperative	33.2 (14.5 to 55.9)	38.7 (13.3 to 64.0)	0.73
1 year postoperative	13.0 (0 to 26.0)	42.7 (14.1 to 71.2)	0.03
2 years postoperative	25.3 (3.1 to 47.4)	48.2 (19.8 to 76.6)	0.14

<sup>‡</sup>VAS 0 = “no pain” or “no functional impairment; VAS 100 = “worst possible pain” or “all functions impaired”.

## Discussion

In RA with hand involvement, arthritis of the TM joint is a common and important source of functional loss and disability. Various surgical options for reconstruction of the TM are available, but the long-term results of implant arthroplasty have been unsatisfactory. Tendon interposition arthroplasty is a reliable method for reconstruction of the TM, but short and long term morbidity related to tendon harvest limits its usefulness, particularly in patients with mobile radiocarpal joints. The present study shows that using the biodegradable PLDLA implant reconstruction of the TM can be equivalent or even a little better than those of tendon interposition arthroplasty.

The PLDLA interposition arthroplasty aims to avoid the foreign body, prosthesis, or fracture complications associated with the use of a silicone implant, or total arthroplasty [15,16]. The procedure is easier than the tendon interposition. No tendon transplants are needed, and so no imbalance or tenosynovitis are expected as with tendon (or half the tendon) transplants.

At the one-year follow-up the function VAS was significantly better in the PLDLA group ( $p = 0.03$ ). This difference was not found 3 months after the operation, and disappeared again by two years. At the one-year and two-year follow-up the mean pain VAS scores were 4.7 and 9.4 in the PLDLA group, and 18.7 and 22 in the tendon group, respectively. This difference was not significant, but shows that the pain relief was at least equivalent to that after tendon interposition. There was no difference between the groups as far as active range of movement of the thumb was concerned (Table IV).

The PLDLA implant is initially invaded by vascularised and cell-rich loose connective tissue. In histological studies the ingrowth of connective tissue occurred in subcutaneous tissue in rats after three weeks [17]. Later the loose connective tissue inside the scaffold construct of the joint has matured to dense fibrous connective tissue with an abundant collagen framework. An experimental study in minipigs showed that in 3 years the structure of the PLDLA implant was almost completely disintegrated and replaced by dense connective tissue [18].

Previous clinical studies have reported favourable results for pain relief, decrease of ulnar deviation, and reasonable range of movement of the MCP I joint in RA [11–13]. The results were comparable with those after the use of silicone implants without the risk of fracture or any signs of periprosthetic osteolysis. As an advantage, the use of the PLDLA implant enabled the intramedullary bone packing in cases that required revision [13].

The synthetic allograft Artelon (Artimplant AB, Sweden) has been used in the TM joint for the treatment of osteoarthritis. Artelon Spacer is synthesised from a degradable polyurethaneurea and it takes about 6 years before the material is hydrolysed. Nilsson et al. [19] reported 10 patients who were given the Artelon spacer and were compared with 5 others given classical methods. At the three-year follow-up the Artelon Spacer group were all pain-free and those in the spacer group had significantly better pinch strength. Jörheim et al. [20] compared the short-term efficacy of the Artelon TM implant with that of total trapeziectomy and using interposition arthroplasty abductor pollicis longus (APL) tendon suspension in TM osteoarthritis. Two patients who had had Artelon had revision operations, and the short-term outcomes were not

Table III(a). Mean grip strength tests preoperatively, one year, and two years after PLDLA or tendon interposition arthroplasty.

Functional ability	PLDLA interposition arthroplasty				Tendon interposition arthroplasty								
	Preoperative	1-year	p1 <sup>b</sup>	2-year	p2 <sup>b</sup>	Preoperative	1-year	p3 <sup>b</sup>	2-year	p4 <sup>b</sup>	p5 <sup>b</sup>	p6 <sup>b</sup>	p7 <sup>b</sup>
Power grip strength <sup>a</sup>	15.6 (12.4–18.8)	19.3 (14.6–24.0)	0.01	16.2 (10.1–22.3)	0.86	10.6 (2.9–18.3)	13.9 (9.7–18.2)	0.15	12.4 (6.3–18.6)	0.58	0.55	0.14	0.59
Tip pinch strength <sup>a</sup>	3.4 (2.3–4.5)	4.0 (2.9–5.1)	0.008	4.0 (2.7–5.2)	0.13	3.5 (1.7–5.3)	3.9 (1.7–6.1)	0.21	4.4 (1.8–7.0)	0.28	0.41	0.53	0.66
Key pinch strength <sup>a</sup>	4.2 (3.2–5.2)	4.3 (3.4–5.3)	0.30	4.2 (3.3–5.2)	0.86	3.6 (1.3–5.9)	4.2 (2.6–5.8)	0.048	4.4 (2.5–6.3)	0.18	0.43	0.44	0.80

<sup>a</sup>mean grip strength, kg (95% CI). <sup>b</sup>p<sub>1</sub> and p<sub>3</sub>: comparison between preoperative and one-year results within group; p<sub>2</sub> and p<sub>4</sub>: comparison between preoperative and two-year results within group; p<sub>5</sub>, p<sub>6</sub> and p<sub>7</sub>: preoperative, one and two-year result comparison between groups, respectively.

Table III(b). Pinch grip ability preoperatively, one year, and two years after PLDLA or tendon interposition arthroplasty. There were no statistically significant differences within or between groups at any time point.

Functional ability	PLDLA interposition arthroplasty						Tendon interposition arthroplasty											
	Preoperative			1-year			2-year			Preoperative			1-year			2-year		
Pinch grip <sup>a</sup>	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Index finger	13	4	0	15	1	0	11	2	0	10	1	0	9	1	0	3	2	0
Middle finger	14	3	0	12	4	0	11	2	0	10	1	0	8	2	0	3	2	1
Ring finger	14	2	1	13	3	0	11	1	1	10	0	1	6	4	0	4	1	1
Little finger	14	1	2	13	2	1	10	0	3	9	0	2	6	3	1	4	1	1

<sup>a</sup>A = normal; B = adapted; C = not able.

Table III(c). Results of functional tests preoperatively, one year, and two years after PLDLA or tendon interposition arthroplasty.

Functional ability	PLDLA interposition arthroplasty						Tendon interposition arthroplasty																										
	Preoperative		1-year		p1 <sup>c</sup>		2-year		p2 <sup>c</sup>		Preoperative		1-year		p3 <sup>c</sup>		2-year		p4 <sup>c</sup>		p5 <sup>c</sup>		p6 <sup>c</sup>		p7 <sup>c</sup>								
	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C						
Jug lift test <sup>a</sup>	10	4	3	11	3	2	0.84	10	3	0	0.27	6	4	1	5	3	0	0.68	4	2	0	0.72	0.69	0.43	0.64								
Glass lift test <sup>a</sup>	12	2	3	13	2	1	0.60	10	3	0	0.24	8	2	1	5	2	2	0.66	4	0	2	0.30	0.76	0.54	0.56								
Knife and fork test <sup>a</sup>	13	4	0	11	5	0	0.62	9	4	0	0.66	8	3	0	7	3	0	0.89	4	2	0	0.79	0.82	0.95	0.91								
Box and Block test <sup>b</sup>	54.6 (47.5–61.6)						60.6 (55.7–65.6)	0.016	61.4 (53.4–69.3)						0.02	65.0 (58.4–71.6)						66.0 (53.2–78.8)	0.88	65.4 (49.2–81.6)						0.94	0.15	0.40	0.92

<sup>a</sup>A = normal; B = adapted; C = not able. <sup>b</sup>Mean number of blocks transported (95% CI) <sup>c</sup>p<sub>1</sub> and p<sub>2</sub>: comparison between preoperative and one-year results within group; p<sub>2</sub> and p<sub>4</sub>: comparison between preoperative and two-year results within group; p<sub>5</sub>, p<sub>6</sub> and p<sub>7</sub>: preoperative, one and two-year result comparison between groups, respectively.

Table IV. Operated thumb active range of movement (ROM) tests preoperatively, one year, and two years after PLDLA or tendon interposition arthroplasty. There were no statistically significant differences within or between groups at any time point.

Active ROM <sup>a</sup>	PLDLA interposition arthroplasty						Tendon interposition arthroplasty					
	Preoperative		1-year		2-year		Preoperative		1-year		2-year	
	Preoperative	1-year	2-year	Preoperative	1-year	2-year	Preoperative	1-year	2-year	Preoperative	1-year	2-year
TM radial abduction	42.2° (35.2°–49.3°)	45.8° (38.3°–53.4°)	54.1° (35.2°–73.1°)	40.4° (28.5°–52.3°)	43.3° (29.8°–56.9°)	41.3° (26.2°–56.3°)						
TM palmar abduction	34.4° (27.9°–40.9°)	39.2° (29.6°–48.7°)	37.7° (28.8°–46.5°)	42.5° (31.8°–53.2°)	42.5° (32.7°–52.3°)	31.3° (10.3°–52.2°)						
MCP I extension	3.2° (-7.2°–13.6°)	5.4° (-4.0°–14.9°)	11.7° (-7.1°–30.4°)	6.3° (-1.1°–13.6°)	2.5° (-1.9°–6.9°)	11.3° (-24.6°–47.1°)						
MCP I flexion	39.1° (28.8°–49.4°)	35.0° (23.0°–47.0°)	44.0° (32.2°–55.8°)	30.4° (19.9°–41.0°)	17.5° (-5.7°–40.7°)	18.8° (-15.9°–53.4°)						
IP I extension	5.6° (0.1°–11.1°)	6.3° (0.2°–12.3°)	5.6° (-2.2°–13.4°)	13.8° (-1.8°–29.3°)	6.7° (-2.5°–15.9°)	5.0° (-23.3°–33.3°)						
IP I flexion	58.5° (49.8°–67.3°)	61.3° (52.6°–69.9°)	57.8° (50.3°–65.3°)	48.3° (32.8°–63.9°)	60.8° (40.3°–81.4°)	58.8° (12.6°–104.9°)						

<sup>a</sup>mean active ROM (95% CI).

better in this study. There have also been case reports of the Artelon spacer causing a foreign body reaction [21,22]. The PLDLA interposition arthroplasty group had no foreign body reactions or abnormal swelling.

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## THE MEAN SEVEN YEARS' RESULTS OF THE USE OF POLY-L/D-LACTIC ACID (PLDLA) INTERPOSITION IMPLANT AND BONE PACKING IN REVISION METACARPOPHALANGEAL ARTHROPLASTY: A PROSPECTIVE COHORT STUDY

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### ABSTRACT

**Background and Aims:** Revision arthroplasty of metacarpophalangeal (MCP) joints in chronic inflammatory arthritis patients after silicone implants is challenging due of severe bone loss and soft tissue deficiencies. The aim of this study was to evaluate the outcome of revision MCP arthroplasty using poly-L/D-lactic acid 96:4 (PLDLA) interposition implant and morcelised allograft or autograft bone packing in patients with failed MCP arthroplasties and severe osteolysis.

**Material and Methods:** The study group consisted of 15 patients (15 hands and 36 joints) at a mean follow-up of seven years (range 5–10 years). The radiographs were reviewed for osteolysis and incorporation of the grafted bone. The clinical assessments included active range of motion, evaluation of pain, subjective outcome and assessment of grip power.

**Results:** PLDLA interposition arthroplasty combined with bone packing provided satisfactory pain relief, but function was limited. Radiographic analysis showed complete incorporation of the grafted bone to the diaphyseal portion of the host metacarpal and phalangeal bones in 30 of the 36 joints. All the patients had very limited grip strength, both on the operated and non-operated side.

**Conclusions:** Due to soft tissue deficiencies long-term function and alignment problems can not be resolved with PLDLA interposition implant.

Key words: Poly-L/D-lactic acid implant; silicone implant; revision metacarpophalangeal arthroplasty; bone packing; osteolysis; inflammatory arthritis

### INTRODUCTION

Several studies have shown that metacarpophalangeal (MCP) joint arthroplasties using a silicone implant provide good pain relief, improve the arc of

motion and correct the deformity (1, 2) though the results deteriorate over time (3, 4). In long-term follow-up studies after silicone arthroplasty of the MCP joints, osteolysis, subsidence and fracture of the implants frequently occur (3, 5, 6). One radiological study showed osteolysis around 89% of the implants (1). Revision MCP arthroplasty after silicone implants is challenging because of severe bone loss and soft tissue deficiencies. The use of a silicone implant in revision MCP arthroplasty is limited by poor survival (7).

A porous, bioabsorbable poly-L/D-lactic acid 96:4 (PLDLA) interposition implant is designed to retain

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its shape long enough to allow the ingrowth of host tissue and then gradually be replaced with fibrous tissue in approximately 2–3 years (8–10). This implant has yielded promising results in both primary and revision MCP arthroplasties (11–14).

In this study, we report the mean seven years follow-up results of revision MCP arthroplasty using PLDLA interposition implants and morcelised allograft or autograft bone packing in patients with failed MCP arthroplasties and severe osteolysis. The one-year results were published earlier (14).

## MATERIAL AND METHODS

This study was approved by the Päijät-Häme Central Hospital district ethical committee, Lahti, Finland. Initially, 18 patients (21 hands; 52 joints) with chronic inflammatory arthritis (all women, all right-handed), previous MCP arthroplasty and severe osteolysis at one or several MCP joints, were recruited to this prospective, non-randomized study. There were three dropout patients (6 hands, 16 joints). One patient of the dropouts had both hands operated (all together eight MCP joints) and two patients had one hand (all together five MCP joints). In two of all analyzed patients both hands were operated, but only one was controlled and thus two hands were dropped out (all together three MCP joints), leaving 15 patients (15 hands; 36 joints) to be assessed. All patients signed a written informed consent and were operated on using morcelised allograft or autograft bone packing and PLDLA interposition implants (Bionx Implants Inc., Tampere, Finland; currently Scaffdex, Tampere, Finland) during the 2001 to 2003 time period at the Rheumatism Foundation Hospital (Heinola, Finland). The mean follow-up time was seven years (range 5–10 years). In addition, one patient had recently suffered a forearm fracture and due to an over-elbow plaster cast she was unable to perform some of the functional tests.

The indication for all of the MCP joint revision arthroplasties was a combination of pain, dysfunction and bone loss. 10 patients had rheumatoid factor positive rheumatoid arthritis (RA), three had juvenile idiopathic arthritis, one had psoriatic arthropathy and one had rheumatoid factor negative chronic polyarthritis.

The procedure was done under tourniquet, and the patient was given routinely single dose antibiotic prophylaxis of cefuroxime 3000 mg. Joint was approached by longitudinal incision adjacent to extensor tendon. Old prostheses were removed. Scar and granulation tissue was removed from inside the metacarpal and phalangeal bones. Volar plate was released, when necessary. Ulnar intrinsic tendons and abductor digiti minimi tendon were always checked and released if not performed previously or if there was found tight scar tissue. Significant cortical bone perforations and periarticular cortical defects were recorded. Allograft bone (fresh frozen femoral heads or tibial/femoral cuts of non-rheumatoid patients) was morcelised to 2–3 mm chips which then were packed inside the bones leaving the juxta-articular portion empty at this stage. Two to three microburr holes were drilled to the distal dorsal aspect of the metacarpal bones. Collateral ligaments were tied with absorbable multi-filament 2–0 or 3–0 hold sutures for later tightening or reconstruction and the threads were passed through the burr holes. A PLDLA scaffold (thickness 4 mm, diameter 12 or 14 mm, provided by Tampere University of Technology (Tampere, Finland) was inserted in the joint space and fixed with a 1–0 absorbable suture passing through the burr holes and grabbing the volar plate adjacent to the base of the phalanx. At this stage the bone packing was completed up to the level of bone ends. After

bone packing the implant fixation suture was tightened and thereafter the collateral ligaments were tightened while balancing the finger alignment simultaneously. Suction drain was applied in revisions of all metacarpophalangeal joints, except not in cases with one or two revised metacarpophalangeal joints. Capsule closure was performed with 3–0 absorbable sutures and extensor tendon was centralized. Duplication or small resection of capsule was performed when necessary. Subcuticular closure with 4–0 absorbable sutures and skin closure with 4–0 non-absorbable sutures. Padded dressing supporting fingers towards the radial direction was used.

On second or third day after operation the fingers were supported with a rest splint. Patients were discharged and they returned to the ward at 10–14 days postoperatively in order to begin the range of motion exercises and dynamic splint. Splints were used for 3 months and the range of motion exercises were supervised by an occupational therapist in the ward and in outpatient follow-ups. Outpatient control visits were programmed at 6 weeks, 3 and 12 months postoperatively with radiographs taken before and after the operation and at 3, 12 and 24 months. The final control was done in this study at 5 to 10 years after revision operation.

The clinical assessments included active ROM measurement of the MCP joints, evaluation of pain and measurement of deformity of the MCP joints and assessment of grip power and functional tip pinch, precision and power grips. Active extension and flexion were measured from the dorsal surface using a goniometer. A visual analogue scale (VAS, 0–100) was used to evaluate pain. Palmar subluxation of the MP joints was measured from standardized supine oblique radiographs with fingers in maximal active extension, and it was graded as 0 = no subluxation, 1 = subluxation less than 50% of metacarpus thickness, 2 = subluxation more than 50% of metacarpus thickness, 3 = complete dislocation. Radiographs were assessed visually the incorporation of the bone grafts. The radiographic osteolysis changes were assigned of the metacarpal and the proximal phalangeal bones to four grades depending on the radiological cortical bone changes (15): Grade I: Osteolysis varying from a single clear line adjacent to the stem of the prosthesis to a larger, clear area which did not involve the bone cortex. Grade II: Osteolysis affecting the bone cortex to a maximum of one half of its thickness. Grade III: Osteolysis affecting the cortex to more than one half of its thickness but not perforating it. Grade IV: Osteolysis perforating the cortex.

Ulnar deviation was measured dorsally using a goniometer with the fingers in maximal active extension. Grip strength in both hands was measured using a Jamar dynamometer (Preston, Jackson, MI, USA) with the handle in position two. The best value of three consecutive measurements was recorded. Function of the hand was evaluated by an occupational therapist. Tip pinch grip was assessed for each finger with a wooden bead of diameter 10 mm: the patient was asked to pick up the bead from the table using tip pinch in each finger by turn. A therapist performed simulated ADL tests, such as ability to handle a knife and fork (precision grip) and a jug with capacity of 0.5 litres (cylinder and transverse volar grip). In the precision grip assessment the patient used a knife and fork to cut a piece of resistive exercise putty (Rolyan A497-280, diameter 7.5 cm). In the cylinder grip test the patient was asked to decant 1 dl water from a jug to a glass (diameter 6–7 cm), and decanting the water back to the jug was assessed as a transverse palmar grip. These functional grips were graded as normal, adapted or not able, the adapted meaning to be able to perform the task but not in the requested way. A timed Box and Block test was used to evaluate the dexterity of the hand (16). The Box and Block test result indicates



Fig. 1 (A–D). (A) Preoperative radiograph rheumatoid arthritis patients with severe osteolysis and broken silicone implants in all four MCP joints. In the metacarpal bones II–V osteolysis is assigned grade III. In the 2<sup>nd</sup> and 5<sup>th</sup> proximal phalanges osteolysis is staged grade III, 3<sup>rd</sup> and 4<sup>th</sup> proximal phalanges grade IV. (B) Postoperative radiograph after bone packing and PLDLA implant interposition arthroplasty. (C) After one-year postoperatively bone graft incorporation was good to the diaphyseal portion of the metacarpal and phalangeal bones, but typical periarticular bone absorption was noticed. (D) After seven years postoperatively.

TABLE 1

The osteolytic grades in metacarpals (n = 36) and proximal phalanges before MCP revision arthroplasty using bone grafting and PLDLA interposition implant.

	Grade of osteolysis <sup>a</sup>			
	I	II	III	IV
Metacarpal II (n = 12) <sup>b</sup>	0	1 (8%)	9 (75%)	2 (17%)
Proximal phalanx II	0	1 (8%)	6 (50%)	5 (42%)
Metacarpal III (n = 9) <sup>b</sup>	1 (11%)	0	7 (78%)	1 (11%)
Proximal phalanx III	1 (11%)	0	4 (44%)	4 (44%)
Metacarpal IV (n = 7) <sup>b</sup>	0	0	5 (71%)	2 (29%)
Proximal phalanx III	0	0	3 (43%)	4 (57%)
Metacarpal V (n = 8) <sup>b</sup>	0	2 (25%)	4 (50%)	2 (25%)
Proximal phalanx V	0	0	7 (88%)	1 (13%)

<sup>a</sup> Grade I: Osteolysis varying from a single clear line adjacent to the stem of the prosthesis to a larger, clear area which did not involve the bone cortex. Grade II: Osteolysis affecting the bone cortex to a maximum of one half of its thickness. Grade III: Osteolysis affecting the cortex to more than one half of its thickness but not perforating it. Grade IV: Osteolysis perforating the cortex.

<sup>b</sup> Number of patients.

the number of cubes transposed per 60 seconds. Patient satisfaction was assessed using a scale indicating excellent, good, satisfactory or poor outcome. Measurements were recorded by an occupational therapist and radiographs were analyzed by an orthopaedic surgeon.

The most descriptive data are presented as mean and (SD) or range. Statistical comparisons were performed using oneway-ANOVA. We used SPSS 17.0 statistical software (SPSS Inc, Chicago, Illinois, U.S.A.) for the statistical analyses.

## RESULTS

Radiographic analysis showed complete incorporation of the grafted bone to the diaphyseal portion of the host metacarpal and phalangeal bones in 30 of the 36 joints. At one-year follow-up complete incorporation in the metacarpal and phalangeal bones was 48/52. Grade III or IV osteolysis recorded in 32 (89%)

of the metacarpals and 34 (94%) of the proximal phalanges (Table 1). Grade I osteolytic changes were only one patient. This patient with single MCP joint silicone implant arthroplasty developed aggressive foreign body reaction against silicone implant, and PLDLA implant and bone packing was chosen to avoid recurrence even in the absence of severe bone loss.

The presence of self-reported pain was favourable and the pain was usually rated mild with mean pain being VAS 12.3 (range: 0–53). At the time of the interview, 13/15 (87%) of the patients had no (n = 5) or minimal pain (VAS less than 27). The patients with a 4-MCP revision had a tendency to have less pain compared to those with a single or 2-MCP revision but there was no statistical difference.

Limited flexion at average seven years after MCP revision arthroplasty was the most common clinical finding in active range of motion examination; detailed results are presented in Table 2. In the measurements made before the operation and at the clinical follow-up, both the active extension and flexion range of motion had a tendency to diminish. The worsening was statistically significant in MCP II active flexion, and almost reached significance in MCP III and IV flexion, despite the small number of patients.

All the patients had very limited grip strength at average seven years follow-up, both on the operated and non-operated side. The mean grip strength was 4.3 kg (range: 0–14) on the operated side (13 right and 2 left hands) and 5.9 kg (range: 0–26) on the non-operated side. Furthermore, only three (20%), five (33%) and two (13%) of patients could perform the power grip jug test, the power grip glass test or the precision grip test, with a normal grip. Results of other function tests are presented in Table 3.

Initially the overall patient satisfaction was good with 93% and 90% good or satisfactory results at three months and one-year, respectively. At the final follow-up, subjective outcome was excellent in one patient with a single-MCP revision. Three patients considered the result to be good, all having undergone a single or 2-MCP revision. Six patients consid-

TABLE 2

Operated MCP joint active range of motion (ROM) before and after MCP revision arthroplasty using bone grafting and PLDLA interposition implant.

Active ROM	Before revision (n = 52 joints)	At 3 months (n = 52 joints)	At 1 year (n = 52 joints)	At mean 7 years (n = 36 joints)	p <sup>b</sup>
Extension lag					
MCP II <sup>a</sup>	10° (0–30)	7° (0–30)	3° (0–10)	9° (0–30)	0.28
MCP III <sup>a</sup>	14° (0–30)	7° (0–15)	10° (0–30)	13° (–10–40)	0.69
MCP IV <sup>a</sup>	4° (–20–25)	1° (–10–10)	9° (0–25)	14° (–5–45)	0.90
MCP V <sup>a</sup>	5° (0–10)	0° (–10–10)	6° (0–15)	10° (–10–45)	0.94
Flexion					
MCP II <sup>a</sup>	66° (60–80)	69° (60–85)	56° (40–80)	55° (40–75)	0.03
MCP III <sup>a</sup>	78° (60–85)	71° (55–85)	61° (40–90)	57° (40–85)	0.23
MCP IV <sup>a</sup>	74° (60–85)	68° (50–85)	64° (40–90)	53° (30–75)	0.20
MCP V <sup>a</sup>	70° (50–85)	61° (30–80)	64° (50–90)	45° (–5–75)	0.51

<sup>a</sup> mean active ROM (range); negative value indicates hyperextension.

<sup>b</sup> oneway-ANOVA comparing ROM before revision, at 1 year and at 7 years after MCP revision.

TABLE 3

Operated hand (n = 15) power, precision, pinch grip and Block and Box tests at mean 7 years after MCP revision arthroplasty using bone grafting and PLDLA interposition implant.

	Normal grip	Adapted grip	Not able	No of blocks transported
Power grip				
Jug test <sup>a</sup>	3 (20%)	9 (60%)	3 (20%)	–
Glass test <sup>a</sup>	5 (33%)	6 (40%)	4 (27%)	–
Precision grip test <sup>a</sup>	2 (13%)	12 (80%)	1 (7%)	–
Pinch grip test				
Index finger <sup>a</sup>	6 (40%)	9 (60%)	–	–
Middle finger <sup>a</sup>	7 (47%)	6 (40%)	2 (13%)	–
Ring finger <sup>a</sup>	9 (60%)	4 (27%)	2 (13%)	–
Little finger <sup>a</sup>	8 (53%)	3 (20%)	4 (27%)	–
Box and Block test				
Operated hand <sup>b</sup>	–	–	–	57.1 (38–71)
Non-operated hand <sup>b</sup>	–	–	–	58.1 (30–70)

<sup>a</sup> number of patients capable of performing the test according to the grip (%).

<sup>b</sup> mean number of blocks transported during 60 seconds (range).

ered the outcome satisfactory and five patients the outcome poor.

Volar displacement of the proximal phalanges occurred in 24 of the 36 joints (67%). Complete dislocation was in 7 joints (table 4). In one juvenile rheumatoid arthritis patient, all four revised MCP joints were completely dislocated at mean seven years follow-up. Recurrent volar displacement occurred already in 33 of the 52 joints (63%) at one-year follow-up. The average ulnar deviation was in 2-MCP 4° (range: –35–25), 3-MCP 10° (0–20), 4-MCP 14° (5–20) and 5-MCP 13° (0–30) at final follow-up. At one-year follow-up ulnar deviation was 5–13° degrees with tendency to be larger towards the ulnar fingers.

No wound healing problems were encountered. Some patients suffered transitional loss of tactile sensation. Three patients required manipulation under regional anaesthesia at five, six and seven weeks after surgery, respectively, because of limited flexion movement in at least one of the fingers which had undergone surgery. In all three patients, the ranges of motion improved notably and were satisfactory at one year follow-up but deteriorated again corresponding to the common tendency.

One patient with severe dorsal defects in the second metacarpal bone underwent additional surgery to excise sharp residual volar osteophytes that were interfering with flexor tendon function in the tenosynovial sheath at eight months after the revision arthroplasty.

## DISCUSSION

Revision MCP arthroplasty using PLDLA interposition implant and bone packing in patients with failed MCP arthroplasty and severe osteolysis can prevent or reduce the rate of bone loss. Pain relief continues

TABLE 4

Number of operated joints (36 joints) presenting volar dislocation at mean 7 years after MCP revision arthroplasty using bone grafting and PLDLA interposition implant.

	Degree of volar dislocation <sup>a</sup>			
	0	1	2	3
MCP II (n = 12)	4	2	5	1
MCP III (n = 9)	4	1	2	2
MCP IV (n = 7)	1	4	0	2
MCP V (n = 8)	3	3	0	2

<sup>a</sup> measured from standardized supine oblique radiographs with fingers in maximal active extension; 0 = no dislocation; 1 = dislocation less than 50% of metacarpus thickness; 2 = dislocation more than 50% of metacarpus thickness; 3 = complete dislocation.

to be good at average seven years after revision but the initially acceptable functional results have a tendency to deteriorate.

Silicone arthroplasty is still the golden standard for MCP primary joint replacement. In a large study, 17 years' survivorship of silastic MCP implant arthroplasty has been 63% using revision or radiographic implant fracture as the end-point (6). In that study revision rate was low: 76 of 1336 implants; 39 implants (2.9%) were reoperated due to fractured stems. Study group concluded that radiographic implant fracture doesn't necessitate revision arthroplasty. There are only a few series concerning revision MCP arthroplasties (4, 17–20). Re-revision rates have varied from 2.1% to 26.5%. In these studies, reported implant fracture rates varied from 2.9% to 10.4%. Broken implants were only one reason to revision surgery, other causes included deformity, stiffness, malalignment and silicone synovitis. Parkkila et al have reported that fractured silicone implants are associated with osteolysis (5). Due to severe osteolysis, bone perforations and diverse soft tissue problems were encountered during revision surgery in our patients, a new silicone implant is not an ideal option in revision MCP arthroplasty. The PLDLA interposition arthroplasty aims to avoid the foreign body reaction, prosthesis wear or fracture complications associated with the use of silicone implant (10, 12, 13).

Revision MCP arthroplasty using a PLDLA implant interposition, provides a good pain relief. Initially good patient satisfaction declined during the follow-up; ultimately 75% of the patients considered the outcome satisfactory or poor. All the patients had very limited grip strength measurements at average seven years' follow-up, both on the operated and non-operated side. These patients had very severe rheumatoid disease and also the other hand was destroyed. Limited flexion was the most common clinical finding of active range of motion.

Volar displacement of the proximal phalanges occurred in 24 of the 36 joints (67%) and complete dislocation in seven joints. One patient had a complete dislocation of all four MCP joints and three patients had a complete volar displacement in one MCP joint. In the one-year results, volar displacement occurred

in 63% (33/52 joints). Ulnar deviation remained the same during follow-up. This study shows that majority of recurring of volar displacement and ulnar deviation occur during first year after revision operation. This trend is also evident in revision arthroplasties using silicone implants: pain relief is excellent but there is only minimal improvement in ulnar drift, a high rate of implant fracture (34%), and no change in arc of motion (7).

The main problem in revision MCP arthroplasty seems to be soft tissue reconstruction. If collateral ligaments and other soft tissue support are lost, none of the available implants or scaffolds can stabilize the MCP joint. All patients of our series presented severe soft tissue deficiencies, including missing or only rudimentary collateral ligaments. Also, the joint capsules and extensor mechanism were stretched and elongated. In revision operation the collateral ligaments were reconstructed through the bone holes with absorbable, multi-filament sutures. When sutures absorb there is no collateral support and volar displacement can occur. After this study, we have started to use non-absorbable instead of absorbable sutures to reconstruct collaterals. Surgical technique has also been altered to include resection of the prominent volar lip of the proximal phalanx, and the attachments of the ligaments are sacrificed. Non-absorbable sutures are passed through drill holes in both phalangeal and metacarpal bones. These sutures are tightened while balancing the finger alignment. We expect these amendments to provide a longer lasting primary support and in the long term diminish recurrence of ulnar deviation.

Incorporation of grafted bone was radiographically complete to the diaphyseal portion of the host metacarpal and phalangeal bones in 30 of the 36 joints. Periarticularly bone absorption was noticed already at one-year after operation. This may have occurred as a result of insufficient blood supply or foreign body reaction caused by the PLDLA interposition implant (14).

In conclusion, revision MCP arthroplasty using PLDLA interposition implants and bone packing provided good pain relief, but functional results were generally poor. This study showed that soft tissues are very critical to the function and alignment. Thus far, none of the available implants or PLDLA interposition arthroplasty can not stabilize the MCP joint in severe cases and malalignment will return soon.

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