

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

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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 (n = 17)	Tendon interposition arthroplasty (n = 12)	p 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 [†] (95% CI)	41.6 (28.8 to 54.4)	31.5 (15.5 to 47.5)	0.25
Mean preoperative function VAS [†] (95% CI)	51.0 (40.2 to 61.8)	63.0 (43.8 to 82.2)	0.21
Mean TM I Larsen grade [‡]	3.0	4.2	-

[†]VAS 0 = “no pain” or “no functional impairment”; VAS 100 = “worst possible pain” or “all functions impaired”. [‡]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 [‡] (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 [‡] (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

[‡]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		2-year		Preoperative		1-year		2-year								
	A	B	C	p1 ^b	2-year	p2 ^b	A	B	C	p3 ^b	2-year	p4 ^b	p5 ^b	p6 ^b	p7 ^b				
Power grip strength ^a	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 ^a	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 ^a	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

^amean grip strength, kg (95% CI). ^bp₁ and p₃: comparison between preoperative and one-year results within group; p₂ and p₄: comparison between preoperative and two-year results within group; p₅, p₆ and p₇: 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							
	A	B	C	A	B	C	A	B	C	A	B	C						
Pinch grip ^a	13	4	0	15	1	0	11	2	0	10	1	0	9	1	0	3	2	0
Index finger	14	3	0	12	4	0	11	2	0	10	1	0	8	2	0	3	2	1
Middle finger	14	2	1	13	3	0	11	1	1	10	0	1	6	4	0	4	1	1
Ring finger	14	1	2	13	2	1	10	0	3	9	0	2	6	3	1	4	1	1

^aA = 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 ^c		2-year		p2 ^c		Preoperative		1-year		p3 ^c		2-year		p4 ^c		p5 ^c		p6 ^c		p7 ^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	A	B
Jug lift test ^a	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 ^a	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 ^a	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 ^b	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	

^aA = normal; B = adapted; C = not able. ^bMean number of blocks transported (95% CI) ^cp₁ and p₃: comparison between preoperative and one-year results within group; p₂ and p₄: comparison between preoperative and two-year results within group; p₅, p₆ and p₇: 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 ^a	PLDLA interposition arthroplasty						Tendon interposition arthroplasty					
	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°)

^amean 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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