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A MIDTERM FOLLOW-UP STUDY OF BIORECONSTRUCTIVE POLYLACTIDE SCAFFOLD IMPLANTS IN METACARPOPHALANGEAL JOINT ARTHROPLASTY IN RHEUMATOID ARTHRITIS PATIENTS

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This paper presents the results of a prospective study of 80 metacarpophalangeal joint arthroplasties, in which biodegradable polylactide 96/4 copolymer scaffolds were used. Twenty-three rheumatoid arthritis patients were assessed at an average of 59 months after operation, which exceeds the resorption time of P(L/D)LA 96/4 according to animal experiments. Palmar subluxation exceeded half of the bone thickness in 39 joints before operation and in nine at the last follow-up. Ulnar deviation decreased from 25° to 5°, extension deficit from 32° to 15° and active flexion from 76° to 63°. The results are comparable with published data on silicone implant arthroplasties. Implant resorption did not induce any significant osteolysis in the medium term and the restoration of the structure and function of the hand was maintained after implant resorption, probably as the guided fibrous tissues had replaced the dissolved implant.

Keywords: metacarpophalangeal joint, rheumatoid arthritis, arthroplasty, implant, surgery

INTRODUCTION

The typical deformity in rheumatoid hand results from the destruction of metacarpophalangeal (MCP) joints, which leads to ulnar deviation and palmar dislocation of the fingers. The one-piece silicone implant is the gold standard for the reconstruction of MCP joints in RA patients. It acts as a joint spacer during an encapsulation process, which leads to formation of a fibrous capsule around the implant (Swanson, 1972). In the long term, breakage (Goldfarb and Stern, 2003; Trail et al., 2004) and osteolytic changes have been reported (Parkkila et al., 2005; Wanivenhaus et al., 1991) and the clinical outcome after silicone arthroplasty deteriorates during long-term follow-up (Goldfarb and Stern, 2003). However, it continues to be the best documented and most widely used implant in MCP joint arthroplasties. Controlled clinical trials will be necessary to show eventual superiority of novel implants.

A porous bioabsorbable poly-L/D-lactide copolymer scaffold, with an L:D monomer ratio of 96:4 (P(L/D)LA 96/4) to obtain a relatively long resorption time, has been developed (Fig 1). This scaffold allows bone grafting at the time of implantation and aims to provide temporary support and a guide to soft tissue ingrowth to allow a gradual optimised replacement of the implant with fibrous tissue, providing a flexible, but durable, pseudojoint (Kellomäki and Törmälä, 2003). In animal tests, connective tissue ingrowth into such porous implant meshes had already started 1 week after implantation (Kellomäki et al., 2000). In the laboratory tests, the scaffolds retained their shape and strength for at least 13 weeks (Kellomäki et al., 2000). In minipig joints, P(L/D)LA 96/4 scaffolds were almost completely degraded at 3 years and had been replaced by longitudinally organised dense connective tissue (Waris et al., 2008a, 2008b).

Preliminary short-term clinical results of P(L/D)LA 96/4 implants in MCP arthroplasties have previously been published (Honkanen et al., 2003). The purpose of this study was to extend this short-term follow-up to beyond the complete resorption of the biodegradable PLA96 scaffolds.

PATIENTS AND METHODS

Polymer used in the scaffolds was medical-grade, highly purified (residual monomer content 0.1% according to the manufacturer) polylactide L- and D-copolymer with an L:D monomer ratio of 96:4 (P(L/D)LA 96/4 (Purac Biochem, Gorinchem, The Netherlands).
Four-ply multifilament yarn was melt-spun from PLA96, using an Axon BX-15 single screw extruder (Axon, Åstorp, Sweden) with a spinneret with four orifices (each with a diameter of 0.5 mm). The yarn was knitted to a tubular mesh, using a tubular single jersey knitting machine (Textilmaschinenfabrik Harry Lucas, Neumünster, Germany). The knitted tube was rolled on to cylindrical scaffolds with diameters 12, 14, 16 and 18 mm, all having nominal thickness 4.5 mm (range 4.3–4.7). All the samples were individually packed and γ-irradiated for sterilisation. The development work and fabrication process of P(L/D)LA 96/4 scaffold are described in more detail in earlier publications (Honkanen et al., 2003; Kellomäki and Törnälä, 2003).

Twenty-three consecutive patients with RA, who underwent MCP arthroplasty in which P(L/D)LA 96/4 interposition scaffolds were used, were included in this prospective study between 1997 and 2000. The indication for the operation was rheumatoid deformation of the MCP joints affecting activities of daily living (ADL). The local ethical committee approved the study protocol and the clinical use of the new joint scaffold prosthesis. Patients were informed of the study protocol, and everyone recruited joined the study. The mean age of the 19 women and four men was 54 (range 37–78) years at the time of the operation, with the mean duration of arthritis being 18 (range 7–41) years. The operated hand was dominant in 11 and non-dominant in 12 cases.

The arthroplasty was done in all four MCP joints in 18 patients, in three MCP joints in one patient, in two MCP joints in one patient and in a single MCP joint in three patients. The MCP joints that were operated on included 22 index fingers, 20 middle fingers, 18 ring fingers and 20 little fingers. The preoperative radiological Larsen grading (Larsen et al., 1977) was III in six joints, IV in 31 joints and V in 18 joints. Previous silicone arthroplasties had been done in eight patients in 25 joints.

In eight patients, additional operations, such as interphalangeal joint fusion, trapzeziometacarpal tendon interposition arthroplasty or removal of fixation material after wrist arthrodesis, were carried out at the same time. Total wrist arthrodesis had been done earlier in 19 wrists and a partial radiocarpal arthrodesis in two. One of the non-operated wrists was Larsen stage III and the other was stage IV, but the alignment in both joints was good. Previous interphalangeal joint fusion had been done in the thumb in 12 patients and in some of the other fingers in four patients.

**Surgical technique (Fig 2) and rehabilitation**

Operations were performed under the control of a tourniquet inflated to 100 mmHg above the systolic blood pressure. Cefuroxime was used for the preoperative antibiotic prophylaxis. The operative technique followed the guidelines recommended for silicone MCP joint arthroplasty by Swanson (1972), but medullary preparation was unnecessary as stemless implants were used. The scaffold was fixed to the metacarpal bone with absorbable mono-filament PDS sutures (Ethicon Inc., Sommerville, NJ, USA). A dorsal transverse skin incision was made and the extensor hood was opened longitudinally on the radial side of the extensor tendon. If the tendon was subluxated, the ulnar sagittal band and transverse fibres were divided to mobilise the tendon in a radial direction. If necessary, the radial sagittal band was overlapped at the end of the operation to centralise the extensor tendon. The extensor hood and capsule were separated. The joint capsule was opened longitudinally and synovectomy was carried out. The metacarpal head was resected just distal to the collateral insertions. The radial and ulnar collateral ligaments were released from their metacarpal origins and picked up by the absorbable holding core suture. The palmar joint capsule was detached from the metacarpal and the palmar plate released by longitudinal incision to correct the palmar subluxation. The aim was to lift the palmar edge of the proximal phalanx to the level of the dorsal edge of the metacarpal bone. If a tendency to palmar subluxation or palmar tightness were still noticed, the ulnar intrinsic muscles were also divided. The abductor digiti minimi of the little finger was divided routinely. A crossed intrinsic transfer was carried out if the radial collateral ligament was markedly weakened.

The size of the PLA scaffold was chosen so that it completely covered the bone of the metacarpal head. The PLA scaffold was fixed with resorbable PDS sutures passing through the metacarpal bone and via the distal palmar plate. In revision cases, intramedullary bone grafts were prepared from the resected metacarpal heads.
or obtained from autologous iliac bone. Balancing and tightening of the collateral ligaments was done by refixation of the ligaments at a more proximal insertion site and slightly dorsally through drill holes in the proximal metacarpal bone. The reinsertion of the ulnar collateral ligament was done to improve soft tissue balance adjustment and to counteract tendency to palmar subluxation. The capsule and extensor hood layers were closed separately and the extensor tendon was centralised.

The hand was first immobilised in a bulky dressing for 2 or 3 days. Then, for up to 7–10 days, after operation the hand was supported in a static palmar splint. Active and passive range of movement exercises were assisted with a low-profile dynamic dorsal splinting, starting 7–10 days postoperatively and continuing for up to 12 weeks after operation. The palmar rest splint was used at night-time for up to 12 weeks. Light activities of daily living, like eating and personal hygiene, were allowed immediately after application of the dynamic splint.
Rehabilitation was supervised and guided by an occupational therapist using a similar rehabilitation programme to that used for Swanson arthroplasties.

Pre- and postoperative assessments were made by an orthopaedic surgeon and always by the same occupational therapist (SM). Wound healing problems and abnormal tissue reaction (swelling or redness) were recorded as complications. Pain, satisfaction, ADL abilities and activities were assessed by questioning. Pain was graded into five categories (no pain, occasional pain, continuous pain in activity, continuous pain also at rest or excruciating pain). Patient satisfaction was assessed using a scale indicating excellent, good, satisfactory or poor results. Ability to perform personal hygiene, dressing, eating and housework were graded by ‘no difficulties’, ‘some difficulties’, and ‘considerable difficulties’ or ‘not able to do’. The ability to work, study or engage in leisure activities were scored using the same scale. Functionality of the hand was assessed by the occupational therapist, who observed simulated ADL tests such as ability to handle a knife and fork, key, jug and waterglass. Tip pinch grip was assessed for each finger and graded as ‘normal’, ‘applied’ or ‘not able’. ‘Timed box and block’ and ‘Nine hole tests’ were used to indicate the dexterity of the hand (Desrosiers et al., 1994; Mathiowitz et al., 1985). Grip strength (mean value of three consecutive measurements) was measured using a Jamar dynamometer (Preston, Jackson, MI, USA) with the handle in position two.

Active extension and flexion in MCP and PIP joints were measured from the dorsal side using a goniometer. The deficiency in total finger flexion was recorded using the distance between finger tips and the distal palmar crease. Ulnar deviation was measured using a goniometer and with the fingers in maximal extension.

Standardised anteroposterior and supine oblique X-rays were taken preoperatively and postoperatively at 3 months, at 1 year and at the final follow-up visit in the same radiology department using the same set up. A supine oblique projection was taken using a cradle. The palmar subluxation was determined from supine oblique X-rays with the fingers in maximal active extension. The difference between the dorsal levels of the metacarpal bone and proximal phalanx was measured. The joint space indicated the distance between the metacarpal and the proximal phalanx bone ends in supine oblique X-rays from the radioulnar middle point of the joint. This was compared between the final follow-up and at 3 months postoperatively. The maximal depth of osteolysis at the ends of the metacarpal and proximal phalangeal bones was measured from both projections at 3 months and at final follow-up.

The paired Student t-test was used for normally distributed variables. The Wilcoxon test was used to analyse differences between groups for skewed variables. Classified variables were analysed using cross tables with Fisher’s exact test, when appropriate. Results are given as mean values and accompanied by range when appropriate, if not otherwise indicated.

RESULTS

All recruited patients, in whom 80 MCP joints underwent surgery, were assessed clinically and radiologically before the operation and at 59 (range 36–71) months after the operation. In an intermediate review at 14 (range 10–18) months, clinical assessments were performed on 21 patients and 72 joints. One elderly woman felt that her health was too poor for the first follow-up visit and one patient refused to attend this review. Both of these patients, however, attended the final follow-up.

None of the implants had to be revised. No infections occurred. One dorsal fistula, which originated from the fixation suture of the scaffold, was revised 10 weeks after operation in an outpatient clinic. At the revision operation, the protruding suture was removed and bacterial samples were taken. After 2 weeks antibiotic therapy, this fistula healed without complications.

Preoperatively five patients had continuous pain, 11 had occasional pain and seven patients did not have any pain. At final follow-up, 13 patients were pain-free and 10 patients had only occasional pain. No patient reported worsened pain. Subjective outcome (patient satisfaction) was excellent or good in 12 patients and satisfactory in 10 patients. One 83-year-old woman considered the result of the operation to be poor. In this particular case, the range of motion at the latest follow-up was low and it had shifted towards extension. Her preoperative flexion was 67° and the lack of extension was 33°, whereas the corresponding values at the latest follow-up were 35° and 0°. The mean ulnar deviation was 46° preoperatively and it was 0° at the latest follow-up. Her operated joints were pain-free and the grip strength was sustained. She felt that the postoperative limitation of flexion was especially troublesome.

Personal activities of daily living improved (Table 1), but this did not influence the ability to work, study or carry out exercise and leisure activities. Preoperatively tip pinch was normal in six fingers, limited in 55 fingers and impossible in 19 fingers. At final follow-up, normal tip pinch was possible in 29 fingers, limited in 36 fingers and impossible in 15 fingers (P = 0.034). No significant changes were observed in the other grasps. A slight, but statistically insignificant, improvement was observed in the dexterity tests. In the timed box and block test the mean score was 61 preoperatively, 64 at intermediate follow-up and 64 at final follow-up (P = 0.188). In the nine hole test, these values were 30, 27 and 28, respectively (P = 0.078). Grip strength increased slightly immediately after the operation, but had deteriorated at final follow-up both in the operated and non-operated hands. In the operated hands, the preoperative median
grip strength was 6 (range 2–24, interquartiles 4–10) kg, at intermediate follow-up it was 7 (range 1–27, interquartiles 5–11) kg and at final follow-up 4.5 (range 1–18, interquartiles 2–9) kg. In the non-operated hand, the corresponding values were 8 (range 3–25, interquartiles 6–14) kg, 9 (range 2–27, interquartiles 5–15) kg and 6.5 (range 2–26, interquartiles 3–11) kg. The differences between preoperative and final follow-up values were statistically significant for both the operated ($P = 0.043$) and non-operated ($P = 0.010$) hands.

The average lack of MCP joint extension improved from 32° preoperatively to 15° at the final follow-up. This improvement had been achieved by the intermediate follow-up and was sustained to the final follow-up. The mean MCP flexion changed from 76° preoperatively to 63° at final follow-up. At intermediate follow-up the mean flexion was 65°. The difference between intermediate and final follow-up was not statistically significant. The arc of motion had shifted towards extension. The preoperative, intermediate and final postoperative ranges of motion are given in Table 2.

The ranges of motion of the proximal interphalangeal joints improved in the little finger. In other fingers the improvement was not statistically significant. The mean PIP flexion in the index finger was 81° preoperatively and 83° at final follow-up ($P = 0.058$), in the middle finger 91° preoperatively and 96° at final follow-up ($P = 0.071$), in the ring finger 88° preoperatively and 99° at final follow-up ($P = 0.094$) and in the little finger 73° preoperatively and 85° at final follow-up ($P = 0.024$), respectively. The deficiency in total finger flexion did not improve either.

Preoperative ulnar deviations were 14°, 22°, 28° and 37° for the index, middle, ring and little finger, respectively. At intermediate follow-up the corresponding figures were 3°, 9°, 7° and 7° and at final follow-up 0°, 5°, 7° and 10°.

The improvement achieved in palmar dislocation is represented in Fig 3. The joint space at the final follow-up was less than 2 mm in 66 (83%) joints

Table 1—Ability to perform activities of daily living (number of patients)

<table>
<thead>
<tr>
<th></th>
<th>Personal hygiene</th>
<th>Dressing</th>
<th>Eating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
<td>Intermediate*</td>
<td>Final**</td>
</tr>
<tr>
<td>No difficulties</td>
<td>1</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Some difficulties</td>
<td>16</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Considerable difficulties</td>
<td>6</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Not able to perform</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>P-value***</td>
<td>0.008</td>
<td>0.034</td>
<td>0.050</td>
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</tbody>
</table>

*mean 14 months after operation.
***mean 59 months after operation.
***preoperative – final follow-up, Wilcoxon’s test.

Table 2—Mean active range of motion (degrees) in metacarpophalangeal joints preoperatively, after 1 year and at final follow-up

<table>
<thead>
<tr>
<th>Extension lack</th>
<th>Flexion</th>
<th>Arc of motion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Index</td>
<td>Middle</td>
</tr>
<tr>
<td>Preoperative</td>
<td>29</td>
<td>32</td>
</tr>
<tr>
<td>Intermediate*</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>Final follow-up**</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>P-value***</td>
<td>0.001</td>
<td>0.005</td>
</tr>
</tbody>
</table>

*mean 14 months after operation.
**mean 59 months after operation.
***preoperative – final follow-up, paired t-test.
and 2.1–4 mm in 11 joints. In three cases, the joint space widened from 4.1 to 7 mm. These three joints were eroded into the metacarpal and/or proximal phalangeal bone surfaces and one of these three joints had also developed palmar subluxation. At final follow-up, the joint space thickness was equal to a value measured at 3 months in 24 joints. The joint space decreased from 1 to 2 mm in 45 joints and increased from 1 to 2 mm in 11 joints. Altogether in 57 joints (71%), the joint space change was within a range from a 1 mm decrease to a 1 mm increase. Osteolytic changes exceeding 2 mm had developed on the surfaces of the metacarpal and/or proximal phalangeal bone surfaces in 4% of cases between the 3 month and final follow-up (Table 3).

**DISCUSSION**

The development of implants for finger joint replacement has not matched the rapid progress in the development of the hip and knee implants. Many different designs and materials have been tested, but the silastic Swanson implant, implemented in the 1960s, still remains the most widely used prosthesis for the MCP joint reconstruction. A need for implants with improved biocompatibility and prolonged implant survival is evident (Goldfarb and Stern, 2003). Fixation of MCP implants is a challenge as forces are concentrated onto small bone areas and minor discrepancies in the centre of motion may transfer extra loads to the bone, especially when stiff and hard implants are used (Schmidt, 2005). In osteoporotic bones, as so often found in rheumatoid patients, the difference in the elasticity of the implant and the bone poses a problem.

The two part hypothesis tested in the present study was that (1) the degradation products of the P(L/D)LA 96/4 scaffold would not provoke foreign body reactions leading to peri-prosthetic bone lysis, as the degradation products can be phagocytosed and degraded and (2) that the absorbable interposition implants, acting as joint spacers would simultaneously be replaced by ingrowing fibrous tissue from the host so that the restored normal anatomy of the rheumatic hand obtained by the arthroplasty operation would be maintained after their absorption. Timing of the final follow-up in this study was selected so that it ensured total dissolution of the bioabsorbable interface scaffold. It was feared that the ulnar and palmar deformities might recur during the bioabsorption period of the scaffold. Despite implant resorption, soft tissue balance and the appearance of the hand were well maintained, probably because the interface scaffold had been replaced with space-occupying fibrotic tissue leading to formation of a fibrotic union (Waris et al., 2008a). The appearance of the hand has been found to be one of the most important determinants for patient satisfaction after MCP arthroplasties (Mandl et al., 2002).

The function of the hand improved as shown by separate tests simulating ADL functions observed and recorded by an occupational therapist. Pre- and postoperative grip strength measurements have been described in only a few previous studies and have been reported to remain unchanged (Blair et al., 1984; Schmidt et al., 1999) although there was a slight improvement in one study (McArthur and Milner, 1998). In our study, grip strength weakened from 1 year to final follow-up, but to a similar extent in both the operated and non-operated hands. This may reflect the general impairment of the muscle strength in this age group and progressive joint disease.

Lack of active extension was significantly reduced but as flexion was diminished, the arc of motion was only slightly improved, which is similar to Silastic MCP arthroplasties (Goldfarb and Stern, 2003). The moderate range of motion achieved seems to be adequate for most of the activities of daily living (Hume et al., 1990). In historical reports recurrence of ulnar drift after Silastic MCP arthroplasty is common (Goldfarb and Stern, 2003; Schmidt et al., 1999; Vahvanen and Viljakka, 1986; Wilson et al., 1993). Maintained correction of ulnar deviation after MCP arthroplasty seems to be related to increased long-term implant survival and to better subjective satisfaction (Clark et al., 2001; Mandl et al., 2002). In our series, correction of ulnar deviation was achieved and well sustained in the mid-term.

Palmar subluxation after MCP arthroplasty has not been much discussed in the literature, although joint space collapse and bone shortening have been reported (Goldfarb and Stern, 2003; Kirschchenbaum et al., 1993). The present study indicated a slight progression of

<table>
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<th>mm*</th>
<th>Metacarpal bone</th>
<th>Phalangeal bone</th>
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<tbody>
<tr>
<td></td>
<td>Index</td>
<td>Middle</td>
</tr>
<tr>
<td>0</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>0.1–2</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2.1–4</td>
<td>1</td>
<td>2</td>
</tr>
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*millimetres.

**Table 3—The maximum bone osteolysis in the metacarpal and phalangeal bones at the final follow-up**
the palmar dislocation. However, in 71 joints (89%) the palmar subluxation was less than half of the bone thickness at follow up and in 27 joints of these palmar subluxation did not occur at all. The clinical significance of the slight increase in palmar dislocation after MCP joint arthroplasty is not clear yet, but it would seem to matter for the outcome of bioabsorbable implants (due to the effects of leverage and stress transfer phenomena). In patients with bioabsorbable or bioabsorbable implants, it could potentially increase the risk of progressive tendon imbalance.

We wanted to see if implant resorption induces osteolysis. Osteolytic changes were minor, in part due to the prosthetic design without intramedullary stems. Changes were restricted to joint surface areas, but were not found in the diaphyseal bone. Alterations in height of the joint space indirectly suggest bone resorption, joint dislocation or changes in implant spacer size. Joint space increased in 14% of the joints. However, the joint space width decreased in the majority of the joints, which may indicate scar shrinkage during implant resorption and fibrous tissue maturation. The drawback of measuring the joint space at the midline of the joint is that it does not take into account new bone formation at the edges of the bone, which was noticed in the recent study in minipigs (Waris et al., 2008a).

This is the first study of the mid-term results attained in MCP arthroplasties using PLA scaffolds. It has shown that implant absorption was not associated with peri-implant osteolysis. The restoration of the structure and function of the hand were maintained in the mid-term, probably because the composition and design of the present PLA96 implant allow fibrous tissue ingrowth and implant replacement with a functional and pain-free fibrous pseudojoint. PLA cannot cause sustained foreign body reactions and the fibrous tissue replacing the implant cushion does not break, so that a grip of more than 5 kg (heavy shopping) is possible. The results at this point are comparable to those described for silicone Swanson implants as reported in earlier papers. A valid comparison with modern Silastic implants requires a controlled trial, which is ongoing in our hospital.

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