Bioreconstructive Joint Scaffold Implant Arthroplasty in Metacarpophalangeal Joints: Short-Term Results of a New Treatment Concept in Rheumatoid Arthritis Patients

P.B. Honkanen, M.D.,¹ M. Kellomäki, Dr.Tech.,² M.Y. Lehtimäki, M.D., Ph.D.,¹ P. Törmälå, Ph.D.,² S. Mäkelä, O.T.,¹ and M.U.K. Lehto, M.D., Ph.D.³

ABSTRACT

Swanson silicone implant is the “gold standard” of metacarpophalangeal joint reconstruction in rheumatoid arthritis (RA) patients. However, durability problems of silicone implants have led us to develop a new technique based on bioreconstructive implants. PLA96 (poly-L,D-lactide copolymer, L:D ratio of 96:4) scaffolds were engineered. Bioabsorption and substitution of porous PLA96 scaffold with living tissue eventually produce a neojoint. In the current prospective study, 23 RA patients (80 joints) were operated on, using PLA96 implants. Fifteen patients (54 joints) have been monitored for at least 1 year. Pain alleviation was well achieved. Range of motion improvement was emphasized to extension direction of functional arc. The average ulnar deviation was preoperatively 26°, and at follow-up it was 6°. Volar subluxation was noticeable in 56% of joints preoperatively and in 6% at 1-year follow-up. This is the first report of the formation of a living, functional joint in situ by means of a synthetic bioreconstructive joint scaffold. Results of this preliminary short-term study are comparable with previously published data on silicone arthroplasty. However, bioreconstructive prostheses can aid in preventing problems that occur with biostable prostheses. Tissue engineering has created a new era in the reconstruction of damaged joints.

INTRODUCTION

The arthritic destruction of metacarpophalangeal (MCP) joints in rheumatoid arthritis (RA) typically leads to ulnar deviation and volar subluxation of the fingers, which greatly impairs the function of the hand, especially the ability to grasp objects of large size (Fig. 1).¹ The MCP joint, with its complex musculotendinous system, its unusual mobility and stability, and its large applied stresses, has proved to be a difficult challenge in joint replacement design. The nonprosthetic tendon and volar plate interposition arthroplasties are of historic interest, and continue to have occasional usage.¹ The prosthetic arthroplasty of MCP joints of the fingers was begun with metallic devices in the 1950s.² A large number of nonmetallic materials including pyrolytic carbon, ceramics, and ultrahigh molecular weight polyethylene have been used to manufacture MCP joint prosthesis.³,⁴ The reports of those studies include several complications: bone resorption, prosthesis migration, infections, foreign body reactions, and prosthesis dismantling.³,⁴ It was in the late 1960s that silicone devices were devel-

¹Division of Orthopedics, Department of Surgery and Department of Physiatrics, Tampere University Hospital and Medical School University of Tampere, Tampere, Finland.
²Institute of Biomaterials, Tampere University of Technology, Tampere, Finland.
³Coxa, Hospital for Joint Replacement, Tampere, Finland.
oped and the concept of prosthetic replacement of MCP joints became widely accepted and applied.²

A one-piece silicone implant with stems and a spacer in the middle is most commonly used for the reconstruction of MCP joints in RA patients. In the operation the stems of the implant are placed in the bone cavities of metacarpus and proximal phalanx. The spacer sets between the bone ends and acts as a joint spacer during the encapsulation process, when the body forms a fibrous capsule around the implant.³ The most used and best documented implant is the so-called Swanson prosthesis.

Breakage of the implants has been a common problem in silicone arthroplasty series. Depending on the length of the follow-up period and study methods used, a range of 5–82% prevalence has been reported in different studies.⁶ Particles released from either intact or broken prosthesis cause tissue reactions such as foreign body granulation in the joint and around the prosthesis inducing osteolysis.⁷,⁸ Resorption of the bone due to the implant or progressive disease can make reoperation using stemmed prosthesis difficult or even impossible to perform. Especially in such cases an implant without stems would be preferable because it enables intramedullary bone grafting.

In clinical work patients with one or more previous silicone arthroplasties with prominent ulnar deviation and volar subluxation of the fingers due to breakage of the implant are commonly met. Usually in these cases silicone arthroplasty is not possible to perform because of insufficient bone stock, as discussed above. Some salvage operation should be offered for the patient to maintain his or her ability to perform daily activities.

The principle of in vivo tissue engineering, meaning that a porous scaffold is implanted in situ and filled with in-grown tissue, thus forming a living, functional tissue or organ, was applied in studies preceding current experiments. In 1994 the concept of the bioreconstructive joint scaffold was developed in our group by performing a first prospective study using commercially available bioabsorbable Vicryl and Ethisorb fleeces folded into small, rectangular scaffolds.⁹ The innovation for the experiment was the so-called Vainio method, in which the extensor tendon is folded between the ends of the metacarpus and phalanx. The tendon creates a sliding surface between the bone ends and acts as a counterforce to volar subluxation tendency.¹⁰

The folded scaffold was intended to behave in a similar way as the tendon. However, the resorption time of both tested materials was too short. The tissue did not have enough time to regenerate and mature, and the joint space collapsed. The principal idea of the scaffold, however, proved to be clinically successful and a scaffold consisting of a porous bioabsorbable poly-L,D-lactide copolymer with an L:D monomer ratio of 96:4 (PLA96) with longer absorption time was designed. The scaffold is intended to be a temporary support and to be filled in by the ingrowing tissue of the host and later to be completely replaced by new living tissue. Thus it can be used to reconstruct a functional joint and the patient can use the hand better than preoperatively. The preceding in vitro experiments have shown that the filaments retain at least 50% of their tensile strength for 13 weeks (phosphate-buffered saline [PBS], pH 7.4, 37°C), and scaffolds retain their shape for at least the same amount of time.¹¹

FIG. 1. Preoperative photograph of the rheumatoid hand with typical volar subluxation and ulnar deviation of the fingers. Picture has been taken with maximum active extension.
Compared with the complete loss of tensile strength of Ethisorb fibers in vivo in 4 weeks (our unpublished results) the strength retention is remarkably longer. The 50% strength retention in 13 weeks has been estimated as minimum strength retention time to keep up the joint space long enough for tissue maturation. In animal tests, connective tissue ingrowth into the mesh structure has been observed after the first week.\textsuperscript{12} PLA96 scaffolds implanted in rat subcutis were filled with tissue in 3 weeks,\textsuperscript{13} and self-reinforced PLA96 copolymer rods were totally absorbed within 3 years.\textsuperscript{14}

The purpose of the present study was to evaluate the clinical, radiological, and functional outcomes of PLA96 joint scaffold arthroplasty in severe arthritic destruction and revision operation after failure of silicone arthroplasties in the metacarpophalangeal joints of RA patients.

\section*{MATERIALS AND METHODS}

\subsection*{Scaffolds}

Polymer used in this study was medical-grade and 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 (PLA96; Purac Biochem, Gorinchem, The Netherlands). Intrinsic viscosity, $\eta_i$, (chloroform, 25°C) was 6.8 dL/g and heat of fusion (value corresponding to crystallinity) was 40.1 J/g (both according to manufacturer). Before processing, the polymer was predried.

Four-ply multifilament yarn was melt-spun from PLA96, using an Axon BX-15 single screw extruder (screw diameter 15 mm; ratio of screw length to diameter 24; Axon, Ästorp, Sweden) with a spinneret with four orifices (each with a diameter of 0.5 mm). The lowest barrel temperature was 158°C and the die temperature was 260°C. The yarn was oriented by drawing it freely in a two-step process to a draw ratio of about 4.5.

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 to cylindrical scaffolds and heat-treated above glass transition temperature ($T_g$) of polymer in the molds. All the samples were packed and sterilized by $\gamma$ irradiation before use.

\subsection*{Methods for yarns and scaffolds}

All the yarns (four-ply multifilaments) were incubated in PBS (pH 7.4, 37°C) for periods of 1, 2, 4, 6, 8, 10, 13, 16, and 19 weeks. The solutions were changed regularly every two weeks and the buffer capacity of the solution was checked by pH measurements. Before testing, all the samples were rinsed with deionized water.

The yarns were tested at a cross-head speed of 30 mm/min, using an Instron 4411 materials testing machine (Instron, High Wycombe, UK). Pneumatic grips were used, and the gauge length was 100 mm. Initial tensile results were measured on dry specimens, and after in vitro hydrolysis wet specimens were tested. Mean and standard deviations of stress and strain at maximum load were calculated ($n=10$).

Porosity of the scaffolds was calculated by determining the weight and size of the scaffolds and calculating against the solid piece of PLA96.

Pore size measurements were done for $\gamma$-sterilized samples. Scaffolds were fixed in epoxy resin. Fixed scaffolds were cut into three sections both in height and in diameter planes and surfaces were polished. Thirty randomly chosen distances between the fibrils in the yarns (small pores) and between the yarns (large pores) were measured on the basis of optical microscopy images of each section. Measured values were multiplied by 1.6 to estimate round pores.

\subsection*{Patients}

Twenty-three rheumatoid arthritis (RA) patients with, altogether, 80 operated metacarpophalangeal (MCP) joints were operated on, using PLA96 scaffolds. All patients were informed of the study protocol and asked to participate. Clinical use of the new interposition joint scaffold prosthesis was confirmed by permission of the Ethics Committee of the Tampere University Hospital and Pirkanmaa Hospital District (Tampere, Finland).

During the study 15 patients and their 54 joints reached the follow-up stage of 1 year and the outcome is reported in this study. Average follow-up is 1 year and 8 months (12–27 months). There were 13 women and 2 men; the mean age of the patients at the time of operation was 54 ± 13 (range, 37–78) years. The mean duration of rheumatoid arthritic diagnosis was 17 ± 8 (range, 7–41) years. The preoperative mean value of C-reactive protein in patients was 21 ± 12 (range, 8–39) and the sedimentation rate was 15 ± 13 (range, 4–40). Eight patients were using cytotoxic medication and 13 patients received glucocorticoid medication at the time of operation. The average time of cytotoxic medication usage was 5.9 ± 3.7 (range, 0.5–11) years and that of glucocorticoid medication was 9.5 ± 4.7 (range, 0.5–15) years. The MCP joint of the index finger (MCP II) was operated on in all 15 patients, the MCP joint of the middle finger (MCP III) in 14 patients, MCP IV in 12 patients, and MCP V in 13 patients.

The preoperative radiological destruction stage of the operated joints, according to Larsen (scale, I–V),\textsuperscript{15} was stage III in 2 of the operated joints (4%), stage IV in 21 joints (39%), and stage V in 13 joints (24%). Stage V presents the most severe destruction of the joint. Previous silicone arthroplasty had been performed for 6 (40%) patients and thus in 18 (33%) joints.
Surgical technique and rehabilitation

Operations were performed with a tourniquet (100 mmHg above systolic blood pressure). Preoperative prophylactic antibiotic (cefuroxime) was used. In the operation resection of the bone was equal to Swanson arthroplasty. The quantity and quality of soft tissue balancing in the operation were determined by grade and type of deformity. When ulnar deviation existed, the proximal bony attachments of both collateral ligaments were released. Deliberation of the volar capsule under metacarpal bone and release of the volar plate were performed to achieve adequate correction of volar subluxation. Ulnar intrinsic muscle contractures were released when required. The abductor digiti minimi of the fifth finger was always dissected. The PLA96 scaffold was fixed with resorbable sutures through the metacarpal bone via the volar plate.

Intramedullary bone grafting was performed in revision arthroplasties. Balancing and tightening of the collateral ligaments were performed by duplicating or refixing the ligament more proximally through drill holes in the proximal metacarpal bone. At the end, the extensor tendon was centralized.

In rehabilitation, the operated MCP joints were supported with a volar static splint during the first 10 days after operation. Active and passive range of movement exercises were assisted with a low-profile dynamic dorsal splinting starting 10 days postoperatively and continued up to 12 weeks. Light activities of daily living (ADL), like eating and personal hygiene, were allowed immediately after dynamic splint initialization. The rehabilitation was controlled by an occupational therapist.

Methods for patient examination

The clinical, radiological, and functional assessments were carried out preoperatively and at follow-up (3 months and 1 and 2 years after surgery). Fifteen patients (54 joints) were monitored for at least 1 year. The mean follow-up time in this prospective study was 1 year and 8 months, with a range of 12 months to 2 years and 3 months. Functional measurements and interviews were performed by the same occupational therapist. Volar subluxation (sliding of the proximal phalange in the palmar direction) and joint space were measured from volar oblique radiographs. Subjective pain was evaluated with a verbal rating scale. Active flexion, lack of active extension, and ulnar deviation (proximal phalange deflection to the lateral side) were measured clinically from a dorsal aspect according to the standards of the American Academy of Orthopaedic Surgeons. Grip strength was measured with a Jamar dynamometer (handle position 2) and according to the standards of the American Society of Hand Therapists. The mean value of three grip strength measurements was considered.

Results are presented as mean, range, standard deviation, and proportion. Statistical analysis of mean values was made using paired sample $t$ test. In comparing classified variables pre- and postoperatively the measure used was either $\kappa$ (for $2 \times 2$ tables), or $\gamma$ (for $m \times n$ tables, $m$ or $n > 2$) statistics. In the case of $\kappa$ and $\gamma$ a value near 0 corresponds to discordance between the variables involved (e.g., lack of correlation between two variables). A $\gamma$ value between 0.4 and 0.7 indicates a moderate concordance, and a value $> 0.7$ great concordance, between the variables. A $\kappa$ value $< 0.20$ means poor, 0.21–0.40

![FIG. 2. Remaining tensile strength (%) of PLA96 yarn plotted against weeks in vitro.](image-url)
fair, 0.41–0.60 moderate, 0.61–0.80 good, and 0.81–1.00 very good concordance. A good congruence between pre- and postoperative values means lower effectiveness of the operation.

RESULTS

Yarns and scaffolds

Diameter of single filament varied between 70 and 80 μm. Processing and γ irradiation decreased the intrinsic viscosity of PLA96 to 1.28 dL/g. Initial tensile strength of the γ-sterilized yarns was 345 ± 40.7 MPa and strain at maximum load was 31 ± 3.1%. Within 19 weeks in vitro the tensile strength of the yarn had dropped to 81 ± 11.0 MPa, that is, 23% of initial strength (Fig. 2).

A typical scaffold is shown in Fig. 3. Calculated porosity of the scaffolds was approximately 80% (varied from 75 to 83%). Scaffolds had open and highly interconnected porosity throughout the structure, because the porosity is formed by mesh loops and by layers of the mesh. Generally, pores can be divided into small pores, meaning spaces between the filaments in yarn, and large pores, consisting of pores inside and between the loops. The average diameter of the small pores was 86 μm and the average diameter of the large pores was 547 μm. In practice, scaffolds have pores ranging from tens of micrometers up to 1 mm, because of the structure.

Clinical results

All patients reported relief from pain at the follow-up of 1 year and 8 months (12–27 months) (Table 1). The range of motion (ROM) improved from a nonfunctional arc of flexion to a more functional arc of extension (Table 2). Preoperatively, the mean ROM of operated joints was 46°, and postoperatively it was 51°. The ROM did not decrease in any of the patients during follow-up. The functional results presented in Table 3 show that patients were able to handle daily activities better than preoperatively.

Volar subluxation of more than half of the bone height was present in 30 joints (56%) preoperatively and in 3 joints (6%) at follow-up (Table 4). Preoperatively, the average ulnar deviation of operated joints was 26 ± 18° (range, 3–51°), and at follow-up it was 6 ± 7° (3–30°) (p < 0.001). The strength of the grip was sustained. Preoperatively, the measurement was 8.0 kg (mean) and postoperatively 8.2 kg (mean), respectively (p = 0.80). At follow-up the mean joint space measured from X-rays was 2.4 ± 1.6 (range, 0–6 mm).

The cosmetic appearance was good; no swelling or fistula formation was observed at the follow-up (Fig. 4). The subjective satisfaction preoperatively was poor in 10 patients and tolerable in 5 patients. Postoperative subjective satisfaction was excellent or good in seven patients, satisfactory in seven patients. There was one patient with poor subjective outcome, and this patient had a humerus fracture with partial radialis paresis 1 year and 2 months after MCP arthroplasty. The fractured humerus may have influenced the overall welfare of the patient.

DISCUSSION

Most of the more recent small joint surgeries have been done with biostable joint prostheses, generally Swanson prostheses. A tissue-engineering approach to create new tissue formation in the joint cavity to form a functional neojoint has not been reported previously. Thus, the bioreconstructive MCP joint scaffold prosthesis is a new

![FIG. 3. The PLA96 joint scaffold implant.](image)

TABLE 1. PAIN PREOPERATIVELY AND AT FOLLOW-UP*

<table>
<thead>
<tr>
<th></th>
<th>No pain</th>
<th>Mild pain in daily activities</th>
<th>Severe pain in daily activities</th>
<th>Severe pain at rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td>5</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>10</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Number of patients.
concept in joint replacement surgery and the results of this short-term study suggest that it may be possible to treat joints in this way.

The function of scaffolds in this particular indication is to create and maintain a space between the bone ends. The surrounding tissue preferably invades the pores of the scaffold and fills in the empty space. The tissue will later function as a neojoint. The scaffold is porous, having all pore sizes from some tens of micrometers in diameter to more than 1 mm in diameter. Most probably the pores are smaller in situ because of the compression caused by bones and ligaments. Filling in the scaffold with tissue probably occurs, because in follow-up radiographs an empty space is seen where the implant was placed. At that time the scaffold has already degraded to such an extent that it no longer withstands applied loads.

The first 10 days in static splint allow undisturbed growth of tissue into the scaffolds. By that time the scaffold is relatively well filled with tissue, because tissue ingrowth had occurred completely in 3 weeks in subcutaneous tissue in rats. At the 3-month follow-up time the dynamic splint was removed from the patients and tissue had probably filled in the scaffold completely. By the 1-year follow-up time, the yarns of the scaffold carry no load, because of degradation, but they still may support the joint cavity. The empty space seen in radiographs where the scaffold had been placed is at that time most probably a combination of the patient’s own tissue and remainders of the PLA96 scaffold.

Although all the operated joints were extensively destroyed by RA and the current material included a great number of revision arthroplasties (40% of the patients and 33% of the operated joints), which are in most cases impossible to treat by any other method, the results are promising and functionality of the hands was at least comparable to those previously reported for silicone arthroplasties.

ROM improved slightly and was broad enough. It is important that the ROM was postoperatively at a good level in the extension–flexion arc for hand function, which enables the patient to grip larger objects. This was seen as improved ability to perform daily activities, such as eating and taking care of personal hygiene. Correction of rheumatic deformations, volar subluxation, and ulnar deviation was achieved and well preserved at least over 12–27 months of follow-up. According to animal and in vitro studies most of the PLA material degrades in this time. Individual results had not deteriorated during this

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### Table 2. Range of Motion

<table>
<thead>
<tr>
<th></th>
<th>MCP II</th>
<th>MCP III</th>
<th>MCP IV</th>
<th>MCP V</th>
<th>All operated joints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperatively</td>
<td>72</td>
<td>76</td>
<td>80</td>
<td>73</td>
<td>75</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>68</td>
<td>75</td>
<td>68</td>
<td>62</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>p = 0.06</td>
<td>p = 0.4</td>
<td>p = 0.0001</td>
<td>p = 0.029</td>
<td></td>
</tr>
<tr>
<td>Active extension lack</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperatively</td>
<td>25</td>
<td>28</td>
<td>34</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>19</td>
<td>23</td>
<td>17</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>p = 0.15</td>
<td>p = 0.22</td>
<td>p = 0.01</td>
<td>p = 0.06</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** MCP II, index finger metacarpophalangeal joint; MCP III, middle finger metacarpophalangeal joint; MCP IV, ring finger metacarpophalangeal joint; MCP V, little finger metacarpophalangeal joint.

*In degrees.*

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### Table 3. Activities of Daily Living

<table>
<thead>
<tr>
<th>Activity</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No problem</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Some problems</td>
<td>11</td>
<td>6</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Considerable</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td><strong>γ</strong></td>
<td>0.59</td>
<td></td>
<td>0.33</td>
<td></td>
</tr>
</tbody>
</table>

*aNumber of patients.*
follow-up time. However, a longer follow-up time is certainly needed to assure permanence of the results after degradation of the PLA scaffold.

In severely deformed rheumatoid hands (fixed deformity) it may occasionally be difficult to achieve proper balancing of soft tissues. When a silicone implant is put in place under compromised circumstances the imbalanced stress to the implant and the sharp irregularities of the resected bones can easily lead to implant breakage and consequently to recurrence of deformity and pain as well as loss of function. With bioreconstructive and bioabsorbable prostheses we can avoid the problems of broken implants. This type of bioreconstructive implant has no stems but the implant is sutured with bioabsorbable stitches inside the joint space. Thus the implant causes no stress and shields the metacarpal diaphysis, which is valuable especially in cases with major bone resorption.

In revision arthroplasties the stemless implant also makes it possible to use intramedullar bone grafting to fill osteolytic cavities. An example of such a patient with major bone resorption caused by implant stems preoper-

<table>
<thead>
<tr>
<th>MCP II</th>
<th>&lt;2 mm</th>
<th>3–5 mm</th>
<th>&gt;6 mm</th>
<th>( \kappa )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td>4(^b)</td>
<td>5</td>
<td>6</td>
<td>0.07</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>13</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>MCP III</td>
<td>&lt;2 mm</td>
<td>3–5 mm</td>
<td>&gt;6 mm</td>
<td>( \kappa )</td>
</tr>
<tr>
<td>Preoperatively</td>
<td>4</td>
<td>3</td>
<td>6</td>
<td>0.14</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>9</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>MCP IV</td>
<td>&lt;2 mm</td>
<td>3–5 mm</td>
<td>&gt;6 mm</td>
<td>( \kappa )</td>
</tr>
<tr>
<td>Preoperatively</td>
<td>2</td>
<td>3</td>
<td>8</td>
<td>0.31</td>
</tr>
<tr>
<td>Postoperatively</td>
<td>7</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>MCP V</td>
<td>&lt;2 mm</td>
<td>3–5 mm</td>
<td>&gt;6 mm</td>
<td>( \kappa )</td>
</tr>
<tr>
<td>Preoperatively</td>
<td>2</td>
<td>1</td>
<td>10</td>
<td></td>
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<tr>
<td>Postoperatively</td>
<td>4</td>
<td>8</td>
<td>1</td>
<td>−0.09</td>
</tr>
</tbody>
</table>

Abbreviations: See Table 2.
\(^a\)Measured from oblique X-rays.
\(^b\)The values indicate the number of joints.

FIG. 4. Postoperative photograph at 3-month follow-up (same patient as in Fig. 1), with maximum active extension. Finger alignment has improved and extension lack reduced. Cosmetic reformation is noticeable.
atively is presented in Fig. 5. In PLA96 arthroplasty the bone cavities were filled in with allograft bank bone, PLA96 scaffold was fixed in its place, and all necessary soft tissue balancing was done. The situation 2 years postoperatively, when PLA96 is heavily degraded, is shown in Fig. 6. Remodeling of the bone and thickening of the cortices can clearly be seen and there is a space between the metacarpus and proximal phalange, indicating present material.

The balancing of the joint is crucial, and the joint should be tight enough at the end of the operation to allow absorption of the implant without malalignment of the hand bones. At the clinical examination it was noticed that the MCP joints functioned and glided nearly like a normal joint and not like a hinge, as is commonly experienced with silastic implants. None of the joints has been opened so far, and thus no histological observations of the quality and quantity of the tissue exist.

FIG. 5. Preoperative radiograph of a revision arthroplasty case. Swanson arthroplasty was performed 10 years previously. Extensive thinning of the diaphyseal cortices around the Swanson implant stems can be seen.

FIG. 6. Postoperative radiograph of the same patient 2 years after PLA96 joint scaffold arthroplasty. In the operation intramedullary defects have been filled with autologous bone graft. Postoperative remodeling of the bone and thickening of the cortices can be observed. “Empty” space between metacarpus and proximal phalanx indicates the location of bioreconstructive joint scaffold implant and in-grown soft tissue.
Follow-up of the present patients to determine the long-term results of this new technique of arthroplasty continue. A check-point at 4 years has been chosen to confirm the situation for those joints from which PLA96 has been completely disappeared. A randomized prospective multicenter study using PLA96 joint scaffold and Swanson implants has also started, to confirm these promising preliminary results.

REFERENCES


Address reprint requests to:
P.B. Honkanen, M.D.
Department of Surgery
Tampere University Hospital
P.O. Box 2000
33521 Tampere, Finland
E-mail: pirjo.honkanen@fimnet.fi