Results From a Degradable TMC Joint Spacer (Artelon) Compared With Tendon Arthroplasty

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Purpose: A new spacer for the trapeziometacarpal joint (TMC) based on a biological and tissue-preserving concept for the treatment of TMC osteoarthritis (OA) has been evaluated. The purpose was to combine a spacing effect with stabilization of the TMC joint.

Methods: Artelon (Artimplant AB, Sweden) TMC Spacer is synthesized of a degradable polyurethaneurea (Artelon), which has been shown to be biocompatible over time and currently is used in ligament augmentation procedures. Fibers of the polymer were woven into a T-shaped device in which the vertical portion separates the bone edges of the TMC joint and the horizontal portion stabilizes the joint. Fifteen patients with disabling pain and isolated TMC OA were included in the study. Ten patients received the spacer device and the remaining 5 (control group) were treated with a trapezium resection arthroplasty with abductor pollicis longus (APL) stabilization. The median ages of the 2 groups were 60 and 59 years, respectively. Pain, strength, stability, and range of motion were measured before and after surgery. Radiographic examination was performed in all patients before and after surgery. At follow-up evaluation 3 years after surgery an unbiased observer evaluated all patients. Biopsy specimens were obtained from 1 patient 6 months after surgery.

Results: All patients were stable clinically without signs of synovitis. In both groups all patients were pain free. The median values for both key pinch and tripod pinch increased compared with before surgery in the spacer group but not in the APL group. The biopsy examinations showed incorporation of the device in the surface of the adjacent bone and the surrounding connective tissue. No signs of foreign-body reaction were seen.

Conclusions: This study showed significantly better pinch strength after Artelon TMC Spacer implantation into the TMC joint compared with APL arthroplasty. (J Hand Surg 2005;30A: 380–389. Copyright © 2005 by the American Society for Surgery of the Hand.)

Key words: CMC-I, degradable biomaterial, implant, OA, TMC.

Surgery often is indicated in more advanced trapeziometacarpal (TMC) osteoarthritis (OA) and includes ligament reconstruction, metacarpal osteotomy, TMC arthrodesis, trapezial excision, soft-tissue interposition with or without ligament reconstruction, silicone elastomer arthroplasty, and total joint arthroplasty.

In TMC OA 2 common surgical procedures are trapezial excision with tendon interposition (tendon arthroplasty) and TMC arthrodesis. Tendon arthroplasty results in good pain relief but there are different opinions as to whether proximal migra-
tion of the first metacarpal bone results in decreased pinch strength or not.9–15 Long-term studies, however, have shown weak lateral pinch after tendon interposition arthroplasties.16,17 Hence it follows that tendon arthroplasty is not perceived as an optimal technique and clinically is used mainly in elderly, less-demanding patients without heavy-labor occupations. Arthrodesis on the other hand is recommended for the relatively young, high-demand individual who needs a strong and stable thumb, although recent studies have shown that the pinch strength is similar to tendon arthroplasty.12,16 Many patients with TMC arthrodesis, however, experience problems with flattening the hand and might have pain from the nearby joints.2,9,12,16,18,19

Endoprosthetic replacement of the TMC joint has been used, either as TMC implants with preservation of the trapezium or as an interposition after trapezium resection. Both implant designs are associated with subluxation, material fatigue, and occurrence of wear debris causing adverse tissue reactions.6,20 In a recent report regarding the cemented surface replacement trapeziometacarpal prosthesis (SR; Avanta Orthopaedics, San Diego, CA), only 40% of the patients maintained an excellent/good result 33 months after surgery.21

A new T-shaped TMC device made of a degradable polycaprolactone-based polyurethaneurea (Artelon; Artimplant AB, Sweden) has been developed. The device has 2 modes of action: to resurface the distal part of the trapezium and to stabilize the TMC joint by augmentation of the joint capsule.

The choice of a degradable biomaterial for the TMC spacer device is based on a biological approach to support the local tissue repair. The purpose of the biomaterial is to prevent bony impingement but also to provide a scaffold for tissue ingrowth. The biomaterial undergoes a slow and controlled degradation to allow the body to form organized tissue; with time a new articular surface is formed. The rationale for the horizontal wings is to offer initial stabilization of the joint capsule as well as provide a scaffold function. With degradation of the biomaterial an increasing amount of mechanical load may be transferred from the device to the remodeling joint capsule.

The treatment of TMC OA with the Artelon spacer was evaluated in an open, controlled, prospective pilot study. The control group consisted of patients who had trapezium excision and abductor pollicis longus (APL) tendon interposition. The results from a re-examination an average of 3 years after surgery are presented.

Materials and Methods

The Implant

The biomaterial (Artelon) used in the TMC device is a polycaprolactone-based polyurethaneurea that degrades by hydrolysis.22 The complete hydrolysis of Artelon takes approximately 6 years, as shown by in vitro degradation studies. The polymer has been used in other medical applications and both in vitro and in vivo studies have shown the safety and biocompatibility of the material.23,24 The T-shaped device was woven from Artelon fibers that were processed by a wet spinning procedure and it has a dry weight of 0.3 g.22 The vertical spacer part of the device serves as an interposition in the TMC joint, preventing the metacarpal base from abutting onto the trapezium bone (Fig. 1). The horizontal wings augment the dorsal joint capsule and thus prevent dorsoradial migration of the proximal metacarpal.

Patients

An open, controlled, prospective pilot study, which followed the Declaration of Helsinki, was performed. Informed consent was obtained from all patients before inclusion into the study. The study protocol was reviewed and approved by the Sahlgrenska Academy Ethics Committee.

Fifteen patients with radiographically verified, isolated TMC OA stage 3 according to Eaton and Glickel25 were included in the study. Indication for surgery was disabling pain for at least 2 years before
surgery and failure of conservative treatment with splints and steroid injections.

Exclusion criteria were diabetes mellitus, kidney insufficiency, OA in the STT joint, ongoing cortisone treatment, or malignancy within the past 10 years. The patients were included consecutively in the clinical study and had surgery between September 1999 and February 2001.

The first 5 patients received the Artelon TMC Spacer anchored to bone with osteosutures, the next 5 patients were treated with APL tendon arthroplasty, and the remaining 5 patients received the Artelon TMC Spacer anchored with titanium screws. There were 9 women and 1 man with an average age of 60 years (range, 22–66 years) in the spacer group and 5 women with an average age of 59 years (range, 51–72 years) in the APL group. Six patients had surgery on the dominant hand in the study group compared with 3 patients in the APL group.

Two patients (1 man, 1 woman) in the spacer group had a previous history of trauma; the remaining patients suffered from OA.

All patients were examined by the surgeon before surgery for baseline measurements and at all follow-up visits. In addition an independent observer who did not know which treatment group the patient had received examined all patients at the 3-year follow-up examination. The clinical examination included both subjective and objective tests.

Pain was evaluated with a visual analogue scale in which 10 represented the highest degree of pain experienced and 0 represented no pain. The visual analog scale measurements were recorded at maximal loading in the key pinch.

Strength was measured for 3 different handgrips: the key pinch (lateral pinch), the tripod pinch, and the transverse volar grip. Measurements were performed with the patient sitting in a chair with the elbow resting on a table. The values of the key pinch and tripod pinch were recorded using a pinch gauge (North Coast Medical, Inc) and the transverse volar grip was recorded with a dynamometer (Jamar; Sammons Preston Inc, Bolingbrook, IL).

Radial and palmar thumb abduction were measured by a goniometer and were recorded between the first and second metacarpals. To evaluate the ability to flatten the hand, the range of retroposition was measured as the distance (cm) between the thumb and table underneath the hand when the dor-
sum of the hand was pressed against the table. The palmar abduction, that is, the distance (cm) between the thumbnail and the nail of the index finger during maximal opening, was measured. Maximal extension and flexion in the metacarpophalangeal and interphalangeal joints were measured using a flexible rod and transferred to a paper chart from which the angle of flexion or extension was measured.

Grip function was measured by the Sollerman hand function test consisting of 20 different activities of daily life in which the main handgrips are used to the same extent as in daily life.26 The testing of the patients was performed by an occupational therapist. The time to return to presurgical occupation was registered. The patients’ subjective assessments of the treatment result measured at 3-year follow-up evaluation were recorded using a Likert scale (1 = poor; 5 = excellent). All patients were examined radiographically before surgery and at follow-up evaluation.

Surgical Technique

The APL arthroplasty was performed according to Sigfusson and Lundborg.5 In brief, a longitudinal curved dorsoradial incision over the trapezium was made. A distally based fascia-capsule flap was raised to expose the first carpometacarpal joint and then the trapezium was excised. A distally based strip, 6- to 7-cm long, of the most radial part of the APL was prepared. The strip was inserted through the radial part of the capsule and then through a cut in the flexor carpi radialis tendon, and then was pulled up and around one of the remaining parts of the APL tendon, twisting the flexor carpi radialis and the APL together.

The implantation of the Artelon TMC Spacer was performed through a dorsal approach with a curved skin incision over the TMC joint. The radial artery was identified and carefully was mobilized proximally and protected. The periosteum of the dorsal trapezium and the capsule of the TMC joint were elevated distally. With traction placed on the thumb the TMC joint was inspected and the articular surface along with the most distal part (2 mm) of the trapezium was removed with an osteotome. The dorsal cortex of both the trapezium and the proximal metacarpal were removed to allow the wings of the device to be in close contact with the trabecular bone and leveled with cortical bone surface. Any bone cysts were filled with excised bone.

The device was anchored to bone with either non-

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Table 1. Continued

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Pain (visual analogue scale) was recorded at maximal loading of key grip. Patient 9 displayed pain only in tripod pinch (5.0).
resorbable coated braided polyester osteosutures (3-0 TiCrone Davis & Geck, Nepean, Canada) or titanium screws (screw diameter, 1.6 mm; Medicon, Tuttlingen, Germany). Bone canals were prepared for the osteosutures with a 1.1-mm–diameter AO hand burr. Thus one wing was anchored to the first metacarpal and the other wing was anchored to the trapezium. In all cases the periostal flap including the dorsal capsule was relocated and sutured with a resorbable suture covering the wings. After surgery the thumb was immobilized in a spica cast for 5 weeks in both groups.

Histology
At 6 months after surgery biopsy specimens were taken from 1 patient (Table 1, patient 9) when 1 of the titanium screws was removed owing to discomfort. The biopsy specimens (~2 × 2 mm) were taken from the distal wing of the spacer close to the metacarpal. After removal the biopsy specimens were immersed immediately in buffered formalin (4%) for 24 hours. The tissue then was dehydrated, embedded in paraffin, and sectioned with a conventional microtome (section thickness, ~4–5 μm). In addition the hard tissue of the biopsy specimen was decalcified in 12% ethylenediaminetetraacetic acid for 2 weeks (shaken and changed daily). The sections were prepared consecutively longitudinally from the surface of the biopsy specimen through the entire biopsy specimen. The majority of the sections (both bone and soft tissue) were stained with toluidine blue because this is one of few stains that adequately stains the biomaterial. Light microscopic analysis was performed.

Statistics
Descriptive statistics was used for presentation of the results. A Wilcoxon rank sum test was used to compare grip strength in the different treatment groups. A significance level of .05 was regarded as statistically significant.

Results
The results in all patients are summarized in Table 1. All spacer patients and 4 APL patients were followed up for 3 years. One APL patient was followed up for 2 years because the patient did not respond to the repeated calls. Except for 2 spacer patients with a transient inflammatory reaction with moderate local swelling and tenderness at 2 weeks after surgery (Table 1, patients 7 and 9), no other postsurgical complications were detected. Routine blood analysis results were normal and the tissue reaction subsided within the following 2 weeks. X-ray examination showed a distance between the trapezium and the metacarpal (Fig. 2). At re-examination all patients were examined with an x-ray and reported major pain relief without any differences between the spacer and the APL group (Fig. 3). Grip and pinch strength, measured for key pinch, tripod pinch, and transverse volar grip, increased in the spacer group compared with presurgical values in contrast to the APL group, in which no improvement was recorded (Figs. 4–6, Table 1). At 3 years the spacer patients were significantly stronger as recorded by both the surgeon and the independent observer in tripod pinch (p ≤ .05) compared with the APL group. The results also revealed a significant difference in key pinch between the 2 groups (p ≤ .05) when recorded by the independent observer. There was no difference in range of motion in the metacarpophalangeal or interphalangeal joints between the groups. The range of motion regarding palmar and radial abduction of the thumb,
as well as the retroposition (Table 1), the palmar abduction, and the ability to flatten the hand, were the same in both groups. The palmar abduction (the distance in cm between the thumb and index finger) was 15.0 before surgery and 13.8 after surgery in the spacer group compared with 15.2 and 14.5, respectively, in the APL group. The ability to flatten the hand (the distance between the thumb and the table) was 1.0 cm before surgery and 0.8 cm after surgery in the spacer group compared with 1.2 cm and 1.3 cm, respectively, in the APL group. Comparable results in the 2 groups were seen in the Sollerman hand function test.

Four patients in the spacer group were working before surgery and at the 3-year follow-up evaluation all had returned to their previous occupations. In the APL group only 1 patient was working before surgery but was retired at the re-examination.

Except for 1 patient (Table 1, patient 9) the patients in both the spacer and APL groups were satisfied with the treatment. Median values on the Likert scale were 4.8 and 5.0 in the spacer and APL groups, respectively. Radiographic examination showed no dislocation or any adverse host tissue response.

Histology
The decalcified sections containing bone showed a close contact between Artelon fibers and bone without intervening structures. The bone adjacent to the Artelon fibers and at a distance from the biomaterial had a mature lamellar appearance.
7). Sections with connective tissue in close contact with Artelon showed tissue in-growth into the woven structure (Fig. 8). There were no chronic inflammatory cells or any foreign-body response in the vicinity of Artelon.

Discussion

The use of a degradable spacer with capsule augmentation might be indicated in patients with isolated OA of the TMC joint with high demands on grip function and pinch strength. These patients often are bad candidates for excision of the trapezium, which for many years has been the benchmark arthroplasty. Resection of the trapezium results in a grossly altered anatomy with subsequent shortening of the thumb and decreased pinch strength. By preserving the trapezium and the surrounding ligaments Artelon TMC Spacer offers the possibility to combine 2 well-documented methods of restoration of degenerated OA joints by joint capsule augmentation (by the horizontal portion of the device) and resurfacing of the articular surface (vertical portion of the device).

The results of this study show that the pain-relieving effect of Artelon TMC Spacer implantation was equivalent to that after a tendon arthroplasty, but the pinch strength was considerably better compared with both presurgical values and the APL group. Range of motion was comparable after both procedures despite the ligament reinforcement producing a firm fixation between the metacarpal base and trapezium. There was no difference between the groups regarding palmar adduction and abduction or regarding retroposition of the thumb; thus flattening of the hand was not a problem.

Figure 6. Strength in transverse volar grip (Jamar) before and 3 years after surgery. Results presented for patients treated with Artelon TMC Spacer (Spacer) and patients treated with trapezium excision and APL tendon interposition (APL). At 3 years values are given for both the surgeon (3 y) and the independent observer (3 y_io).

Figure 7. Light micrograph from a patient with an Artelon TMC Spacer 6 months after implantation. Artelon (A) can be seen as light turquoise areas incorporated in the host bone. The bone with osteocytes (Oc) is surrounding the material and show a close contact (I: interface) with the biomaterial without signs of adverse reactions. Bar = 50 μm.
Previous efforts to replace the TMC joint with implants made from materials such as silicone, expanded polytetrafluoroethylene, polypropylene, and collagen have been associated with some disadvantages.

The use of silicone trapezial implants was previously a common procedure but wear and deformation of the implant has been shown to cause foreign-body reactions characterized by multinucleated giant cells containing small particles of silicone. Pellegrini and Burton found a 25% failure rate with silicone implants and a high rate of revision surgery caused by subluxed implants and marked silicone synovitis. This can be associated with erosion of adjacent bone, and 56% cyst formation has been reported.

Reactions after implantation of expanded polytetrafluoroethylene implants also have been reported. Greenberg et al. observed osteolytic changes around the Gore-Tex implants in 80% of their patients and histologic examination of 1 retrieved implant showed frayed graft material and giant cells. Muermans and Coenen compared the use of Gore-Tex and polypropylene (Marlex) implants with the interposition of a strip of extensor carpi radialis longus tendon after trapeziectomy. Marlex was well tolerated but they reported a 30% incidence of synovitis characterized by pain and osteolysis in patients with Gore-Tex implants. Belcher and Zic compared trapeziectomy alone with interposition of porcine dermal collagen xenograft (Permacol) in 26 patients with OA of the TMC joint. The study was terminated prematurely because of adverse reactions to the implant in 6 of 13 patients. Three implants were examined histologically, all showing foreign-body reactions with numerous multinucleated giant cells. Patients with Permacol implants reported significantly more pain after surgery than control patients.

A previous effort to replace the trapezium with a solid polyurethane implant showed encouraging results with no adverse tissue reaction from the polyurethane but also a similar frequency of implant dislocations as seen after silicone implants.

During the degradation of Artelon, which takes place by hydrolysis, the mechanical properties and the weight of the material decrease, as does the molar mass of the polymer. It is important to emphasize that when the hydrolysis is completed, part of the degraded material (approximately 50% of the initial weight) will remain incorporated at the site of implantation.

The tissues adjacent to the Artelon devices, however, show a normal vascularization and a very limited amount of plasma and giant cells, which normally is a fairly common event in tissues surrounding different implants.

The degradation rate is an inherent property of the
biomaterial and in the case of Artelon it takes approximately 6 years before the material is hydrolyzed. It may be argued that the entire degradation needs to be followed up before any conclusions can be drawn. With the new degradable and woven TMC device, however, we aim to obtain formation of a new functional surface. Such a tissue formation is possible to study as early as 6 months after surgery. In fact this study shows that the patients have a good outcome after implantation of the spacer and the biopsy specimens show that a host tissue is present in the device.

The results show a noteworthy and clinically significant postsurgical increase of key pinch and tripod pinch in the spacer group compared with the APL group. As this pilot study proceeds more data of both long-term clinical and radiographic results will be obtained.

Scott McDonald is gratefully acknowledged for skillful occupational therapy. Professor Bengt Edberg, Pia Roy, and Rolf Nilsson are acknowledged for textile development and manufacturing. and Karin Darle Ols-son is acknowledged for technical assistance.

References


