A retrospective multicenter study of the Artelon[®] carpometacarpal joint implant

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Abstract

Background This study aims to evaluate patient outcomes associated with use of the Artelon[®] Spacer for the treatment of arthritis of the carpometacarpal joint (CMCJ) of the thumb.

Methods Patients with Eaton stage I, II, or III carpometacarpal (CMC) joint arthritis and disabling pain that had failed conservative treatment were evaluated at 12, 36, and 48 months postsurgery for changes in pinch, patient satisfaction, pain, range of motion, grip strength, grind test, operative time, and X-ray evidence of subsidence.

Results Complete data was available for 46 subjects and 49 thumbs. A statistically significant improvement in pain

when subjected to a first CMC joint grind test, CMCJ stability and patient perception of hand and wrist function following implant insertion was seen. Patient-oriented outcomes showed statistically significant improvement in the Disabilities of the Arm, Shoulder, and Hand; pain; pinch and grip strength; and range of motion. X-ray analysis revealed that none of the distributions of measures of osteophytes, subluxation, and joint space narrowing showed statistically significant change. Bone erosion/remodeling changes of the first metacarpal were statistically significant.

Conclusions At a follow-up period of 4 years, patients had measured improvement as well as positive self-reported functional improvements following Artelon[®] implant insertion for the treatment of arthritis of the thumb CMCJ.

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Introduction

Osteoarthritis of the carpometacarpal (CMC) joint of the thumb is a disabling condition for which conservative, non-operative treatment is frequently not successful [12, 16, 29]. Several surgical options have been used to treat persistent pain and dysfunction in these patients. However, there is no evidence to suggest that any one surgical procedure is superior to another. In 2009, a Cochrane systematic review compared the effect of different surgical techniques in reducing pain and improving physical function, patient global assessment, range of motion, and strength in patients with trapeziometacarpal osteoarthritis to determine if there was any improvement or deterioration in outcomes between 12 months and 5 year follow-up [28]. In nine studies

included in the review of 477 patients, seven different surgical procedures were identified. No procedure demonstrated any superiority over another in terms of pain, physical function, patient global assessment, or range of motion. It was determined that there was insufficient evidence to provide conclusive treatment recommendations [28]. There is evidence that the majority of these surgical procedures relieve pain; however, they do not reliably restore or improve upon the decreased preoperative pinch and grip strength that is such a disabling portion of this disease process [3, 7, 18, 19, 22, 27].

The Artelon® CMC Spacer is a biologic approach to reconstructing the trapeziometacarpal (TMC) joint. It provides the trapezoid surface with a material that both resurfaces the worn-out arthritic joint and provides a scaffold for tissue ingrowth. As the biomaterial (Artelon®) undergoes a slow and controlled hydrolytic degradation, newly organized tissue is produced by the body which incorporates with the Artelon® scaffold, eventually forming a new articular surface. Complete hydrolysis of the degradable portion of the Artelon® Spacer has been shown by *in vitro* studies to take about 6 years [24]. The horizontal wings of the implant, which are fixed at the time of surgery to the first metacarpal base and trapezoid body, augment the joint capsule and thus help to stabilize the TMC joint [24].

The purpose of this study was to evaluate short-term patient outcomes associated with use of the Artelon® CMC Spacer for the treatment of arthritis of the carpometacarpal joint of the thumb in the USA.

Materials and Methods

Study Protocol

This was an institutional review board-approved case series of consecutive patients undergoing implantation of the Artelon® carpometacarpal joint (CMCJ) spacer from the practice of four hand surgeons. Inclusion criteria included: provision of informed consent; Eaton stage I, II, or III CMC joint arthritis; age 35 years or older; presence of disabling pain that had failed conservative treatment; and follow-up of at least 3 months postsurgery [11]. Exclusion criteria included, Eaton stage IV CMC arthritis, patients who underwent additional procedures on the thumb at the time of insertion of the Artelon® Spacer, presence of ongoing infection or insulin dependent diabetes, patients receiving steroids or chemotherapeutic drugs, and workers' compensation cases.

All patients were examined before surgery and at each follow-up visit by their surgeon. Data was scheduled for collection at 12, 36, and 48 months postsurgery. Primary efficacy outcomes included: key and opposition pinch,

patient satisfaction, and functional improvement utilizing the Disabilities of the Arm, Shoulder, and Hand (DASH) score. Secondary efficacy outcomes included: pain, thumb range of motion, grip strength, grind test, operative time, and X-ray evidence of osteophytes, subsidence, joint subluxation, and erosive/remodeling changes about the implant. The primary safety outcome was operative and postoperative adverse events.

Both subjective and objective data were gathered, including key and opposition pinch, grip strength, and range of motion by both physician measurement and patient reports using visual analog scales (VAS). Physician data included manual assessment of CMCJ stability, grind test, fixation methods, operative time, and complications. A patient satisfaction survey was administered in which patients were asked to judge how adequately their preoperative expectations were met by the operative procedure in regard to: improvement in symptoms; the ability to return to everyday activities, exercise, recreational activities, and work; and improvement in appearance. As limited preoperative data was available on some subjects, patients were also asked to complete a DASH questionnaire and assess through recall their preoperative pain, pinch strength, grip strength, and range of motion on a VAS by recalling, as best as possible, their preoperative status.

Data was entered by each study site into an internet-based clinical study database (Boundary Medical, Minneapolis, MN, USA). De-identified data was output into an MS Excel™ spreadsheet for analysis. All analyses were conducted using PASW v 18.0™ (SPSS, Inc.) and MedCalc™ v 11.4.2.0 (MedCalc, Mariakerke, Belgium). Descriptive statistics were used to describe data at each collection point. Chi-square was used for comparisons of categorical data. *T* tests were used for bivariate comparisons of continuous data. Repeated measures analysis of variance was employed to assess differences across time points. For statistical testing, an alpha of 0.05 was used as an acceptance standard and all testing was conducted as two tailed. Also determined were 95% confidence intervals for point estimates and for change differences. Analysis was conducted across thumbs of patients for whom there were complete data at all follow-up points.

Device Description

The Artelon® CMC joint spacer is a T-shaped biodegradable implant composed of a polycaprolactone-based polyurethane urea. The device is used to treat individuals suffering from early to midstage osteoarthritis of the carpometacarpal joint of the thumb. The Artelon® CMC spacer was approved for sale in the USA in 2004. Its insertion is made through a small dorsal radial thumb incision centered over the thumb carpometacarpal joint. Approximately 2 mm of the distal aspect of the trapezium is

resected and the dorsal surfaces of the trapezium and first metacarpal base are abraded to obtain bleeding bone, facilitating ingrowth under the wings. The implant is inserted between the first metacarpal base and the distal trapezium and fixed to the first metacarpal and trapezium with screws or suture anchors. Postoperatively, the joint is immobilized for approximately 5–6 weeks [24].

Results

From an initial group of 65 subjects and 69 thumbs (including bilateral implant patients), complete clinical and outcome follow-up data was available for 46 subjects and 49 thumb CMC joints (Fig. 1). Demographic information for the patients included in the analysis is shown in Table 1. Surgical operative data is shown in Table 2. The majority of fixations were accomplished with metacarpal and trapezium bone anchors after surgical entry via curvilinear incision at the thumb base in the abductor pollicis/thenar muscle interval in an average operating time of 34 min. Suture anchors were used to fix the Artelon® implant to the base of the first metacarpal in 40 thumbs and the trapezium in 39 thumbs with screw fixation used in the others (Table 2). There were no surgical complications noted for any patient in this group.

Physician outcome assessment data is shown in Table 3. The statistically significant changes found over time are: a significant improvement in the percentage of patients reporting no pain when subjected to the grind test of the first CMC joint from 2.9% to 93.9% ($\chi^2=77.3$, $p<0.0001$,

95%CI 76.5–96.4%) and a statistically significant increase in the percentage of patients demonstrating stability of the first CMCJ when subjected to physician manual stress from 52.8% to 100% ($\chi^2=47.2$, $p<0.0001$, 95%CI 31.5–61.9%).

Patient-oriented outcomes are presented in Table 4. The DASH scale was administered at each of the three follow-ups [2, 8, 10]. In addition, patients were asked to complete the DASH in consideration of their functioning prior to surgery. The DASH is inversely scored so that lower scores indicate lesser disability and greater functioning. As can be seen in Fig. 2, the DASH scores were very low at follow-up 1 and this reported high functioning continued through follow-up 3. There was a statistical difference between the retrospectively obtained preoperative data and all follow-up data. There is no statistical difference between the first and the last follow-up.

Patients completed VAS at each follow-up as well as responding retrospectively at baseline (Table 4). Differences on the four VAS items were significant from the baseline to the first follow-up. This was true for difference in thumb pain ($t=11.38$, $p<0.0001$, 95%CI 54.7–38.4), pinch strength ($t=3.52$, $p<0.0008$, 95%CI 7.71–28.1), grip strength ($t=4.84$, $p<0.0001$, 95%CI 10.7–29.2), and range of motion ($t=4.7$, $p<0.0001$, 95%CI 12.1–29.7).

When measured from first follow-up to last follow-up, which reflects actual experience, patients reported improvement in all measures for both pinch strength ($F=12.7$, $p<0.001$, 95%CI 9.4–32.5), grip strength ($F=11.34$, $p<0.0001$, 95%CI 6.01–30.5), and range of motion ($F=3.95$, $p<0.02$, 95%CI 4.3–19.4). These differences were significant. While there was continued improvement in thumb pain levels over time, this was not statistically significant.

Patients also completed Likert scale items designed to assess: return to daily activities, satisfaction with hand and wrist appearance and functioning as well as an assessment of their satisfaction with surgery (Table 4). Because of differences in item presentation between the first follow-up and the last, items were rescored to dichotomous values reflecting “improvement” or “non-improvement” for functioning and appearance and as “yes” or “no” for satisfaction.

At first follow-up, patients reported high improvement and satisfaction as a result of surgery. These high levels of improvement and satisfaction continued through the final follow-up. There was a statistically significant improvement in satisfaction with patients’ perception of their wrist and hand functioning ($\chi^2=4.2$, $p<0.04$, 95%CI 1.4–32.3). Other assessments evidencing high values of improvement at the first follow-up continued but were not statistically significant.

Table 5 summarizes changes evident upon examination of X-ray images of the included thumbs. None of the distributions of the measures of osteophytes (medial and lateral), subluxation (mm), and joint space narrowing showed statistically significant change over time from first

Fig. 1 CONSORT table of subjects and thumbs through follow-up 3

Table 1 Patient demographics

Category	N	Value
Age		
Females	54	58.8 years (95% CI 54.9–61.5 years)
Males	11	56.8 years (95% IC 49.6–64.0 years)
Thumbs		
Female left	25	0.36% (95% IC 23.7–49.5)
Female right	29	0.42% (95% IC 29.0–55.8)
Female both	3	0.04% (95% IC 0.59–12.8)
Male left	5	0.07% (95% IC 0.01–34.0)
Male right	6	0.08% (95% IC 0.04–35.4)
Male both	1	0.01% (95% IC 0.0–28.1)
Time to follow-up		
Time to follow-up 1	46	13.0 months ($\pm$ 6.5 months)
Time to follow-up 2	46	31.8 months ($\pm$ 6.2 months)
Time to follow-up 3	46	50.3 months ($\pm$ 6.9 months)
Osteoarthritis Eaton stage		
Stage 1	4	10.5% (95%CI 2.9–24.8%)
Stage 2	13	34.2% (95%CI 19.6–51.3%)
Stage 3	21	55.3% (95%CI 38.3–71.4%)

For patients with complete data ($n=46$ subjects and 49 thumbs)

follow-up through final follow-up. The occurrence of bone erosion/remodeling changes of the base of the first metacarpal (but not the trapezium) seen between visits 2 and 3 was statistically significant.

Discussion

The goals of first metacarpal trapezial surgery are: provide pain relief, increase pinch and grip strength, increase thumb

motion, maintain/restore thumb length, and maintain/restore joint stability [3, 5, 13, 18, 28]. Trapezial resection with ligament reconstruction and tendon interposition (LRTI) is the most popular of the available surgical alternatives while others favor surgery without ligament reconstruction or the less complicated trapezial resection alone [5, 14] but patients may experience thumb subsidence and other resultant symptoms and therefore, trapezial retention arthroplasty may be preferable [1, 9, 20, 22].

Other deterrents to trapezial resection and tendon interposition with or without ligament reconstruction are: the need for secondary incisions to harvest the tendon graft, complexity of the procedure, harvesting the entire flexor carpi radialis tendon may alter wrist kinematics, and need to remove all or most of the trapezium [23].

Nilsson et al.'s initial study of Artelon® vs. a control group of patients undergoing trapezial resection with LRTI (using the abductor pollicis longus (APL) tendon), found at 3 years all patients were stable clinically and pain-free without signs of synovitis [24]. Artelon® patients, however, showed significantly better pinch strength. In a 2010 study at seven Swedish hospitals, they were not able to confirm these results. At 1-year follow-up, mild to moderate swelling was noted in 32% of thumbs in Artelon® patients and in 3% of controls, but the authors acknowledged that many patients were not treated according to the study protocol. Nonetheless, they concluded that there was not significant superiority of the Artelon® Spacer over tendon interposition arthroplasty [25].

Jorheim et al. compared the short-term efficacy of the Artelon® TMC implant with complete trapeziectomy and APL tendon suspension interposition arthroplasty, suggesting that in the short term the Artelon® was not superior [17]. Other authors have suggested foreign body reaction to the Artelon® implant as evidenced by pain and swelling [6, 15].

Table 2 Operative data

	N	Value
Implant fixation		
Metacarpal		
Bone anchor	40	81.6% (95% CI 67.9–91.2%)
Screw fixation	9	6.1% (95% CI 1.3–16.8%)
Trapezial		
Bone anchor	39	79.6% (95% CI 65.7–89.8%)
Screw fixation	10	8.2% (95% CI 2.3–19.7%)
Technique/incision		
Curvilinear at thumb base. Abductor pollicis/thenar muscle interval	46	93.8% (95% CI 83.0–96.7%)
Transverse skin over CMC and longitudinal subcutaneous dissection in line with thenar muscle	2	4.1% (95% CI 0.5–14.0%)
Volar between FCR and radial artery across wrist flexion crease and distal between abductor pollicis and thenar muscle. Oblique at wrist crease	1	2.0% (95% CI 0.04–10.8%)
Skin-to-skin operative time	49	Mean 34.1 min (SD $\pm$ 6.7 min)

For patients with complete data ($n=46$ subjects and 49 thumbs). Analysis at the thumb level

Table 3 Physician outcome assessment

Category	At baseline	Follow-up 1	Follow-up 2	Follow-up 3
Key pinch (kg)	4.5 kg (± 2.1 kg)	6.3 kg (± 3.8 kg)	6.4 kg (± 4.0 kg)	6.1 kg (± 2.3 kg)
Opposition pinch (kg)	4.5 kg (± 2.1 kg)	4.5 kg (± 3.5 kg)	5.2 kg (± 3.3 kg)	5.6 kg (± 2.3 kg)
Grip strength (kg)	–	24.8 kg (± 10.4 kg)	25.6 kg (± 11.6 kg)	27.9 kg (± 11.9 kg)
Grind test first CMC joint (% reporting no pain)	2.90% 95% CI 0.18–18.2%	70.20% 95% CI 55.4–82.4%	97.40% 95% CI 88.3–99.9%	93.90% 95% CI 83.1–98.7%
STT Joint Physician applied pressure (% reporting no pain)	88.60% 95% CI 76.3–95.9%	74.10% 95% CI 59.6–85.5%	84.20% 95% CI 70.9–93.0%	91.70% 95% CI 80.2–97.7%
First CMC Joint stability—to physician manually stressing	52.80% 95% CI 38.0–67.2%	73.30% 95% CI 58.7–84.9%	96.40% 95% CI 86.7–99.6%	100.00% 95% CI 92.7–100.0%

For patients with complete data ($n=46$ subjects and 49 thumbs). Analysis at the thumb level

To confirm the results of Nilsson's original paper [24], and to compare our results with the Artelon® implant with the results of others, our retrospective multicenter study was undertaken. As new studies on the treatment of CMCJ disease became available during the study period, the importance of following patients for longer than 1 or 2 years became evident. The protocol was modified and

patients reconsented to extend data collection. In the interim, some patients were lost and some were unable to complete follow-up. As a result, for the initial group of 65 subjects and 69 thumbs, 46 subjects and 49 thumbs were available for follow-up at 48 months postsurgery.

Outcomes were measured by objective data collection by the operative physician, subjective data collection through

Table 4 Patients' outcome assessments

	At baseline	Follow-up 1	Follow-up 2	Follow-up 3
DASH ^a (disabilities of the arm, shoulder and hand)	47.9 (95%CI 41.8–54.0)	15 (95%CI 10.1–19.9)	9.3 (95%CI 5.9–12.7)	10.1 (95%CI 4.9–15.4)
VAS ^c thumb pain (0=no pain)	72.9 $\pm$ 18.1	27.1 $\pm$ 26.8	26.4 $\pm$ 24.0	13.7 $\pm$ 16.8
VAS pinch strength (100=maximum)	41.7 $\pm$ 27.8	59.2 $\pm$ 27.5	75.2 $\pm$ 21.4	83.1 $\pm$ 19.9
VAS grip strength (100=maximum)	39.9 $\pm$ 28.5	59.4 $\pm$ 23.4	73.4 $\pm$ 22.9	76.6 $\pm$ 25.6
VAS range of motion (100=maximum)	47.7 $\pm$ 26.1	68.3 $\pm$ 23.4	81.9 $\pm$ 16.4	76.9 $\pm$ 23.7
Relief from or avoidance of symptoms (% yes)	NA	75.00 $\pm$ 59.7–86.8%	95.50 $\pm$ 84.0–99.3%	90.90 $\pm$ 78.3–97.4%
Able to return to everyday household or yard activities (% yes)	NA	87.20 $\pm$ 73.7–95.3%	97.70 $\pm$ 87.3–99.9%	95.50 $\pm$ 84.0–99.3%
Satisfied with appearance of hand and wrist (% yes)	NA	84.70 $\pm$ 70.6–93.7%	85.40 $\pm$ 71.5–98.2%	83.70 $\pm$ 69.4–93.1%
Able to go back to my usual job (% Yes)	NA	88.60 $\pm$ 75.4–96.2%	95.50 $\pm$ 84.0–99.3%	90.90 $\pm$ 78.3–97.4%
Able to exercise and to participate in recreational activities (% yes)	NA	84.70 $\pm$ 70.6–93.7%	95.50 $\pm$ 84.0–99.3%	90.90 $\pm$ 78.3–97.4%
As a result of thumb surgery how has quality of your life changed? (% Somewhat or greatly improved)	NA	92.30 $\pm$ 80.1–98.1%	90.90 $\pm$ 78.3–97.4%	90.90 $\pm$ 78.3–97.4%
Satisfied with way wrist and hand are functioning (% yes)	NA	76.90 $\pm$ 61.7–88.2%	94.7 $\pm$ 83.4–99.2%	93.20 $\pm$ 81.3–98.6%
Would you still choose to have the thumb surgery? (% Definitely or probably yes)	NA	90.90 $\pm$ 78.3–97.4%	95.50 $\pm$ 84.0–99.3%	90.90 $\pm$ 78.3–97.4%

For patients with complete data ($n=46$ subjects and 49 thumbs). Analysis at the thumb level

^a DASH lower scores indicate lower disability

^c VAS visual analog scale, scored 0–100

Fig. 2 Distribution of DASH scores. Scored 0–100 with higher scores indicating greater disability

patient oriented outcomes assessment tools, and X-ray evaluation by a qualified independent observer. Subjective data was collected at all follow-up visits by having patients complete a DASH Outcomes questionnaire, VAS questionnaires regarding pain, pinch strength, grip strength and

range of motion, and Likert-style questions regarding satisfaction with the operative procedure (Table 4). As the available preoperative data was incomplete, patients were asked at the first follow-up visit to also complete the DASH Outcomes and VAS questionnaires, as best as possible, by recalling their preoperative status. Patients did not appear to have any difficulty providing answers to the questionnaires in this retrospective manner so such data has been included. We caution the reader, however, that the DASH Outcomes questionnaire has not been validated for use as a retrospective outcomes measurement tool.

Physician-Oriented Outcome

Physician assessment of patients provided valuable information regarding key and opposition pinch, grip strength, pain in conjunction with the grind test, and stability of the CMCJ to manual stressing (Table 3). Data was available, in most instances, preoperatively as well as at follow-up visits 1, 2, and 3. Decrease in pain with the grind test and increased stability of the CMCJ following Artelon® implant insertion were both found to be objectively statistically significant.

Table 5 Analysis of X-ray data

Category	Follow-up 1 (%)	Follow-up 2 (%)	Follow-up 3 (%)
Osteophytes ^a			
Medial	None: <i>n</i> =30 (76.9) 1 or 2: <i>n</i> =9 (23.1)	None: <i>n</i> =29 (65.9) 1 or 2: <i>n</i> =11 (25.0) Multiple: <i>n</i> =4 (9.1)	None: <i>n</i> =35 (72.9) 1 or 2: <i>n</i> =12 (25.0) Multiple: <i>n</i> =1 (2.1)
Lateral	None: <i>n</i> =33 (80.5) 1 or 2: <i>n</i> =8 (19.5)	None: <i>n</i> =32 (80) 1 or 2: <i>n</i> =6 (15) Multiple: <i>n</i> =2 (5)	None: <i>n</i> =36 (76.5) 1 or 2: <i>n</i> =11 (23.5)
Subluxation (mm)	0 mm: <i>n</i> =31 (77.5) 1 mm: <i>n</i> =5 (12.5) 2 mm: <i>n</i> =4 (10)	0 mm: <i>n</i> =29 (72.5) 1 mm: <i>n</i> =5 (12.5) 2 mm: <i>n</i> =6 (15)	0 mm: <i>n</i> =34 (70.8) 1 mm: <i>n</i> =8 (16.6) 2 mm: <i>n</i> =6 (12.5)
Joint space narrowing (mm)	0 mm: <i>n</i> =1 (2.5) 1 mm: <i>n</i> =28 (70) 2 mm: <i>n</i> =11 (27.5)	0 mm: <i>n</i> =1 (2.5) 1 mm: <i>n</i> =20 (50) 2 mm: <i>n</i> =19 (47.5)	0 mm: <i>n</i> =5 (10.4) 1 mm: <i>n</i> =27 (56.3) 2 mm: <i>n</i> =14 (2.9) 3 mm: <i>n</i> =2 (4.2)
Bone Erosion/cyst formation/joint remodeling ^b			
Metacarpal	None: <i>n</i> =14 (35) ≤50%: <i>n</i> =18 (45) >50%: <i>n</i> =8 (20)	None: <i>n</i> =15 (37.5) ≤50%: <i>n</i> =20 (50) >50%: <i>n</i> =5 (12.5)	None: <i>n</i> =5 (10.4) ≤50%: <i>n</i> =19 (39.6) >50%: <i>n</i> =24 (50.0)
Trapezium	None: <i>n</i> =13 (32.5) ≤50%: <i>n</i> =19 (47.5) >50%: <i>n</i> =8 (20.0)	None: <i>n</i> =15 (37.5) ≤50%: <i>n</i> =19 (47.5) >50%: <i>n</i> =6 (15)	None: <i>n</i> =16 (33.3) ≤50%: <i>n</i> =28 (70.0) >50%: <i>n</i> =4 (8.3)

For patients with complete data (*n*=46 subjects and 49 thumbs). Analysis at the thumb level

^a Osteophyte categories: none, 1 or 2, multiple

^b Erosion/remodeling categories: none, <50%, >50%

Patient-Oriented Outcomes

The DASH is a disability and functioning outcome measure with excellent test–retest reliability [2, 8, 10]. Beaton suggests that a change in DASH score of 15 points is the minimal score change to most accurately identify improved patients [2]. This has been confirmed by others [1, 8, 9]. In our study, the DASH showed a mean pre- and postoperative score difference of 32.9 (Table 4). While there was no significant difference between subsequent follow-up scores, the difference to the preoperative score remained significant throughout the follow-up period. While some may find it difficult to draw a statistical conclusion regarding this data in light of the lack of validation of the DASH as a retrospective instrument, we feel the data does confirm our patients' impressions that their function was markedly improved as a result of the Artelon® arthroplasty.

As measured by the VAS, there was a statistically significant improvement in pain, pinch and grip strength, range of motion, as well as a statistically significant improvement noted in patients' perception of their wrist and hand functioning (Table 4).

Patients' perception of: relief from symptoms, ability to return to everyday activities, satisfaction with appearance, ability to return to work, ability to exercise, and improved quality of life remained high throughout the entire postoperative period (Table 4).

Adverse Events

There were no operative complications. There were no infections. Screw fixation of the implant to the first metacarpal was used in nine cases and to the trapezium in ten. Screw loosening and subsequent removal was not reported in any instance although screw fixation of the implant is no longer recommended.

Four patients were not included in the statistical analysis due to incomplete data as a result of having undergone explant of the Artelon® implant for thumb pain—three between follow-up visits 1 and 2 and one between follow-up visits 2 and 3. Of the three undergoing explant between visits 1 and 2, it was noted in two patients that the implant was intact and well fixed. The operative note of the third patient undergoing explant of the implant during this time period described “extrusion of the Artelon® Spacer” and “extensive osteolysis throughout the base of the thumb metacarpal, residual trapezium and distal pole of the scaphoid.” In the fourth patient undergoing explant (between visits 2 and 3), the Artelon® implant was said to be intact and well-fixed. Scaphotrapezial trapezoidal (STT) arthritis was noted. One patient had pain that was attributed to implant extrusion and bone osteolysis—an obvious failure of the Artelon® implant. No cause of the thumb pain was found in two patients but as

Fig. 3 An X-ray of the TMCJ 3 years following Artelon® implantation with excellent joint space maintenance

the implant was removed, some would consider these failures. In the fourth explant case, the implant did not fail but arthritis progressed to involve the STT joint, necessitating complete trapeziectomy.

X-ray Evaluation

There were no statistically significant changes in postoperative X-rays of study patients in osteophytes, joint subluxation, or joint space narrowing. The occurrence of bone erosion/remodeling changes of the base of the first

Fig. 4 An X-ray of the TMCJ 3 years following Artelon® implantation showing evidence of bone erosion/remodeling of both the first metacarpal base and distal trapezium

metacarpal but not the trapezium seen between visits 2 and 3 was statistically significant (Table 5). Although these erosive/remodeling changes are inconsistent with our patients' excellent clinical results, there may be clinical significance to such erosive/remodeling changes. At follow-up visit 1, 35% of our patients (Fig. 3) showed no evidence of erosive/remodeling changes of the first metacarpal and at follow-up visit 3, 89.6% (Fig. 4) showed some erosive/remodeling changes at the first metacarpal base.

Devices made from silicone, Gore-Tex, Marlex, and other synthetic materials have previously been linked to pain, redness, chronic inflammation, and erosive/remodeling changes in bone [20]. Compressive loads and shear forces in the thumb base may have caused these implants to wear, resulting in reactive changes to microscopic particles of silicone or other materials being attacked by the body's immunological system. However, the presence of foreign body giant cells and granulomas found about these devices has led some to the belief that the affected patients' bodies are "rejecting" these implants. Recent case reports associating Artelon® spacers with similar foreign body reactions have implied that some patients were "rejecting" the Artelon® material [4, 6, 15, 17, 21, 26]. Careful review of each of these reports reveals other possible explanations for the "foreign body reactions seen" other than the body rejecting the implant, such as complete decortication of the first metacarpal leading to possible screw loosening, possible screw penetration into the joint, use of resorbable bone anchors, use of titanium screws for fixation and placement of the Artelon® CMC Spacer into the STT joint—an "off label" use.

Many of the erosive/remodeling changes seen with the Artelon® implant may be, we believe, directly related to surgical technique and methods of fixation. Avoidance of such surgical technique variations will hopefully decrease the erosive/remodeling changes seen. Such variations in the surgical technique are:

- Insufficient distal trapezial bone resection such that impingement occurs at the extremes of thumb motion. This is most commonly seen when medial and/or volar osteophytes are present and not fully resected.
- Resection of both sides of the joint—creating ingrowth into both sides of the Artelon® device—eventually leading to a possible chronic inflammatory condition when the sides of the implant pull away from one another following resumption of movement.
- Improper trimming of the Artelon®—improper trimming can result in fraying of the woven fibers that in turn act as a "brush" to the surrounding bone and soft tissue, causing irritation.
- Insufficient fixation—permitting micromotion of the implant leading to chronic inflammation.

- Fixation with resorbable materials—which may be resorbed too quickly, leading to fixation failure.
- Excessive dorsal decortication in areas under Artelon® wings—only sufficient dorsal decortication should be done to result in bleeding bony surfaces for wing fixation.
- Foreign body reaction—bone erosion and resorption about resorbable bone anchors themselves is a reported problem [4].

We believe such erosive/remodeling changes, as we report in this study, will require further investigation even though there was no correlation between the X-ray findings noted and our patient results as measured by both objective and subjective findings. Surgeons' careful attention to bone preparation and resection, implant sizing, placements, and both method and application of fixation may have contributed to our relatively good clinical results.

In our short-term (4 year) study, both objective and subjective data was collected. X-rays were evaluated by a qualified independent observer. All de-identified data was subjected to statistical analysis by independent statisticians. The study was limited by a number of factors including: a retrospective study, use of the DASH instrument in a nonvalidated manner, the relatively small sample size, some initial data not being available and therefore asking patients to comment from "recall" on these items, and an X-ray analysis that was hindered by differences in X-ray technique and quality of films available for analysis.

Physician assessment of patients revealed a statistically significant improvement in pain on the grind test as well as in the stability of the CMCJ with Artelon® interposition arthroplasty. Patient-oriented outcomes showed statistically significant improvement in the DASH, pain, pinch and grip strength, range of motion, and patient's perception of wrist and hand function.

We feel the data presented herein supports the continued use of the Artelon® spacer in the treatment of arthritis of the CMCJ of the thumb with strict adherence to the recommended operative technique. In light of the finding of erosive changes about the implant on some postoperative X-rays, continued long-term evaluation of patients undergoing Artelon® implant arthroplasty is recommended.

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