Complications with the use of Artelon in thumb CMC joint arthritis

Sylvan Clarke · William Hagberg ·
Robert A. Kaufmann · Aaron Grand · Ronit Wollstein

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Abstract

Background Complications with the use of the Artelon spacer in thumb carpometacarpal (CMC) joint arthritis include inflammation, osteolysis, and persistent pain. We evaluated our short-term results and complications.

Methods A retrospective review of 29 patients was performed. Pre- and postoperative radiographs, operative techniques, complications, and subsequent surgeries were analyzed. Pearson's and chi-squared testing was used to identify associations between complications and surgical technique or preoperative radiographic criteria. The average age was age 51 ± 7.7 (34–66), average follow-up was 8 months (1–26).

Results Twelve patients sustained complications. Nine patients displayed postoperative osteolysis. Four patients underwent conversion to CMC suspensionplasty due to persistent pain. The rate of revision surgery and radiographic postoperative osteolysis were not significantly associated with preoperative arthritis grade, metacarpal subluxation, or surgical techniques: fixation method, the bony surface(s) involved in the osteotomy, or spacer modifications.

Conclusions Our study found a significant short-term complication rate following Artelon spacer arthroplasty of the CMC joint. This is higher than previously described.

We could not identify any factors that were significantly associated with the complications. It is possible that the inherent instability of the joint or the material of the spacer is involved in implant failure. Further study is necessary to better define the indications for use and specific techniques for the use of the implant.

Keywords Artelon spacer · Complications · Thumb CMC joint · Arthroplasty

Introduction

Thumb carpometacarpal (CMC) joint arthritis is a common condition, which is often treated surgically. Some surgical treatments for thumb CMC joint arthritis are associated with relatively high complication rates. Hemiarthroplasty with pyrolytic carbon implants have been associated with a 28% reoperation rate and 70% patient satisfaction rate at a mean of 14 months, while trapeziometacarpal arthrodesis has been associated with 15% nonunion rate, 26% rate of scaphotrapezial arthritis, and 8% reoperation rate at minimum 2-year follow-up [1]. In contrast, simple trapezium excision without reconstruction has been associated with an 80% satisfaction rate and no reoperations at 7 years postoperatively [1]. Resection arthroplasty with ligament interposition or tendon transfer, cemented total joint arthroplasty, and silicone arthroplasty have also been proposed for treatment of thumb CMC arthritis [5–7, 12].

The Artelon spacer is a T-shaped device made of a degradable polycaprolactone-based polyurethaneurea that was developed for use in thumb CMC arthritis to resurface the distal aspect of the trapezium and to stabilize the trapeziometacarpal joint by augmentation of the joint capsule [8–11]. The device is meant as a biological spacer

S. Clarke · A. Grand · R. Wollstein (✉)
Department of Orthopedic Surgery, and the Department of
Surgery, Division of Plastic and Reconstructive Surgery,
University of Pittsburgh Medical Center,
Pittsburgh, PA, USA
e-mail: wollsteinr@upmc.edu

W. Hagberg · R. A. Kaufmann
Department of Orthopedic Surgery,
University of Pittsburgh Medical Center,
Pittsburgh, PA, USA

to prevent bony impingement while providing a scaffold for tissue ingrowth to occur as resorption of the device occurs. Some of the complications reported with use of this device include transient inflammatory reaction, which may be related to technical issues, as well as persistent pain requiring revision to abductor pollicis longus arthroplasty or screw removal [8, 10, 12]. Anecdotal reports, however, do suggest a significant complication rate associated with the Artelon implant that does not appear to be in the literature.

The goal of this study was to evaluate our short- to mid-term outcomes following Artelon spacer use in thumb CMC arthritis, with attention to the complications and any association between the complications and technical factors or patient characteristics.

Materials and Methods

A retrospective review of patients who underwent Artelon CMC arthroplasty by three fellowship-trained hand surgeons between May 2007 and October 2009 was performed. The study was exempt from approval by the institutional review board since it included a review of results by the treating surgeons. Twenty-nine patients, average age 51 ± 7.7 years (range, 34–66 years), were included in the study. Sixteen patients were male, and 13 were female. Fourteen right hands and 15 left hands were involved. Average follow-up was 8 months (range, 1–26 months). The indications for surgery were basal thumb pain that was not resolved by non-operative management, tenderness at the trapeziometacarpal joint, and radiographic evidence of thumb CMC joint arthritis. Underlying diagnoses included osteoarthritis in 27 patients, painful hyperlaxity in one patient, and posttraumatic arthritis in one patient who had persistent pain following failed trapeziometacarpal arthrodesis.

The surgical technique, as previously described [10], was modified at the discretion of the attending surgeon as follows. Articular surface osteotomy was performed of either the trapezium alone or both the trapezium and the metacarpal. Instruments used to perform the osteotomy included burrs, rongeurs, sagittal saws, osteotomes, or drills. The spacer was cut to the appropriate size to fit the patient's joint. The spacers were secured in position using screws, sutures, or suture anchors, and reinforced with additional suture as deemed appropriate. Additional procedures were performed on the thumb as necessary. These procedures included thumb CMC joint capsulodesis or extensor pollicis brevis transfer to abductor pollicis longus tendon to decrease thumb metacarpophalangeal hyperextension, and thumb A1 pulley release (Fig. 1).

Charts were also reviewed to evaluate the patients' postoperative course. Significant complications included cellulitis, excessive swelling, synovitis, delayed incisional healing, and persistent pain requiring treatment. The details of subsequent surgeries were also documented. Preoperative radiographs were reviewed for the stage of the arthrosis according to the classification of Eaton and Littler and the presence of metacarpal subluxation[4]. Preoperative radiographic evaluation demonstrated one stage 1 disease, 11 radiographs with stage 2, 13 with stage 3 and four with stage 4 diseases. Postoperative radiographs were reviewed for evidence of osteolysis, metacarpal subluxation, bony resorption or CMC joint interval narrowing (Fig. 2).

Fisher's exact testing was performed using Stata/IC version 11.0 (StataCorp LP, College Station, TX, USA; 2009) to identify associations between significant complications and either surgical technical factors or preoperative radiographic traits.

Results

Twelve patients (41%) demonstrated postoperative complications including cellulitis, excessive swelling, synovitis, delayed incisional healing, and/or persistent pain (Table 1). Nine patients (31%) demonstrated postoperative radiographic osteolysis and four patients (13%) required a conversion to CMC joint suspensionplasty. One of these was attributed to a traumatic postoperative injury. Intra-articular CMC screw penetration was not noted, although one patient was noted to have screw penetration into the first intermetacarpal space.

Screws were used for implant stabilization in 12 surgeries, sutures alone were used in four, and suture anchors were used in 13 cases. The implant was fixed to the trapezium alone in one case, to the metacarpal only in five, and to both bones in 23 surgeries. In 17 cases, the trapezium was osteotomized; in 12, both the metacarpal and the trapezium were osteotomized. The surfaces were not decorticated on 14 patients, and both surfaces were decorticated in 15 patients. The instruments used for the osteotomy included a burr, drill, osteotome, rongeur, and sagittal saw. The implant was modified (most often the distal phalange was cut) in seven cases. The occurrence of revision surgery was not significantly associated with any of these technical surgical factors.

Thumb subluxation was present in 22 of 29 cases. The occurrence of revision surgery was not significantly associated with preoperative radiological stage of disease or metacarpal subluxation. The occurrence of radiographic osteolysis was not significantly associated with the surgical technical factors or the preoperative radiological signs of instability. There tended to be more frequent osteolysis

Fig. 1 **a** Case 1: radiograph of the thumb carpometacarpal (CMC) joint. An Eaton stage 4 osteoarthritis is demonstrated [includes the scaphotrapezotrapezoidal (STT) joint] as well as significant narrowing of the joint with periarticular sclerosis and some cyst like lucencies. **b** Same patient immediately following surgery with an Artelon spacer and screw fixation. **c** Radiograph of the thumb CMC joint 5 months after surgery. Significant osteolysis can be seen surrounding the phalanges of the implant

when preoperative metacarpal subluxation was present as well as when osteotomy of the trapezium was performed without osteotomy of the metacarpal ($p=0.08$).

Discussion

Our study found a significant short-term rate of adverse events following Artelon spacer arthroplasty of the thumb CMC joint. Twelve of 29 patients demonstrated a clinical adverse event, while nine of 29 patients demonstrated radiographic osteolysis. Four patients underwent revision surgery. This rate is substantially higher than previously reported [8–11]. We could not identify any factors that were

significantly associated with the revision rate. There was no significant relationship to the type of fixation or to preoperative radiographic parameters of joint stability. Therefore, we could not substantiate a relationship between the stability of the implant and postoperative complications and osteolysis. The thumb CMC joint has 360° of motion and is therefore an inherently unstable joint, dependent on ligamentous stability. Perhaps, implant instability in this joint exists because of the joint characteristics, no matter what type of fixation, especially since the implant is traditionally attached to the metacarpal base, which is mobile. It is possible, however, that the cause of complications was not implant stability or that our study did not have enough power to detect a significant relationship. It is

Fig. 2 **a** Case 2: radiograph of the thumb carpometacarpal (CMC) joint. An Eaton stage 2–3 osteoarthritis is demonstrated with significant narrowing of the joint with periarticular sclerosis and many cyst like lucencies. **b** Same patient immediately following surgery with an Artelon spacer and screw fixation. The articular space is increased. **c** Radiograph of the thumb CMC joint 6 months after surgery. Significant osteolysis can be seen with subluxation

also possible that our indirect methods of evaluating stability do not truly reflect the actual stability of the implant in a given joint.

The reaction to the material itself may cause an inflammatory reaction with resultant synovitis and osteolysis. Although short term in vivo results of ACL reconstruction in rabbits and pigs using polyurethane urea have not shown significant adverse joint reactions, few reports of the use of this material in humans are documented [9].

Previous replacement of the trapezium with polyurethane has been noted to have outcomes similar to silicone arthroplasty, with fair to poor results in eight of 25 patients [10]. Radiographs revealed dislocation in ten of 25 implants, with no signs of obvious wear or adverse tissue reaction

around the implants [10]. The instability associated with this implant was attributed to lack of biological reaction to the polyurethane preventing encapsulation of the implant as occurs in silicone implants [10]. The few published results

Table 1 Postoperative complications ($n=12$ patients)

Complication	Number of patients	All patients (%)
Cellulitis	1	3
Swelling	3	10
Synovitis	1	3
Delayed incisional healing	2	7
Persistent pain	7	24

on the Artelon spacer are varied. One study comparing five patients who underwent APL tendon arthroplasty to five patients with Artelon spacer anchored with osteosutures and five patients with Artelon spacer anchored with titanium screws [11]. Grip and pinch strength showed greater postoperative improvement for the Artelon group than for the APL group at 3 years of follow-up, with no significant difference in thumb range of motion or in patient satisfaction [11]. Another study comparing 13 patients with Artelon spacer arthroplasty to 40 patients with APL arthroplasty with mean follow-up approximately 1 year found a statistically non-significant trend toward decreased patient satisfaction in the Artelon spacer group. There were no statistically significant differences between the two groups in grip or pinch strength or thumb range of motion [9].

One anecdotal report suggested satisfactory results “in the vast majority of cases” with only two of 50 patients requiring revision surgery (the need for revision was attributed to inadequate correction of bony deformity on the distal trapezium) [2, 3].

In summary, our study found a considerable rate of adverse events following Artelon spacer thumb CMC arthroplasty. Following our experience, the authors feel that, at this time, the use of artelon in the thumb CMC joint is unpredictable and have therefore considerably reduced its use in our practices. The study is a retrospective evaluation of patient charts and radiographs and has a limited number of subjects. Further study is needed to identify potential associations between the complications and either technical or preoperative factors. This would allow better delineation of the indications for the use of this device, and the appropriate surgical technique.

References

1. Amadio PC. What's new in hand surgery. *J Bone Joint Surg.* 2008;90A:453–7.
2. Choung EW, Tan V. Foreign-body reaction to the Artelon CMC joint spacer: case report. *J Hand Surg.* 2008;33A:1617–20.
3. Diao E. Foreign-body reaction to the Artelon CMC joint spacer. *J Hand Surg.* 2009;34A:1158–9. author reply 1159–1160.
4. Eaton RG, Littler JW. Ligament reconstruction for the painful thumb carpometacarpal joint. *J Bone Joint Surg.* 1973;55A:1655–66.
5. Ferrari B, Steffee AD. Trapeziometacarpal total joint replacement using the Steffee prosthesis. *J Bone Joint Surg.* 1986;68A:1177–84.
6. Heyworth BE, Jobin CM, Monica JT, et al. Long-term follow-up of basal joint resection arthroplasty of the thumb with transfer of the abductor pollicis brevis origin to the flexor carpi radialis tendon. *J Hand Surg.* 2009;34A:1021–8.
7. Hofmann DY, Ferlic DC, Clayton ML. Arthroplasty of the basal joint of the thumb using a silicone prosthesis. Long-term follow-up. *J Bone Joint Surg.* 1987;69A:993–7.
8. Jorheim M, Isaxon I, Flondell M, et al. Short-term outcomes of trapeziometacarpal artelon implant compared with tendon suspension interposition arthroplasty for osteoarthritis: a matched cohort study. *J Hand Surg.* 2009;34A:1381–7.
9. Liljensten E, Gisseloft K, Edberg B, et al. Studies of polyurethane urea bands for ACL reconstruction. *J Mater Sci Mater Med.* 2002;13:351–9.
10. Nilsson A, Liljensten E, Bergstrom C, et al. Results from a degradable TMC joint Spacer (Artelon) compared with tendon arthroplasty. *J Hand Surg.* 2005;30A:380–9.
11. Sollerman C, Hasselgren G, Westermark J, et al. Replacement of the os trapezium by polyurethane implants. *Scand J Plast Reconstr Surg Hand Surg.* 1993;27:217–21.
12. Tomaino MM, Pellegrini Jr VD, Burton RI. Arthroplasty of the basal joint of the thumb. Long-term follow-up after ligament reconstruction with tendon interposition. *J Bone Joint Surg.* 1995;77A:346–55.