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Special Issue

The use of the Artelon CMC Spacer for osteoarthritis of the basal joint of the thumb

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ABSTRACT

Introduction: Favorable clinical outcomes have been reported with the Artelon CMC Spacer, however, several studies have documented complications with the device.
Purpose of the study: The purpose of this study is to review a single surgeon's experience with the Artelon CMC Spacer for the treatment of basal joint arthritis of the thumb.
Methods: Five thumbs in 6 patients with symptomatic osteoarthritis of the thumb carpometacarpal (CMC) joint were treated with the Artelon CMC Spacer. The mean age of the patients was 60.8 years old. Patients were followed for a mean of 39.3 months (6–63) post-operatively.
Results: Complications occurred in 4 of the 6 thumbs and half of the thumbs required at least one secondary operative procedure. A documented foreign-body reaction was present in 2 of the 6 thumbs.
Discussion: The Artelon CMC Spacer is an interposition material that acts as a biologic spacer for arthritic joints while maintaining mechanical strength.
Conclusions: Due to an unacceptably high complication rate, we no longer use the Artelon CMC Spacer for the management of basal joint arthritis of the thumb.
Level of evidence: 4

The carpometacarpal (CMC) joint of the thumb is the second most common site of arthritis in the hand. Due to the functional requirements of the thumb, symptomatic arthritis often leads to measureable limitations for patients and is a common condition treated by hand surgeons and therapists. When conservative management fails to provide relief, patients often benefit from surgical intervention. There are numerous reconstructive procedures described for symptomatic osteoarthritis of the basal joint of the thumb. It remains unclear which surgical options are the best to maximize patient satisfaction and functional outcomes.[1,2]

Traditional techniques for surgical management of basal joint arthritis include either arthrodesis, implant arthroplasty, or trapeziectomy with or without some form of joint stabilization. Trapeziectomy with ligament reconstruction and tendon interposition (LRTI) remains a popular surgical option for advanced, symptomatic basal joint arthritis.

For younger patients, there is concern for the long-term durability of LRTI. These patients tend to be more active and are likely to put more stress on their thumbs. Similarly, because of their age, they require longer survivability of the index procedure or suitable revision alternatives. The Artelon CMC Spacer (Artimplant, Vastra Frolunda, Sweden) was developed as an option for this patient population.

Artelon is a degradable biomaterial that serves as a scaffold for tissue ingrowth. Because it is slowly degraded, it serves as a temporary support for healing tissue. It is a proprietary biomaterial composed of polyurethane urea. Artelon acts as mechanical support during the healing process. Simultaneously, it acts as a temporary scaffold for host cells. The material completely degrades in approximately six years, and about half of the original mass will remain at the site and is integrated into the host tissue.

Originally, the goal was to design a material to be used for reconstruction of the anterior cruciate ligament (ACL) in the knee. With different processing of the material, Artelon was able to be produced for different uses.[3] Spinning the polymer into fibers creates a filament that can be used as biologic spacer for the management of arthritic joints. The fiber maintains its mechanical strength through the degradation process and the company reports that it retains 50% of its tensile strength after four years.[4]

The Artelon spacer is a T-shaped fabric of the polymer that is inserted between the base of the thumb metacarpal and the distal

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trapezium after minimal resection of the arthritic joint. With the longitudinal limb in place at the CMC joint, the horizontal flaps of the spacer are secured to the dorsal metacarpal and trapezium respectively.

When evaluating new technology, several criteria must be satisfied in order to justify its use. Firstly, the technology must be proven to be both safe and effective to warrant its evaluation. Once this has been proven, the technology is evaluated for its potential benefits for the selected indication. Nilsson et al performed a pilot study to evaluate this new device in the treatment of basal joint arthritis of the thumb.[5] The rationale for the device was that the implant stabilizes the CMC joint by augmenting the joint capsule and resurfaces the distal aspect of the trapezium. It is a biological approach that provides a scaffold for tissue ingrowth while preventing impingement between the arthritic joint surfaces. In this study, they compared the Artelon spacer to trapeziectomy with tendon arthroplasty. Ten patients underwent the Artelon procedure while 5 control patients had a tendon arthroplasty. Follow-up was 3 years and results demonstrated better pinch strength in the Artelon patients with no difference between groups in range of motion or performance on the Sollerman Hand Function Test. Biopsy specimens were only obtained from one patient and showed incorporation of the spacer without evidence of foreign-body reaction.

Basal joint arthritis of the thumb typically affects older patients. The established treatment options yield excellent outcomes when evaluated for pain relief and return to activities of daily living. The long-term outcomes of these procedures, when performed in younger or high-demand patients, remain unknown. This creates an opportunity for new technology to potentially solve this problem. A new surgical technique that returns younger patients to high demand activities is an attractive alternative.

Inherent to new technology is a lack of long-term outcome data. In evaluating new technology, it is imperative for the surgeon to consider subsequent treatment options in the event that a procedure fails or lacks durability. While novel techniques or devices may prove effective in the short term, time and continued investigation are required to determine continued efficacy. In considering the use of Artelon for the treatment of CMC arthritis, the procedure does not limit the conversion to a standard LRTI at a later time. The concept of not "burning bridges" adds value to new technology.

Trapeziectomy with LRTI remains our preferred procedure for the operative management of basal joint arthritis of the thumb. The results of this procedure for older patients with refractory symptoms are generally very favorable. In our practice, patients have been very pleased with this intervention and have returned to low demand avocations and ADLs with minimal difficulty. The major dissatisfaction with this surgery is the prolonged rehabilitation and associated convalescence. We typically counsel our patients that they should expect not to use their thumb normally for four months post-operatively. The other concern for this procedure is its durability long term in younger, active patients.

Artelon spacers were specifically indicated for two cohorts of patients. Firstly, young, active patients who were otherwise indicated for a CMC arthrodesis were considered candidates for the spacer. Some patients do not desire arthrodesis because of the prolonged immobilization to attain union, the position of the thumb that prevents placing the palm flat, or the irreversible nature of joint fusion. Secondly, patients with early stage basal joint arthritis of the thumb that remained symptomatic despite conservative management were also considered candidates for Artelon spacers.

The surgical technique for implantation of the Artelon spacer is comparatively simple. A longitudinal incision is made over the dorsal aspect of the CMC joint. Full thickness skin flaps are elevated and care is taken to identify and protect the branches of the superficial radial nerve. The abductor pollicis longus (APL) tendon is retracted volarly and the extensor pollicis brevis (EPB) tendon is retracted dorsally revealing the CMC joint.

A distally-based periosteal flap inclusive of the joint capsule of the CMC is elevated, centered on the joint and measuring 2 cm in length. An oscillating saw is used to resect 1–2 mm of the distal trapezial articular surface into the subchondral bone. The resection is evaluated for the presence of bleeding bone and serial resections are made until this is confirmed. Osteophytes are removed with a rongeur.

The Artelon Spacer is inserted between the metacarpal base and distal trapezium with the longitudinal limb in the joint space and the transverse limbs overlying the dorsal surface of the metacarpal and trapezium. The underlying cortical bone on these surfaces is removed with a high-speed burr to achieve a bleeding surface. The transverse flaps are then secured with either suture anchors or 2.0 mm screws according to the surgeon's preferred technique. It has been our preference to use screw fixation for the spacer. The skin is then closed in layers with closure of the periosteal flap over the implant. Post-operatively, the surgical site is immobilized in a thumb spica orthosis or cast for a minimum of 6 weeks, but total immobilization can be up to 12 weeks.

A review of a single surgeon series at our institution yielded 6 cases utilizing Artelon spacers to treat basal joint arthritis of the thumb in 5 patients (Table 1). The mean age of the patients in this group was 60.8 years-old (45–71) and there was a mean follow up of 39.3 months (6–63). Complications were present in 4 of the 6 thumbs. The two thumbs without complications included a 45 year-old woman with excellent, pain-free function at 6 months post-operatively (Fig. 1) and a 71 year-old woman with moderate pain relief and function at 49 months after her surgery. The four complications included swelling at the surgical site in all cases with removal of Artelon spacer in two cases for documented foreign-body reaction, hardware complication requiring removal in one case, and failure of the spacer to completely incorporate in one patient.

One patient had screw loosening three months after her procedure and required removal of the screw. At the time of revision surgery, it was noted that there was only partial incorporation of the proximal flap of the spacer and the failed portion was excised. Synovial biopsy revealed chronic inflammatory cells present in the adjacent synovium. Her basal joint symptoms were improved but she still intermittently wore a hand-based thumb spica orthosis for some activities and 47 months after the index procedure, developed an area of erythema, swelling, and draining ulcer over the surgical site. It was unclear if this was secondary to the spacer or irritation from her orthosis, but it cleared with a course of oral antibiotics and local wound care.

A 58 year-old woman with bilateral CMC arthritis underwent the procedure on her dominant thumb and after excellent early

Table 1
Patients treated with the Artelon CMC Spacer

Patient	Age (yrs)	Follow-up (mos)	Complication	Treatment
1	45	6	None	None
2 right	58	63	Foreign-body reaction	Removal of Artelon, revision LRTI
2 left	58	58	Foreign-body reaction	Removal of Artelon, revision LRTI
3	59	11	Swelling	None
4	71	49	None	None
5	71	49	Hardware loosening, failure to incorporate, draining ulcer	Removal of hardware, partial excision of Artelon, oral antibiotics

Fig. 1. (A, B) Pre-operative X rays in a 45 year-old woman with symptomatic osteoarthritis of the right thumb CMC joint. (C, D) X rays obtained 6 months following implantation of the Artelon CMC Spacer.

results, elected to have her contralateral thumb treated with the same procedure. She had an excellent early result until 15 months after her first surgery (10 months after her second) when she developed an area of erythema, warmth, and swelling over bilateral thumbs at the surgical sites. She was afebrile and had no areas of fluctuance on examination nor leukocytosis on blood work. Radiographs demonstrated areas osteolysis at the CMC joint bilaterally. She subsequently underwent removal of both spacers and pathology demonstrated necrotizing granulomatous synovitis. The skin changes subsequently subsided however, her symptoms returned and she ultimately elected for bilateral trapeziectomies. At final follow-up 63 months after her index procedure, she still wore rigid thumb spica orthoses intermittently for symptom control.

Advantages of this surgical technique include its ease of use, faster operating time, maintenance of native anatomy, and its theoretical ability to stabilize the joint. Similarly, the minimal resection does not obviate the potential to perform a formal trapeziectomy and LRTI in the future if necessary. Disadvantages include a prolonged immobilization post-operatively and an oft-reported foreign body reaction that, while sterile, can be confused for infection.

Foreign-body reactions to Artelon spacers at the basal joint of the thumb have been well documented in the literature.[6–8] Choung and Tan reported a case occurring ten weeks after the initial surgery and documented a chronic inflammatory synovitis without evidence of infection on pathology.[6] Giuffrida et al reported a case of foreign body reaction at 9 months in a patient treated with Artelon spacer for scaphotrapezio-trapezoidal arthritis requiring implant removal.[7] Marked osteolysis was reported at the time of reoperation. Robinson et al also reported three cases of foreign-body

reaction associated with Artelon implants at the CMC joint.[8] All three patients required subsequent trapeziectomy to clear the reaction and stabilize the joint.

Clarke et al reported on complications associated with Artelon over a series of 29 patients with a mean follow-up of 8 months (1–26).[9] Twelve of the 29 patients (41%) sustained complications with osteolysis being most common. Twenty-two patients had evidence of joint subluxation post-operatively and 4 patients (13%) required revision surgery.

Nilsson et al performed a prospectively randomized, controlled multicenter study comparing Artelon CMC spacer with trapeziectomy and tendon interposition arthroplasty.[10] One hundred and nine patients were randomized to Artelon or trapeziectomy at a 2:1 ratio and followed for a minimum of one year. Swelling and pain were more common in the Artelon group (32% vs. 3%) and 6 spacers were removed for these symptoms. There was no significant difference between pain scores or pinch strength in each group. Overall, there were more complications and no demonstrable improvement in patients treated with the Artelon spacer as compared to trapeziectomy. These conclusions were shared by Jorheim et al.[11]

Conversely, Bell et al reported their experience with Artelon spacers and 4 year follow-up.[12] They had complete data on 49 of 69 patients and reported no complications and an overall improvement in pain, stability, Disabilities of the Arm, Shoulder and Hand (DASH) scores, and pinch strength. However, of the 20 patients with incomplete data, 4 were known to have implant removal for swelling and pain.

With regards to post-operative therapy for patients treated with the Artelon spacer, the rehabilitation process was very similar to most other physician directed treatment regimens used in CMC arthroplasties. Review of patients treated with Artelon spacers at our institution revealed that the most noticeable deviation in therapy was the duration of immobilization required. Unlike a trapeziectomy, where immobilization of the CMC joint is between 4 and 8 weeks depending upon physician preferred program, surgery utilizing Artelon spacers require 10–12 weeks of immobilization. Despite the increased immobilization time, these patients still required few clinical visits (2–4 visits). Similar to a trapeziectomy, the rehabilitation program primarily consists of a custom hand-based thumb spica orthosis with the IP joint free and patient education providing a structured home program. Home programs typically included a combination of the following: custom orthoses, prefabricated orthoses, range of motion (A/AA/PROM) of forearm, wrist, and hand, scar management, edema control, desensitization, strengthening for grip and pinch, progressive resistance exercise for wrist, and resisted thumb abduction exercise, and modalities as clinically relevant. Due to the limited number of patients at our institution who underwent this procedure, there is not a clearly defined sample clinic regimen. Evaluation includes range of motion measurements of wrist and hand, grip and pinch strength testing, an outcome measure (QuickDash) and patient self reported functional goals. The identified limitations would dictate which treatment interventions would best serve that individual patient.

As with all basal joint procedures, the specific procedure, intraoperative findings, comorbidities, patient factors, and surgeon preference will dictate length of immobilization and a general therapy guideline. But since many of these factors are based on anatomy, biology, and wound healing principles, therapists need to understand the surgical techniques performed and how these affect the rehabilitation. Unlike an LRTI, when you can typically initiate opposition of the tip of the involved thumb to small finger at 6 weeks, patients who have undergone an Artelon spacer initiate opposition at 10–12 weeks. It is imperative to educate the patient to develop new motor planning patterns at the CMC joint. Utilization of custom orthoses, range of motion exercises, and isometric strengthening of the opponens pollicis can be incorporated to prevent pre-surgical compensatory or deformity patterns such as CMC adduction, CMC flexion, and MCP hyperextension during functional use.

One of the inherent challenges to the application of new technology is often a paucity of data to guide decision-making for clinicians. Similarly, there are typically no mid- or long-term results to share with patients in order to help with their understanding of outcomes. There is no published data to guide therapy protocols for patients treated with Artelon spacers. In reviewing our cohort of patients treated with Artelon spacers, the duration of post-operative immobilization is longer than for traditional LRTI patients. This likely represents the learning curve of applying new technology. Despite the theoretical ability to utilize an expedited rehabilitation, we were conservative in our evaluation and advancement of patients post-operatively.

Applying advances in technology has the potential to significantly improve patient outcomes and change the way in which we manage common disorders like basal joint arthritis. Thoughtful evaluation of techniques and subsequent follow-up is critical to determine its risks, benefits, and outcomes. As surgeons and therapists, we must remain committed to providing our patients with the best available surgical techniques and therapies.

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Quiz: #306

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#1. The Artelon CMC spacer was developed because of a concern for
   a. synovitis secondary to the traditional implant
   b. cost
   c. the projected limited usefulness of the LRTI in female amateur athletes
   d. the durability of the LRTI anchovy over time, especially in a younger patient population

#2. After 4 years, the Artelon material retains _____ % of its tensile strength
   a. 50
   b. 75
   c. 95
   d. 5

#3. Post operatively a thumb spica is utilized for a period of
   a. 10-12 weeks
   b. 4 weeks
   c. 6 weeks
   d. 8 weeks

#4. A departure from other post op regimes is that in therapy following an Artelon CMC spacer
   a. only Artelon trained and licensed orthotists are permitted to construct the thumb spicas
   b. thumb opposition is delayed until 10-12 weeks
   c. the hand therapist applies the spica in the OR
   d. surface biofeedback is routinely ordered

#5. The paper offers significant evidence of a direct correlation between bad outcomes and splint usage
   a. true
   b. false

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