Clinical Evaluation of the Articulinx Intercarpometacarpal Cushion for the First CMC Joint: A Feasibility Study

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Abstract

Background The Intercarpometacarpal Cushion (ICMC; Articulinx, Cupertino, CA, USA) is an implantable spacer designed as a less invasive surgical treatment for osteoarthritis (OA) of the first carpometacarpal joint (CMC-1).

Description of Technique Following local anesthesia and exposure of the joint capsule the ICMC, attached to a needle and suture tethers, is guided into the joint space under fluoroscopic visualization through a dorsal approach. The needle is pulled through the thenar eminence to the opposite side of the hand and, once proper device placement is confirmed, cut free and the joint capsule closed.

Patients and Methods Eight female patients (median age 56 years; range, 42–83) were treated and followed for 6 to 24 months. Safety of the implant procedure was evaluated intraoperatively. Pain, joint function, and strength were evaluated at 6 weeks, 3, 6, 12 and 24 months with a Visual Analog Scale (VAS) for pain, the QuickDASH inventory, Canadian Occupational Performance Measure (COPM), and pinch and grip strength measurements.

Results At 2 years ($n = 6$), mean VAS pain scores decreased from $6.3 (\pm 1.5)$ to $2.2 (\pm 1.1)$ ($p < 0.001$), mean QuickDASH scores improved from $47 (\pm 15)$ to $31 (\pm 11)$ ($p < 0.10$), mean COPM performance scores improved from $5.0 (\pm 1.2)$ to $5.5 (\pm 1.3)$ ($p = \text{NS}$). Mean pinch and grip strength measurements also improved compared with baseline. No serious adverse events occurred. Two device removals occurred, associated with a traumatic event and Stage IV OA with device displacement, at 6 and 9 months respectively.

Conclusion The ICMC can be implanted safely. Effectiveness needs to be confirmed in future studies.

Keywords

- carpometacarpal
- osteoarthritis
- spacer
- arthroplasty
- intercarpometacarpal cushion

Osteoarthritis (OA) is the most common arthritis worldwide.¹ OA occurs most commonly in the hand and can severely limit daily activities, reducing productivity at home and work. Because the thumb supports half the workload of the hand, the carpometacarpal joint of the first ray of the hand (CMC-1)

is particularly susceptible to wear and tear and the development of OA.

Nonsurgical treatment of CMC-1 arthritis includes anti-inflammatory medication, thumb spica splint immobilization, occupational therapy, and intra-articular corticosteroid

injection. Even though none of these measures provides long-lasting relief, there is general agreement that more conservative nonsurgical alternatives should be considered first when treating symptomatic CMC-1 arthritis, especially during early disease stages.

Because current surgical procedures grossly alter the anatomy of the joint space by materially changing the articular relationships among the native bone and soft tissues, they also alter normal biodynamics, resulting in reduced strength and grip function. Consequently, such procedures are not recommended for younger or active patients, particularly early in the disease cycle. Current surgical remedies are generally indicated late in the disease cycle, when pain is persistent and unresponsive to other nonsurgical measures. These procedures may include ligament reconstruction of the CMC-1 joint,¹⁻³ metacarpal extension osteotomy,²⁻⁶ total joint arthroplasty,⁷ silicone arthroplasty,⁸ carpometacarpal arthrodesis,^{9,10} implant arthroplasty,^{11,12} and trapezium resection with or without ligament reconstruction and soft tissue interposition.¹³⁻¹⁵

Total or hemiresection of the trapezium is the most commonly performed procedure and is associated with high rates of pain relief. However, it is also associated with proximal metacarpal migration, leading to loss of thumb length and inconsistent results with respect to improved pinch and grip strength.¹⁶⁻¹⁹ Arthroscopic hemitrapeziectomy, which has the advantage of a less invasive surgical approach, is gaining in popularity, and good mid- to long-term outcomes have been reported; however, this procedure still requires bony resection.^{20,21}

Trapezium-sparing surgical options are being explored but have not gained widespread adoption, in large part because of the high degree of technical difficulty associated with such procedures.^{16,22} CMC-1 arthroscopy is a minimally invasive procedure that targets early-stage OA.²³⁻²⁵ Arthroscopic débridement and synovectomy, with or without electrothermal shrinkage of the volar ligaments, have been used in the treatment of early-stage CMC-1 OA with good results.²⁶⁻²⁹ Selective denervation of the CMC-1 joint has also been reported, with pain relief reportedly comparable to that achieved with trapeziectomy or joint fusion and associated with minimal complications.³⁰

Bone-on-bone contact following the loss of articular cartilage is an important contributing factor to pain and reduced mobility and function in patients with CMC-1 OA, and most of the above-described surgical procedures involve bony resection to eliminate the source of pain. Articulinx, Inc. (Cupertino, California, USA) has developed the "Intercarpometacarpal Cushion" (ICMC), an implantable spacer, as a minimally invasive alternative that does not require bone or tissue resection.

The purpose of this feasibility study was to evaluate the safety of the device and implantation procedure in patients with CMC-1 OA. Patients were followed up to 2 years to evaluate whether treatment with the ICMC results in pain relief, and improved function and strength.

Level of Evidence. Level IV case series

Surgical Technique

The ICMC is an implantable device with a central bearing surface consisting of a Nitinol radiopaque marker with a polymer over-molding (►Fig. 1). It is supplied with a delivery system comprising a standard tapered needle and primary/auxiliary suture tethers.

All implantation procedures are performed by two senior hand surgeons trained to use the ICMC. The patients are given a single-dose of antibiotics prophylactically before surgery. The joint is anesthetized using a local intraarticular lidocaine injection, and a tourniquet is applied. Using a dorsal approach, the ICMC is implanted between the extensor pollicis brevis (EPB) and extensor pollicis longus (EPL) tendons through a 1-cm incision and 1-cm transverse arthrotomy (►Fig. 2a). Prior to device insertion, a Freer elevator is inserted through the arthrotomy into the joint space under fluoroscopy to confirm the implantation trajectory (►Fig. 2b). Starting on the dorsoradial aspect of the thumb, the ICMC is delivered into the CMC-1 joint using a straight needle temporarily tethered to the device with nonabsorbable braided polyester suture material. First the needle is passed through the incision/arthrotomy and joint space between the metacarpal and trapezial articular surfaces, exiting the thenar eminence with the needle directed toward the fifth metacarpophalangeal (MCP) joint. Once the needle and primary suture/tether are pulled through the joint space, the needle is cut away from the suture/tether (►Fig. 2c). Aligning the ICMC with the joint plane, the surgeon compresses the device with one hand while pulling on the suture/tether (from the palmar side) with the other hand until the ICMC enters the joint space. Once in situ, the ICMC conforms to the articular surfaces within the joint, which can be confirmed fluoroscopically along with correct positioning of the device. If necessary, the primary and auxiliary tethers can be used to adjust the implant position until it is

Fig. 1 The Articulinx ICMC implant is a C-shaped ring with a central modified bearing surface. The ring is constructed of two components: a Nitinol (nickel titanium alloy) "backbone" with an over-molding of polycarbonate urethane (PCU).

Fig. 2 (a) A small stab incision (< 1 cm) is made in the skin. (b) Open the joint space by making a small transverse arthrotomy, insert a Freer elevator into the joint space, and confirm its correct position under fluoroscopy. (c) Pull the needle and primary delivery suture tether through the joint. On the palmar side the needle may be removed from the suture. Align the implant with the plane of the joint space and continue pulling on the primary delivery suture until the device enters the joint space.

positioned centrally within the joint. Once satisfactory position is confirmed fluoroscopically, the primary and auxiliary suture-tethers are cut and removed and the arthrotomy and incision are closed with absorbable suture. The treated hand is immobilized postoperatively using a thumb spica cast for 2 to 4 weeks. After removal of the spica cast, the patient is provided with a removable splint and instructed to begin active range of motion (ROM) exercises.

Patients and Methods

This first-in-human (FIH) clinical feasibility study was conducted at the Vrije Universiteit (VU) University Medical Center (Amsterdam, The Netherlands) and approved by the University Medical Center Ethics Committee. The first eight patients enrolled in this feasibility study, the majority of whom had stage III CMC-1 OA according to the Eaton-Littler classification,³¹ were treated with a prototype (first-generation) device that was discontinued due to a design flaw (five devices failed, all of which were removed; three devices remained in situ through 2-year follow-up). This report describes the clinical experience of eight patients implanted with the second-generation (Gen 2) ICMC device.

Adults with symptomatic Stage I, II, or III osteoarthritis of the CMC-1 joint were enrolled. Key exclusion criteria included presence of significant osteophytes in the CMC joint, significant pathology of the radial side of the hand and wrist (e.g., scaphotrapeziotrapezoid [STT] OA), prior CMC joint surgery that precluded device placement (e.g., trapeziectomy), and metabolic disorders affecting the bone (e.g., osteomalacia). Patients with CMC-1 joint subluxation greater than one-third were not initially excluded from this feasibility study, but the protocol was amended to exclude these patients after it was determined that excessive joint instability and subluxation was associated with poor outcomes in patients treated with the first-generation device.

Patients were enrolled and treated with the Gen 2 ICMC in May 2009 and June 2009. All patients were examined by both a resident in hand surgery and a hand therapist before surgery for baseline measurements and at 3, 6, 12, and 24 months follow-up. Radiographs were taken prior to surgery and at each follow-up visit.

Clinical outcomes included pain severity, joint function/disability, and strength. Pain was evaluated using a 10-cm Visual Analogue Scale (VAS), with a 0–10 scale (0 = no pain, 10 = unbearable pain). Subject-perceived disability was evaluated using the QuickDASH questionnaire with values ranging from 1 (“no difficulty/none”) to 5 (“unable/extreme”).³² Subject-perceived occupational performance was evaluated using the Canadian Occupational Performance Measure (COPM; Law, Baptiste, Carswell, McColl, Polatajko & Pollock, Hamilton, Ontario, Canada).³³ Tripod pinch and lateral key pinch strength were measured using a pinch gauge (B&L Engineering, Santa Ana, California, USA), and transverse volar grip strength was measured using a dynamometer (Jamar, Patterson Medical, Bolingbrook, Illinois, USA).

Results

Eight female patients with symptomatic CMC-1 joint OA were treated with the Gen 2 ICMC (► **Table 1**). No patient was lost to follow-up, and, aside from two patients who had the device removed, all patients were followed for 2 years. The median age was 56 (range, 42–83) years. In six cases, no prior surgery of the CMC-1 joint had been performed. Two patients had previously been implanted with the prototype (Gen 1) ICMC which failed in situ, and both requested reimplantation with the Gen 2 devices.

Among the 6 patients with 2-year follow-up, average VAS pain intensity decreased significantly (from 6.33 ± 1.51 at baseline to 2.25 ± 1.08 , $p < 0.001$). Average QuickDASH and COPM scores and postoperative pinch and grip strength also improved (► **Table 2**).

Two device removals occurred, associated with a traumatic event and stage IV OA with device displacement, at 6 and 9 months, respectively. In both cases, the devices were removed without complication, and concomitant trapeziectomy with ligament arthroplasty was performed.

Discussion

There are few surgical options available to patients with symptomatic CMC-1 OA that do not involve bone or tissue removal. There remains an unmet need to develop

Table 1 Patients treated with the Gen 2 Articulinx ICMC

Patient	Age (years)	OA Stage	CMC > 1/3 Subluxed	Followed (months)	Prior CMC Surgery
09	42	II	No	6 ^a	No
10	83	III/IV	No	8 ^a	No
11	42	III	No	24	No
12	47	II	No	24	No
13	52	II	No	24	No
14	60	II	No	24	No
15*	60	III	Yes	24	Yes ^b
16*	62	III	Yes	24	Yes ^b

^aDevice explanted and trapeziectomy/ligament arthroplasty performed.

^bPreviously implanted with the first-generation ICMC.

alternatives for those patients who desire symptom relief but do not want permanent, joint-modifying surgery and also do not wish to, or cannot, undergo long-term pharmaceutical management of their symptoms.

The Articulinx ICMC is a nonautogenous interpositional spacer that can be implanted without bone or tissue removal using a joint-preserving, less invasive surgical approach that leaves future treatment options open. Other interpositional spacers are currently commercially available in the United States or Europe, but they do not offer the advantage of complete joint preservation. The Artelon CMC Spacer and Artelon CMC Spacer Arthro (Artimplant, Västra Frölunda, Sweden) are bioresorbable, polycaprolactone-based polyurethaneurea (PURR) interpositional spacers designed to treat patients with early- to mid-stage CMC-1 OA.^{34,35} However, implanting the Artelon spacers requires cartilage resection and device fixation, and there have been recent reports of foreign body reaction not related to the method of fixation or suture material.³⁶ The PyroDisk (Integra LifeSciences Corp., Plainsboro Township, New Jersey, USA) and Pyrocardan (Tornier, Inc., Montbonnot Saint Martin, France) are pyrocarbon-based interpositional spacers that have recently become commercially available in Europe.³⁷ As of this writing, reports of clinical experience for these pyrocarbon products have not yet been published in peer-reviewed literature. Other synthetic materials that have been used for interpositional arthroplasty, with mixed results, include Gore-Tex (polytetrafluoroethylene), Marlex (polypropylene), Gelfoam, and Zirconia.³⁸

The results from this feasibility study suggest the Articulinx ICMC holds promise as a new surgical treatment alternative for CMC-1 OA patients. However, the results also showed that further device design improvements were necessary. The Nitinol radiopaque marker was subject to loading fatigue, and at routine follow-ups, radiographic examination revealed breaks in the marker in the majority of devices. Because there were no serious adverse clinical events associated with the wire breaks, and since the wire remained embedded within the PCU, the devices were not explanted at the time the wire breaks were observed. Subsequently, the

ICMC has been modified to replace the Nitinol radiopaque marker with a polymeric marker.

In two cases, the device was explanted within the first year. One subject suffered an acute external trauma to the treated hand 3 months after her device was implanted. Pain and swelling did not resolve after the incident, and ~6 months after the ICMC was implanted, it was explanted and a trapeziectomy and ligament arthroplasty performed. In the second case, the subject was 83 years old with stage III/IV CMC-1 OA with significant joint subluxation and concomitant STT joint disease, and she was treated under a protocol exemption. The subject complained of insufficient pain resolution and at 6 weeks, X-rays showed the device displaced to the medial side of the joint. After an additional 8 months of conservative therapy, the ICMC was explanted and a trapeziectomy and ligament arthroplasty performed.

This study revealed some specific considerations regarding the use of the ICMC in treating OA in the CMC-1 joint. Perhaps of greatest importance, because the ICMC is unconstrained within the joint space, joint laxity (implied by the presence of extensive subluxation) may not sufficiently constrain the ICMC to keep the device properly positioned between the articular surfaces of the CMC-1 joint. The results of this study suggest that the ICMC is less effective in cases where the target CMC-1 joint is subluxed greater than one-third and, as a consequence, the ICMC's ability to relieve pain is compromised.

Additionally, notwithstanding the minimally invasive nature of the implantation procedure, postoperative recovery time is longer than was originally envisioned. Pain originates in OA from bone-on-bone contact and from associated peri-articular and synovial inflammation. This is further provoked by the insult of the surgical intervention into the joint capsule. Therefore, postoperative recovery will involve recovery from the procedure as well as recovery from the inflammation. All of this must pass before the effect of the implanted device can be appreciated. To facilitate this process, subjects may need to be splinted for up to 4 weeks and nonsteroidal anti-inflammatory drugs (NSAIDs) prescribed for ~4–6 weeks postoperatively as needed to help reduce inflammation. Subsequently,

Table 2 Results of treatment at 24 months postoperative

Variable	All Patients		Completed Patients	
	Baseline	Post-treatment	Baseline	Post-treatment
	Mean $\pm$ SD ($n = 8$)	Mean $\pm$ SD ($n = 8$)	Mean $\pm$ SD ($n = 6$)	Mean $\pm$ SD ($n = 6$)
VAS Pain (0 to 10)				
At rest	5.25 $\pm$ 2.38	2.25 $\pm$ 3.11 ^a	4.67 $\pm$ 2.42	0.67 $\pm$ 1.03 ^a
With activity	8.25 $\pm$ 1.28	4.88 $\pm$ 2.47 ^a	8.00 $\pm$ 1.26	3.83 $\pm$ 1.83 ^a
Average	6.75 $\pm$ 1.49	3.56 $\pm$ 2.61 ^a	6.33 $\pm$ 1.51	2.25 $\pm$ 1.08 ^a
QuickDASH (0 to 100)				
Function	50.6 $\pm$ 14.8	34.9 $\pm$ 11.2 ^b	47.0 $\pm$ 15.3	31.8 $\pm$ 10.8 ^c
COPM (1 to 10)				
Performance	5.00 $\pm$ 1.14	5.55 $\pm$ 1.16	5.00 $\pm$ 1.19	5.50 $\pm$ 1.30
Satisfaction	2.63 $\pm$ 1.76	4.87 $\pm$ 1.68 ^c	2.10 $\pm$ 1.31	5.16 $\pm$ 1.40 ^b
Strength (kg)				
Lateral key pinch	3.86 $\pm$ 1.66	4.79 $\pm$ 1.75	3.35 $\pm$ 1.35	5.32 $\pm$ 1.53 ^c
Tripod pinch	2.73 $\pm$ 1.43	4.38 $\pm$ 1.69 ^c	2.43 $\pm$ 1.36	4.65 $\pm$ 1.64 ^c
Grip	11.54 $\pm$ 9.32	15.84 $\pm$ 6.13	11.55 $\pm$ 9.74	18.12 $\pm$ 4.20

For explanted patients, the last value prior to explant was used.

VAS and QuickDASH: low scores are best; COPM and Strength: high scores are best.

^aSignificantly different from baseline according to paired *t*-test, $p < 0.01$.

^bSignificantly different from baseline according to paired *t*-test, $p < 0.05$.

^cSignificantly different from baseline according to paired *t*-test, $p < 0.10$.

subject and surgeon expectations must be managed to ensure an understanding that even though the procedure is minimally invasive, inflammation associated with OA takes time to abate, and recovery may take several weeks.

Overall, the results from this feasibility study demonstrated that the Articulinx ICMC can be successfully implanted following a minimally invasive approach. No hard or soft tissue was altered or removed during the procedures, and the average procedure time was 13.4 minutes—substantially lower than other current arthroplasty procedures. Furthermore, no intraoperative adverse events occurred, and no serious postoperative adverse events occurred during 2-year follow-up. Among the six patients who were followed for 2 years, average pain scores, QuickDASH symptom disability scores, COPM performance scores, and pinch and grip strength measurements showed substantial improvements compared with baseline. These results suggest the Articulinx ICMC may be a promising alternative, and further study of the new, modified device design is necessary.

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Conflict of Interests

The study was sponsored by Articulinx, Inc., Cupertino, California. The sponsor monitored the study, collected, and

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