Medical Research Archives

European Society of Medicine

OPEN ACCESS

Published: November 30, 2023

Citation: Lofink S and Trumble T, 2023. Ensemble Pyrocarbon™ Hemiarthroplasty for the Treatment of Painful Thumb Carpometacarpal Joint Arthritis with Sparing of the Trapezium, Medical Research Archives, [online] 11(11). https://doi.org/10.18103/mra.v11i11.4642

DOI
https://doi.org/10.18103/mra.v11i11.4642

ISSN: 2375-1924

RESEARCH ARTICLE

Ensemble Pyrocarbon™ Hemiarthroplasty for the Treatment of Painful Thumb Carpometacarpal Joint Arthritis with Sparing of the Trapezium

Spencer Lofink, B.S.*; Thomas Trumble, MD

***Corresponding author:** spencerl@bellevuehand.com

ABSTRACT:
Due to its remarkable mechanical properties and excellent biocompatibility, Pyrocarbon™ is an ideal material for articular use. Various Pyrocarbon implants for the hand and wrist have been developed over the past 25 years. The Ensemble implant is unique in that it can be inserted as a minimally invasive hemiarthroplasty technique that does not require any preparation to insert a stem into the thumb metacarpal. The device has a unique three-dimensional design that locks onto the surface of the trapezium without requiring any internal fixation. We report on our first 12 cases with 1 year follow-up. There was significant improvement in the DASH score and pinch strength at 1 year follow-up ($p < 0.5$) with no significant decrease in thumb motion or instances of dislocation. One patient was revised due to rapid progression arthritis at the scaphoid trapezial interface that required revision to an arthroplasty with complete removal of the trapezium.

Introduction:

Thumb arthritis is an extremely common and painful condition that limits patient strength and dexterity. When conservative methods of bracing and injection of steroid, medication, or other biologic compounds are not successful, arthroplasty or arthrodesis of the thumb basal joint is the only other alternative.[1-4] The choices for thumb arthroplasty can be broken down into the following options:

1. Hemiarthroplasty with
    a. An interposition position spacer
    b. No interposition spacer
2. Complete Excision of the Trapezium with
    a. No interposition spacer
    b. An interposition spacer without ligament reconstruction
    c. Ligament reconstruction and an interposition spacer
3. Thumb CMC joint arthrodesis

When the arthritis mainly involves the carpometacarpal thumb joint and spares the scaphotrapezial joint, the surgeon has the option for a less invasive technique that spares most of the trapezium. Operations that fully excise the trapezium result in the loss of the key fulcrum the trapezium provides for thumb pinch strength and stability. Biomechanical studies have demonstrated that with the absence of a trapezium, proximal thumb migration occurs, and only the use of an implant to replace the trapezium can this be prevented.[5] Without the trapezium, the thumb often becomes shorter and is weaker. Although biologic implants using materials such as human cartilage have been successful as a spacer to relieve the pain from the arthritic CMC joint, the supply of allograft cartilage is unreliable, especially in terms of their availability as well as the size of the material available.[6] Furthermore, if the ligaments do not heal as strong as the original ligaments, the thumb has an increased degree of instability. The Ensemble implant is ideally suited for thumb hemiarthroplasty because it is fabricated from a Pyrocarbon material that is extremely durable with excellent biologic compatibility.[7-12] The other devices that are used as a spacer require a stem that is inserted into the metacarpal. In order to create the space necessary to insert the stem, most of the key thumb ligaments have to be divided and repaired during surgery. The repaired ligaments may heal, but the healing time for the ligaments also increases the time that the patient must be immobilized post operatively. Furthermore, if the ligaments do not heal as strong as they were preoperatively, an increased degree of thumb instability has been created. The Ensemble implant is designed with unique three-dimensional prominences that lock onto the trapezium to provide stability (Figure 1). As a result, this device can be inserted with minimal disruption of the key ligaments that stabilize the thumb, resulting in a more stable thumb arthroplasty that eliminates proximal migration of the metacarpal to prevent loss of pinch strength.

Fig 1: The unique design of the Ensemble implant with special prominences or "bumps" allows it to fit in a stable fashion as a spacer in the thumb carpometacarpal (CMC) joint.

Methods:

The Ensemble device was available in 2021 as a thumb hemiarthroplasty for the use of stage I carpometacarpal (CMC) arthritis (Figure 2). [1] All candidates had persistent pain despite nonoperative treatment with bracing and/or steroid injections. The study was HIPPA compliant and conformed to the ethical guidelines of the 1975 Declaration of Helsinki, and institutional review board approval was obtained. The goal of this study was to evaluate our first cohort of patients treated with the Ensemble implant in a group of patients with arthritis limited to just the CMC joint (stage one CMC arthritis). The inclusion criteria were patients with stage one CMC arthritis who failed

conservative treatment that included bracing, anti-inflammatory medications, and steroid injections). The results of the patient's range of motion, grip strength, and pinch strength, as well as the DASH questionnaire and the VAS pain score were compared between preoperative and postoperative evaluations to determine if arthroplasty with the Ensemble implant was able to improve the patient's objective measurements, as well as their subjective outcome scores. The grip strength, pinch strength, and range of motion measurements were obtained in a blinded fashion by the hand therapists working with the patients.

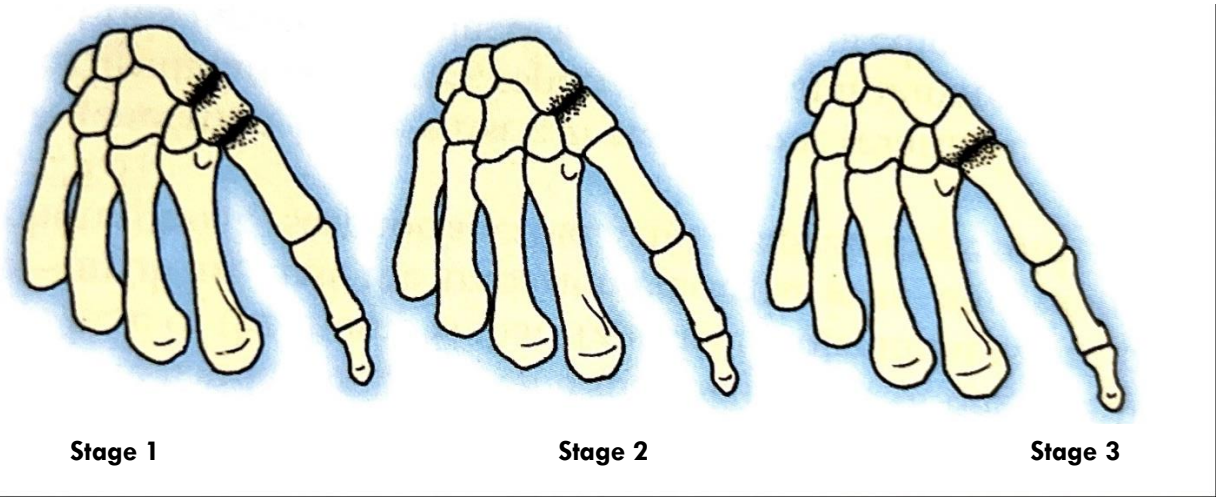


Fig 2: The more practical classification for CMC joint arthritis involves three stages. 1. Arthritis that only involves the CMC joint. 2. Arthritis that only involves the scaphotrapeziotrapezoidal (STT) joint. 3. Arthritis that involves both the CMC and the STT joints.

Contraindications to the use of the Ensemble implant:

Patient selection and surgical technique: Patient selection and sound surgical principles apply to the use of the Ensemble CMC in each clinical setting. The decision to use an implant as well as the size and shape of the implant used must be based on sound medical judgment. The CMC Ensemble implant should not be used if any of the following are present:

1. Evidence of deformity at the base of the metacarpal
2. Infection in the joint
3. Inadequate bone stock or soft tissue integrity
4. Skeletal immaturity
5. Patient is unwilling or unable to follow post-operative care instructions.

Surgical technique:

The first step is to use x-rays to identify the center point of the trapezium on a lateral view with fluoroscopy (Figure 3). A hypodermic needle can be placed to mark the spot as the center point of the thumb CMC joint on the lateral x-ray. Next, a 2 cm skin incision should be made in line with the glabrous of the skin (Figure 4). The sensory branches of the radial nerve are retracted. Once the joint capsule has been exposed with retraction, the abductor pollicis longus, (APL) is then mobilized and retracted, so that incision can be made between the anterior oblique ligament (AOL) and the dorsal radial long ligament (DRL) (Figure 5). Using rongeurs, a power bur and /or the peripheral rasp, the medial osteophyte is completely removed (Figure 6). The bump/saddle rasp is used to create the convexities necessary to help the ensemble implant lock into the thumb metacarpal-trapezial space (Figure 7). The trial implants have a handle on them to make them easy to manipulate, and they are used to check that the implant correctly engages the base of the thumb metacarpal as well as the distal surface of the trapezium (Figure 8). This placement should then be checked on both AP as well as lateral fluoroscopic views (Figure 9). The final radiopaque implant is inserted by hand with fluoroscopic images to confirm the correct placement of the implant (Figure 10).

Post-operative Rehabilitation:

Postoperatively, the patients were mobilized in a fiberglass splint for one week. After one week, the fiberglass was removed and a removeable forearm-based splint was applied by the hand therapists. The patients were encouraged to begin gentle wrist and thumb motion at this time. Four weeks after the surgery, the patients were placed into a hand-based removable splint, while the therapy was directed at improving the thumb motion. At 8 weeks after the surgery, the patients graduated out of any remaining splint use and started on a strengthening program in therapy.

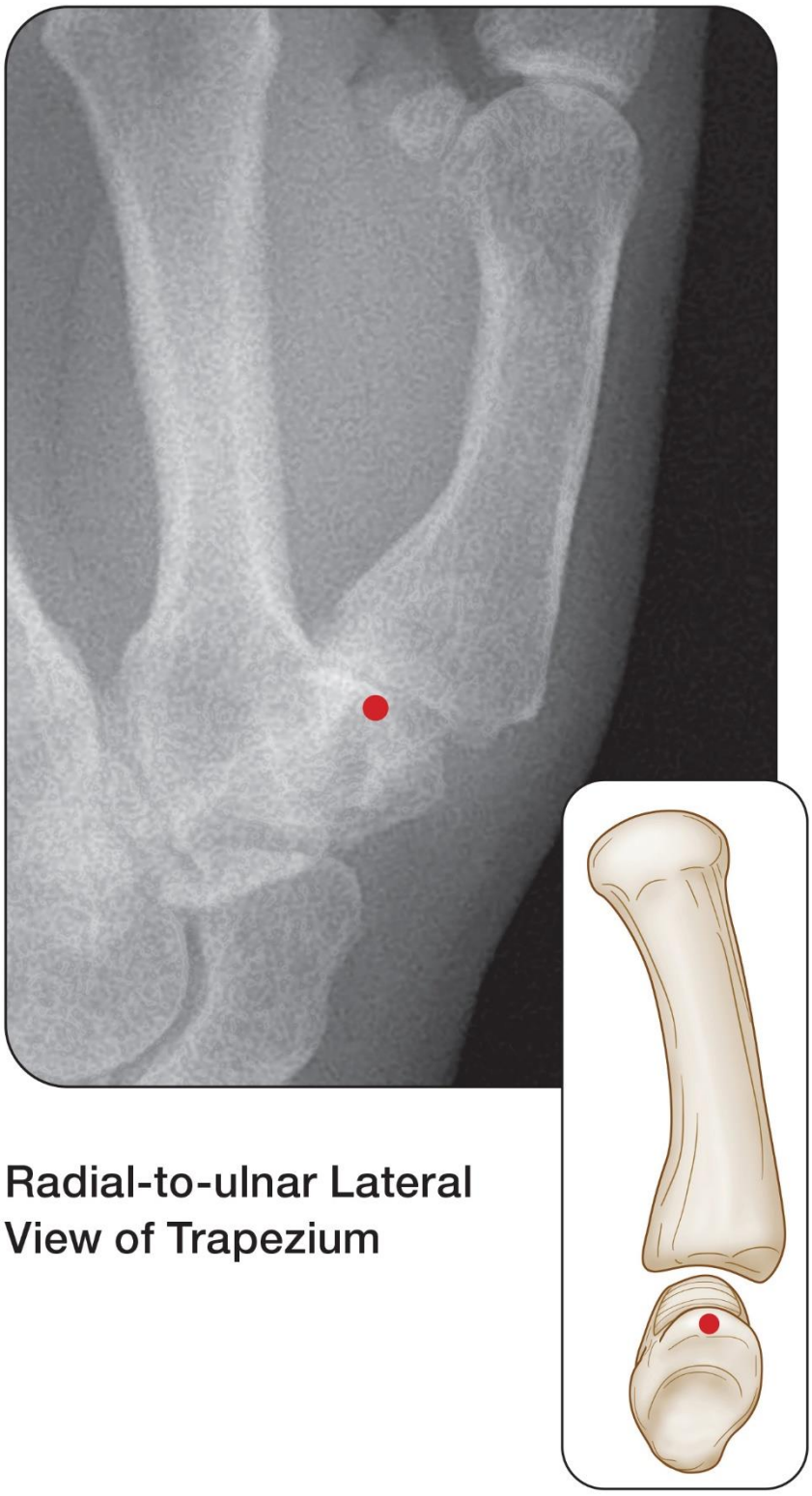


Fig 3: Make a 2 cm Glabrous skin incision centered on the CMC joint exposing the palmar edge of the APL. Make a capsular incision along APL. Elevate capsule edges and APL to expose radial horn of trapezium.

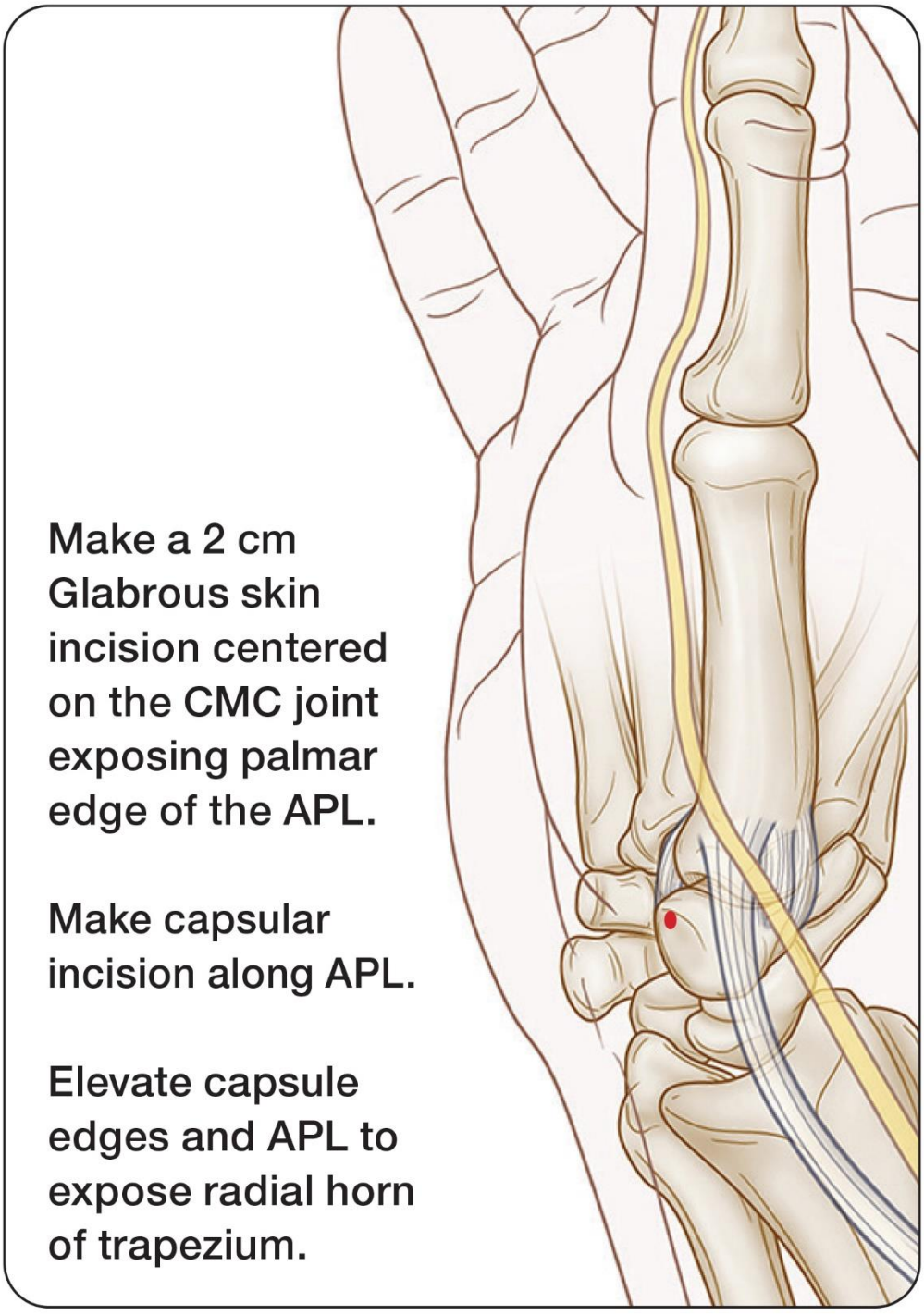


Fig 4: The Radial-to-ulnar Lateral View of Trapezium helps the surgeon pick the center point for the incision.

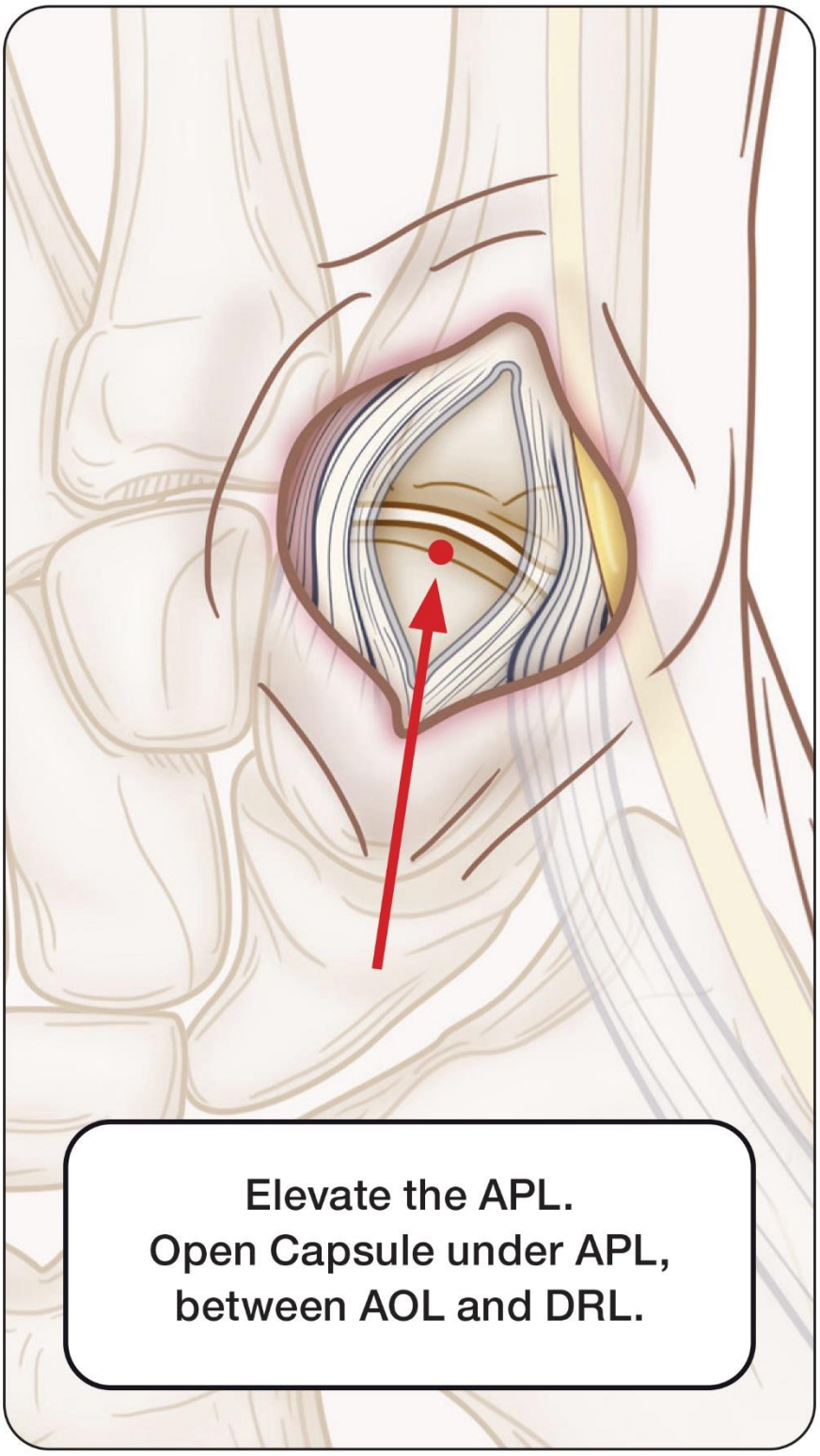


Fig 5: Next, elevate the APL. Open the capsule under APL, between the AOL and DRL.

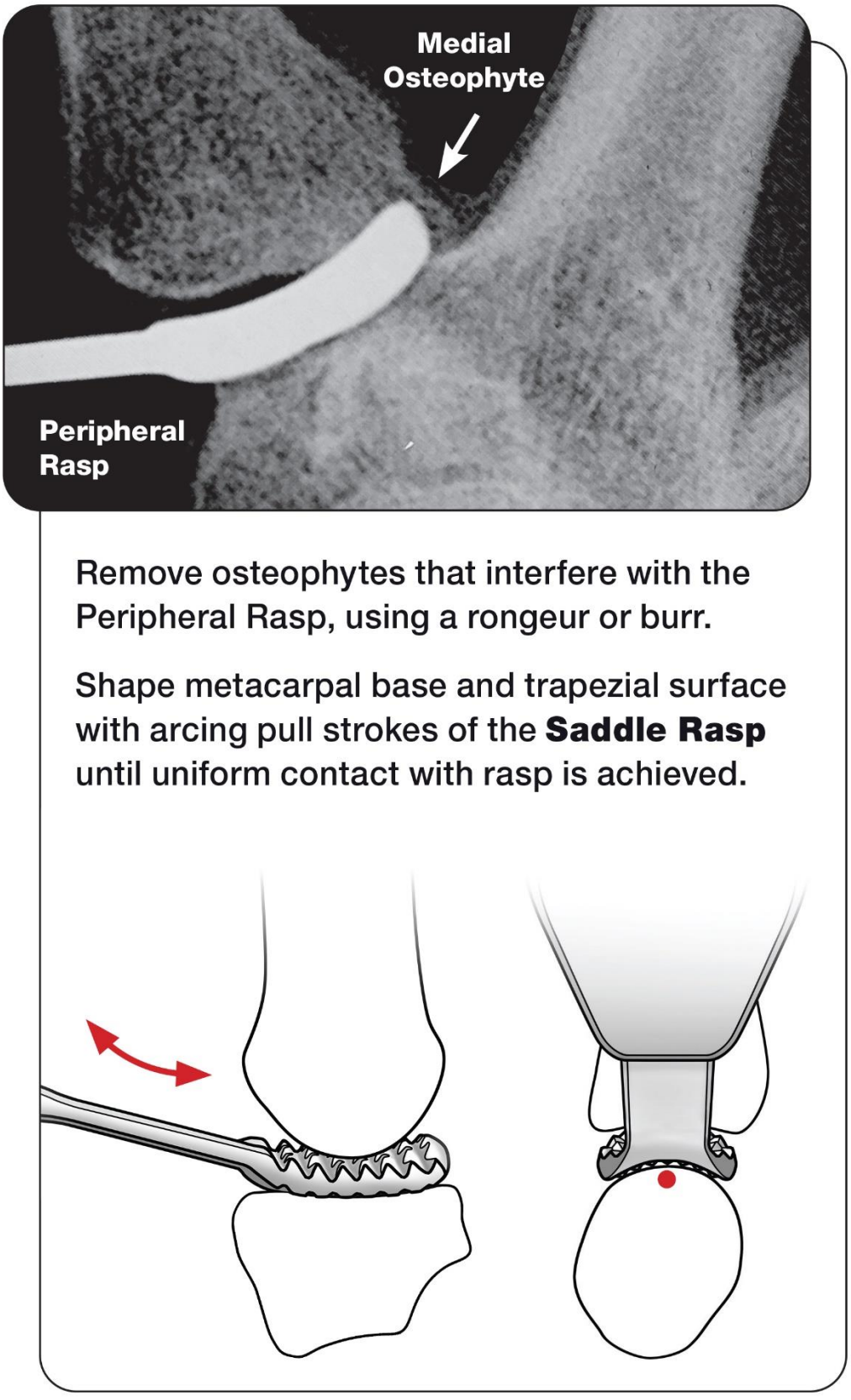


Fig 6: Using rongeurs and the peripheral rasp, the joint space is cleared.

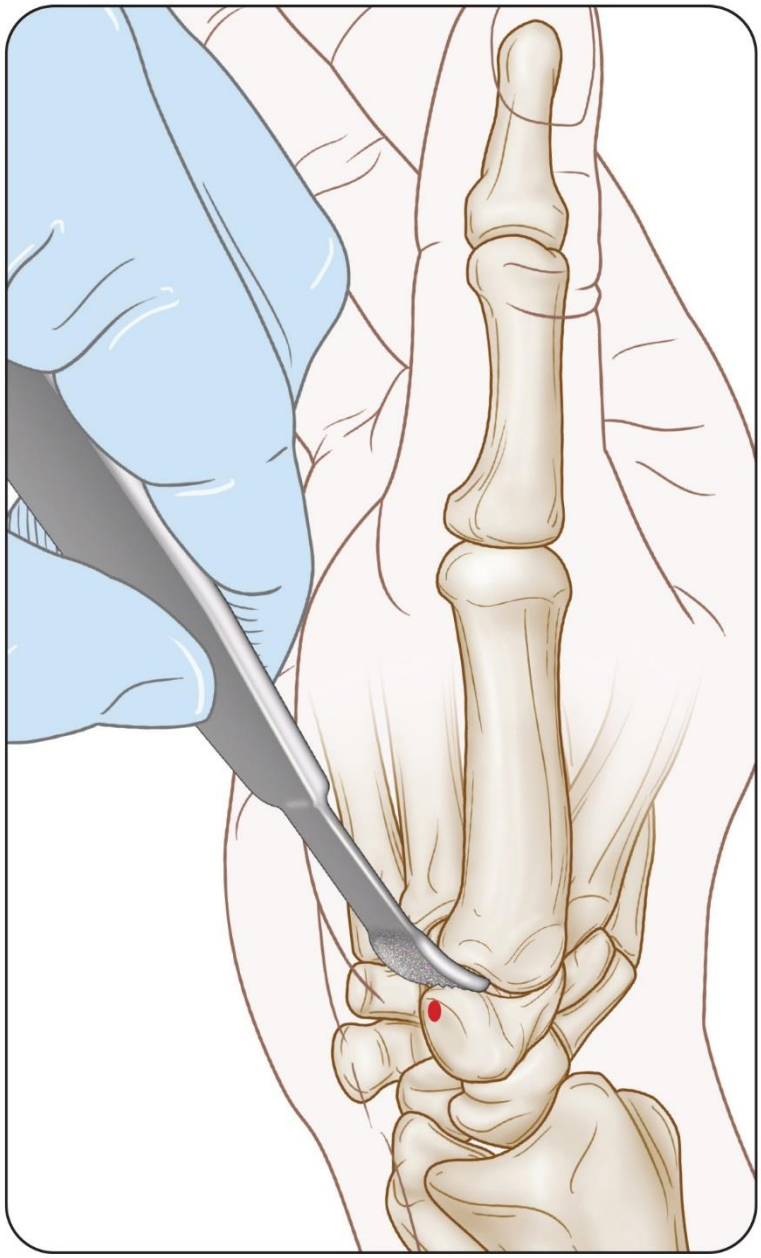
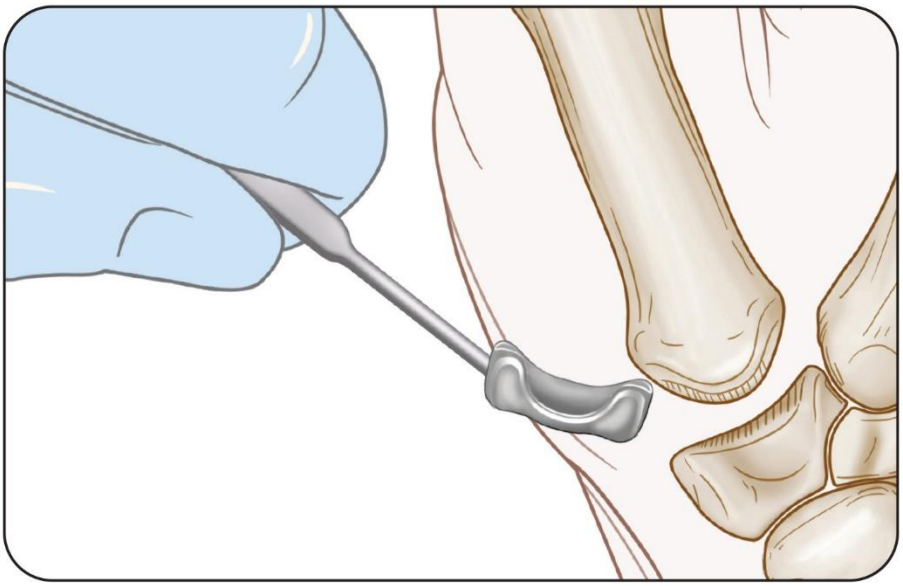


Fig 7: Flat pull/push radial-to-medial strokes of the Bump Rasp are used to create two grooves across the trapezial surface for ease of implant insertion. Continue shaping until center contact of the rasp on the trapezium is achieved.



The trial should insert easily across the joint and be stable. If not, assess the A/P radiograph, then continue to remove osteophytes and shape joint surfaces to create more joint space.

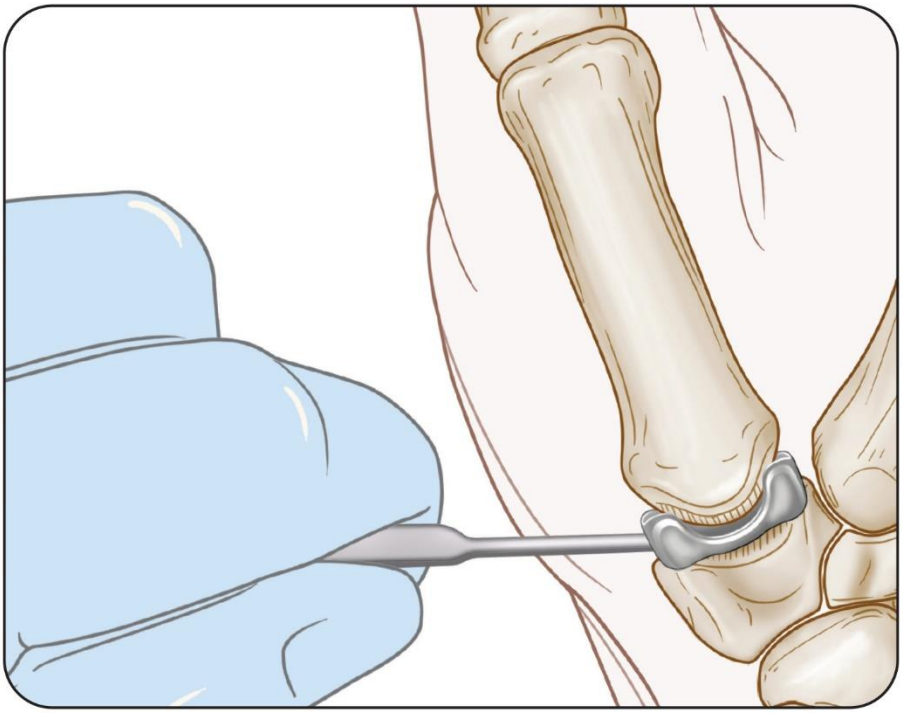


Fig 8: The trial implant is inserted to confirm correct sizing and fit for the implant.

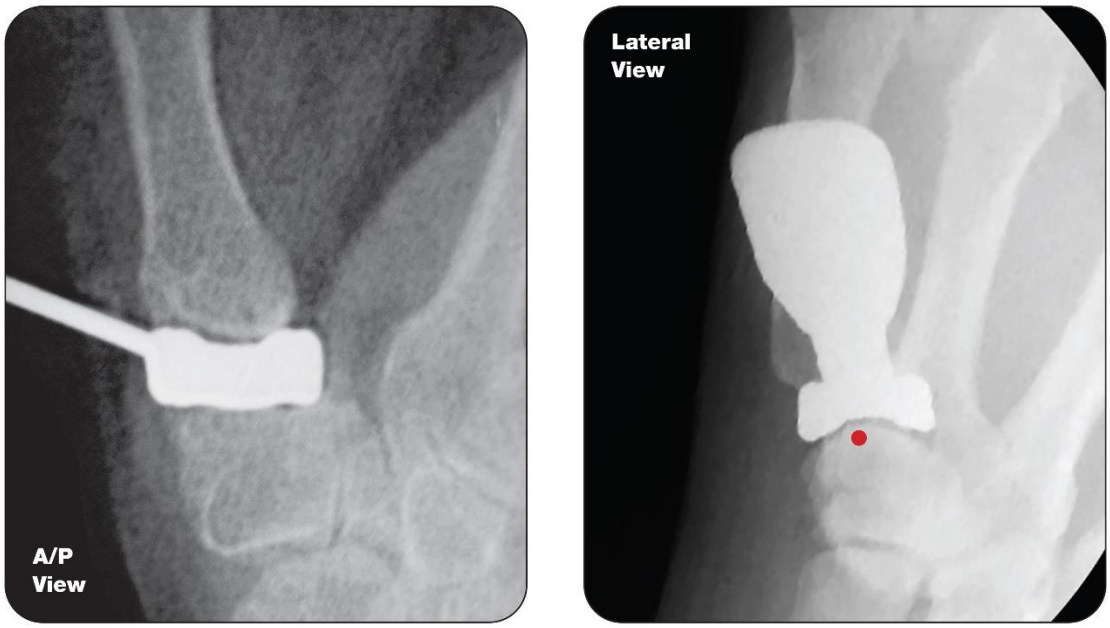


Fig 9: Fluoroscopic guidance is used to confirm that the trial implant does not interfere with joint range of motion and there is center contact of the implant on both the metacarpal and trapezium.

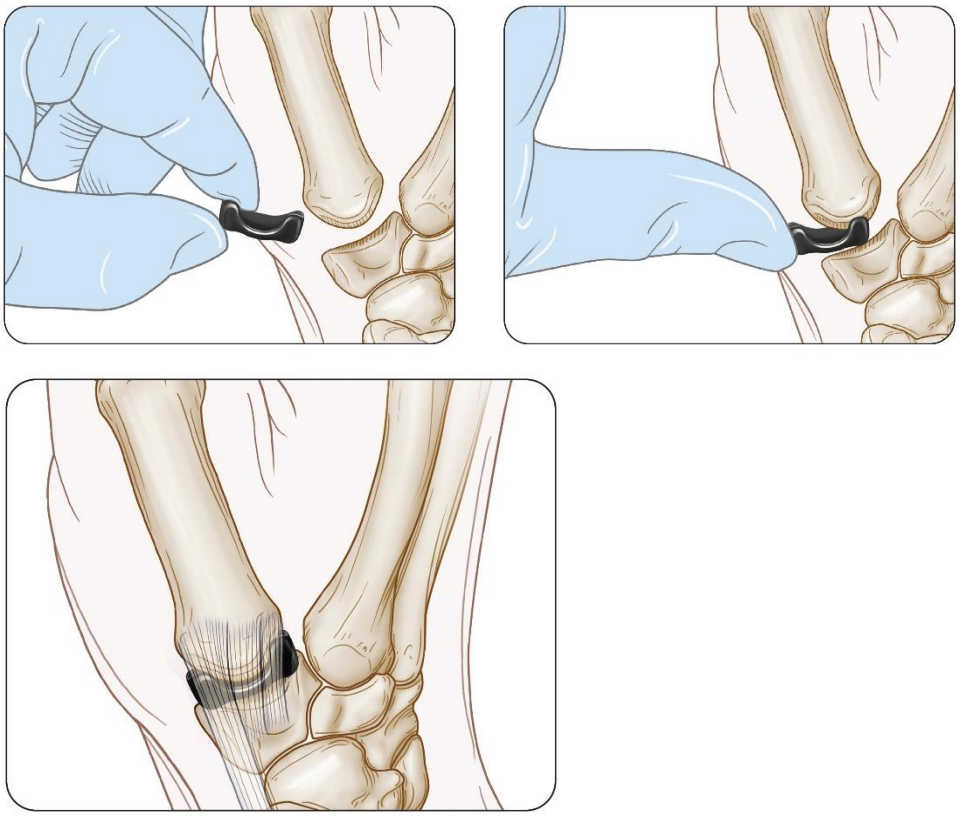


Fig 10: The final implant is inserted, and fluoroscopy is used once again to confirm proper placement of the implant in the joint.

Data Analysis:

Statistical analysis was performed using Paired *t*-tests were used to compare preoperative and postoperative values for the implant space height as well as grip and pinch strengths. Spearman correlation coefficients (*r*) were used to analyze relationships between grip and pinch strength, thumb motion, and the parameters determined in the DASH and VAS questionnaires.

12 patients were evaluated at regular intervals from before surgery to 12 months following

surgery. The grip strength, pinch strength and thumb range of motion were objective measurements taken during this period to evaluate patient progress. In addition, all the patients completed a DASH questionnaire, and a VAS pain score before surgery and after the 12 month postoperative follow up evaluation. There were seven men and five women in the study. The average age was 58 years for men and 56 years for women. No significant differences in the preoperative or postoperative measurements for men versus women. Thumb range of motion measurements included radial abduction, opposition, and abduction performed by hand therapists in a blinded fashion preoperatively and then again at the final follow up evaluation at 12 months. The measurement for range of motion, and grip strength were performed as described in the guidelines for measuring permanent partial impairment they were published by the American Medical Association.[13] Grip strength and lateral pinch strength were determined for both hands using a Jamar dynamometer (Asimov Engineering, Los Angeles, CA) and a pinch meter (Therapeutic Instruments, Clifton, NJ).

Plain radiographs were taken preoperatively as well as at each of the postoperative evaluation times. The difference in height between the interoperative space between the metacarpal and trapezium was evaluated on both anterior-posterior radiographs as well as lateral radiographs. The metacarpal trapezial space was also evaluated at the end of the study and compared to the preoperative results. The goal of this radiographic comparison was to evaluate if there was any collapse in the space between the metacarpal and trapezium to evaluate for any implant wear or erosion of the bone. The radiographs were also evaluated for evidence of cyst formation or sclerosis that would indicate a reaction of the bone to the implant.

Results:

There were no implant dislocations, infections, or other complications found in this cohort. One patient noted persistent pain in the months following surgery, but after further evaluation, the patient was found to have rapid progression from stage one to stage three basal joint arthritis with significant involvement of the scaphoid-trapezium articulation. Nine months after the initial surgery the patient opted to have a revisionary procedure with trapezium excision and ligament reconstruction with good post-operative satisfaction.

As noted in table one, there was a significant improvement in pinch strength from 15 ± 3.2 pounds prior to surgery to 24 ± 6.1 pounds after surgery $p < 0.05$. There was also a significant improvement in the DASH score from 42 ± 8.5 before surgery to 15 ± 3.4 after surgery ($p < 0.05$). The VASP score also significantly improved from 7.4 ± 2.3 to 2.4 ± 1.2 $p < .05$. (Table 1)

There was no significant improvement in grip strength or thumb range of motion, including thumb, abduction, thumb, adduction, and thumb opposition. (Table 2) There was no significant improvement in range of motion at the MCP joint or the thumb IP joint. (Table 3)

Ensemble Table 1

Preop Grip	Post op Grip (lbs)	P value for Grip strength (lbs)	Preop Pinch (lbs)	Postop Pinch (lbs)	p value for Pinch	Preop DASH	Postop DASH	p value for DASH	Preop VAS	Postop VAS	p value for VAS
42± 6.7	48 ± 7.4	p > 0.5	15 ± 3.2	24 ± 6.1	**p < 0.05**	42 ± 8.5	15 ± 3.4	**p < 0.05**	7.4 ± 2.3	2.4 ± 1.2	**p < .05**

Thumb Adbuction Preop (degrees)	Thumb Adbuction Postop (degrees)	p value for Thumb Abduction	Thumb Adduction Preop (cm)	Thumb Adductio n Postop (cm)	P value for Thumb Adduction	Thumb Opposition Preop (cm)	Thumb Opposition Postop (cm)	p value for Thumb opposition
43 ± 6.1	47 ± 5.7	p > 0.05	1.5 ± 0.3	0.5 ± 0.1	p > 0.05	6 ± 2.1	7 ± 3.3	p > 0.05

MCP Range of Motion Preop (degrees)	MCP Range of Motion Preop (degrees)	p value for MCP motion	IP Range of Motion Preop (degrees)	IP Range of Motion Preop (degrees)	p value for IP motion
73 ± 9.2	71 ± 9.3	p > 0.05	76 ± 11.4	81 ± 10.6	p > 0.05

Legend

preop =	pre- operative	DASH =	disability arm shoulder hand	CMC =	carpo-metacarpal joint	IP =	thumb inter-phalangeal joint
postop =	pos- toperative	VAS =	visual analog scale	MCP =	metacarpo-phalangel joint		

The height of the implant space as measured from the base of the thumb metacarpal did not change from 5.1 mm before and after surgery on the anterior-posterior radiograph and the lateral radiograph, whereas the space increased from 4.9 mm on the AP view preoperatively to 5.0 post-operatively. However, this was not considered to be a significant change. No bone erosions or sclerosis were noted along the bone surfaces in contact with the implant. No cysts or osteophytes developed during the post-operative period. The radiographic measurements were made by measuring the space between the metacarpal and the trapezium at the mid-point on lateral and AP radiographs for consistency.

Discussion:

This study of our preliminary cohort of patients was able to demonstrate that the Ensemble implant is a safe and effective way to treat stage one thumb CMC arthritis restricted to the carpometacarpal joint. The results are similar to those with other techniques for hemiarthroplasty, but those techniques with cartilage spacers or tendon spacers, tend to collapse overtime compared to the structural integrity of the Pyrocarbon Ensemble implant.[7, 8, 10-12]

Pyrocarbon spacers for hemiarthroplasty have been used in Europe with success for over a decade, but the Ensemble implant is the only Pyrocarbon resurfacing implant available in the United States that does not require a peg or stem to be inserted into the thumb metacarpal.[14] To insert this type of peg or stem, the surgeon needs to remove a substantial amount of capsule around the joint, which results in a much more invasive technique. Spherical and hemispherical implants made of ceramic or Pyrocarbon have also been used, but these have a much higher rate of dislocation than the Ensemble implant experience which had a 0% rate of dislocation in our cohort.[7-11, 14, 15] This is due to the unique feature of the Ensemble spacer having bumps or prominences on the margins that allow it to lock onto the surface of the trapezium, providing an extremely stable implant without need for additional tendon transfers.

The Ensemble implant works in effect as a resurfacing of a joint articulation instead of a complete joint replacement which minimizes the amount of bone resection required in surgery, decreases the post-surgical healing and rehabilitation time, and potentially has uses in many other locations in the upper extremity. The ensemble implant effectively prevented proximal migration of the thumb metacarpal. Although this cannot be directly correlated to pinch strength, the patients in the study did have improvements in their pinned strength, in addition to their DASH and VAS pain scores.

The shortcoming of this study is that this was a non-randomized cohort used to evaluate the initial treatment group with this implant. However, the results were consistent with the literature in Europe, these types of resurfacing implants that do not require insertion into the metacarpal canal of the thumb have been highly successful while requiring minimal bone and ligament removal. A particularly encouraging aspect of this study is that none of the implants dislocated in any of the patients in our cohort, which has been a problem with other resurfacing implants of the of the metacarpal trapezial interface. The fact that there has been a low or zero dislocation rate with the benefit of avoiding the dissection to insert a stem into the canal has demonstrated that the Ensemble arthroplasty has made a substantial advance in the treatment of thumb arthritis.

References:

1. Day CS, Gelberman R, Patel AA, Vogt MT, Ditsios K, Boyer MI. Basal joint osteoarthritis of the thumb: a prospective trial of steroid injection and splinting. J Hand Surg Am. 2004;29(2):247-51.
2. Shuler MS, Luria S, Trumble TE. Basal joint arthritis of the thumb. J Am Acad Orthop Surg. 2008;16(7):418-23.
3. Raven EE, Kerkhoffs GM, Rutten S, Marsman AJ, Marti RK, Albers GH. Long term results of surgical intervention for osteoarthritis of the trapeziometacarpal joint : comparison of resection arthroplasty, trapeziectomy with tendon interposition and trapezio-metacarpal arthrodesis. Int Orthop. 2007;31(4):547-54.
4. Vermeulen GM, Slijper H, Feitz R, Hovius SE, Moojen TM, Selles RW. Surgical management of primary thumb carpometacarpal osteoarthritis: a systematic review. J Hand Surg Am. 2011;36(1):157-69.
5. Luria S, Waitayawinyu T, Nemechek N, Huber P, Tencer AF, Trumble TE. Biomechanic analysis of trapeziectomy, ligament reconstruction with tendon interposition, and tie-in trapezium implant arthroplasty for thumb carpometacarpal arthritis: a cadaver study. J Hand Surg Am. 2007;32(5):697-706.
6. Trumble TE, Rafijah G, Gilbert M, Allan CH, North E, McCallister WV. Thumb trapeziometacarpal joint arthritis: partial trapeziectomy with ligament reconstruction and interposition costochondral allograft. J Hand Surg Am. 2000;25(1):61-76.
7. Bellemere P. Pyrocarbon implants for the basal thumb arthritis. Hand Surg Rehabil. 2021;40S:S90-S101.
8. Bellemere P. Pyrocarbon implants for the hand and wrist. Hand Surg Rehabil. 2018;37(3):129-54.
9. Cummings PE, Claxton MR, Wagner ER, Rizzo M. Outcomes of Pyrocarbon Arthroplasty in Metacarpophalangeal Joints Affected by Rheumatoid Arthritis. Hand (N Y). 2022:15589447211063577.
10. Gerace E, Royaux D, Gaisne E, Ardouin L, Bellemere P. Pyrocardan(R) implant arthroplasty for trapeziometacarpal osteoarthritis with a minimum follow-up of 5 years. Hand Surg Rehabil. 2020;39(6):528-38.
11. Pouedras M, Chaves C, Gaisne E, Ardouin L, Bellemere P. Pyrocardan(R) implant after failed trapeziectomy. Hand Surg Rehabil. 2021;40(1):51-6.
12. Trumble TE, Heaton DJ. Outcomes of Surface Replacement Proximal Interphalangeal Joint Arthroplasty Through a Volar Approach: A Prospective Study. Hand (N Y). 2017;12(3):290-6.
13. Cocchiarella LA, G.B.J. Upper Extremity Impairment Evaluation. In: Cocchiarella LA, G.B.J., editor. Guidelines to the Evaluation of Permanent Impairment. 5th ed. United States: AMA Press; 2000. p. 437-510.
14. Woodward JF, Heller JB, Jones NF. PyroCarbon implant hemiarthroplasty for trapeziometacarpal arthritis. Tech Hand Up Extrem Surg. 2013;17(1):7-12.
15. Adams BD, Pomerance J, Nguyen A, Kuhl TL. Early outcome of spherical ceramic trapezial-metacarpal arthroplasty. J Hand Surg Am. 2009;34(2):213-8.