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Bio-integrative, fiber-reinforced fixation device in carpometacarpal (CMC) joint fusions following carpal boss removal: A case series

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A B S T R A C T

Purpose: The purpose of this case series is to provide insight into the surgical treatment of carpometacarpal (CMC) instability after carpal boss removal with the OSSIOfiber® trimmable fixation nail, a bio-integrative fixation device.
Methods: This review includes five patients who underwent CMC joint fusions post removal of symptomatic carpal boss presenting for surgical management from one board certified hand surgeon. Patient information, clinical images, and outcome scores are collected through retrospective chart review.
Results: There is evidence of CMC joint fusion at three months for all five subjects based on radiographic evidence. All subjects were pain free at 6 weeks post operation. Range of wrist motion was within normal limits for all subjects prior to surgery and again at 3 months for 4/5 subjects. No tissue reaction to the OSSIOfiber® trimmable bone nail was noted in the five subjects.
Conclusion: The outcome of the joints treated includes rate of CMC joint fusion at 3 months with no significant adverse events to the trimmable bone nail. Using a fiber-reinforced bio-integrative implant that integrates naturally within the bone may be a desired choice over using a metallic fixation device for many orthopedic hand surgeons.

1. Introduction

Carpometacarpal (CMC) joint instability is a challenge in orthopedics often following trauma or fracture dislocation. Furthermore, CMC joint instability can be seen in cases following removal of a traumatic or painful carpal boss.[1] Carpal boss is a bony protuberance on the dorsal base of the quadrangular joint formed by the 2nd and 3rd metacarpal, trapezoid, and capitate in the wrist.[2] The etiology of carpal boss is uncertain but may stem from congenital, degenerative, overuse or traumatic causes.[1,3–6] If conservative treatment is not successful within 6 weeks surgery should be considered.[7] In the event the wedge resection fails and the carpal boss returns or, as the CMC joint becomes unstable due to carpal boss removal, an arthrodesis (joint fusion) can be performed.[1] Arthrodesis can be achieved in many ways using bone grafts, Kirschener wires, or other hardware fixations.[8]

The OSSIOfiber® Trimmable Fixation Nails are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone grafts in the presence of appropriate additional immobilization. The OSSIO solid core nail is composed of a natural fiber matrix with high mineral content and engineered to achieve the optimal balance of flexural, torque, axial and shear strength. The fibers are made from materials that are found in natural bone such as calcium, silica, and magnesium and have been shown to promote bone regeneration and growth in vitro and in vivo.[9–11] The fixation device is made of poly (L-lactide-co-D, L-lactide) (PLDLA) reinforced with continuous mineral fibers.[12] The Ossiofiber fixation device has a lower polymer content that degrades by hydrolysis into alpha-hydroxy acids which are metabolized by the body, ensuring that the product can be progressively cleared by the body while avoiding polymer accumulation and foreign body reactions seen in previous bioabsorbable devices.[12,13] OSSIOfiber® implants have been shown to be biocompatible in animal studies showing maintenance of strength during bone healing with a controlled, gradual degradation.[14] Substantial bone integration takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery.[15] The decision to start using the OSSIO nail was due to its success in treating hammertoe deformities.[16] In one year follow up of the patients that had their hammertoe deformity corrected with the OSSIOfiber® Hammertoe Fixation Implant, the proximal interphalangeal joint radiographic fusion rate was 92 %.[15]

To our knowledge, this is the first case series looking at the OSSIOfiber nail as a fusion material for treating hand carpometacarpal (CMC)

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instability following carpal boss removal. Key metrics include time to joint fusion, pain cessation, and complications such as instability, return of pain, return of bossing, reduced range of motion (ROM) and tissue reaction to the fixation device.

2. Case report

1.1 Study Population: This IRB approved case series of five patients treated at a single orthopedic center by a single orthopedic surgeon. Participant average age of 52 years old with three males and two females.
1.2 Patient Selection: Patients were identified through electronic medical records using ICD-9 and ICD-10 codes for arthrodesis in the carpometacarpal joint for digits other than the thumb (CPT26843). Selection of these patients included those who underwent fusion surgery at the carpometacarpal joint due to a painful carpal boss that had failed conservative treatment. All patients were skeletally mature and sought consultation for a painful carpal boss at the quadrangular joint or at the 2nd, 3rd, 4th, or 5th carpometacarpal joint.

3. Clinical findings

2.1 Reasons for seeking initial treatment of carpal boss included: wrist pain, with varying degrees
of severity and associated symptoms: 4/5 reporting wrist pain with only 1/5 (Subject 4) reporting mild wrist pain and 0/5 reporting severe pain. All patients reported pain with movements and presence of a dorsal hand mass.
2.2 All 5 patients were diagnosed with carpal boss based on clinical exam and imaging. Subject 1 experienced pain at dorsal aspect of the wrist, primary with extension, Subject 4 had discomfort when hyperextending the wrist occasionally at dorsal aspect of the 2nd CMC joint, and Patient 5 felt pain and with certain movements, even writing. We are choosing to highlight Subjects 2 and 3 with clinical presentation at their initial pre-operative visits and location of Carpal Boss for each subject (Table 1).
2.3 Subject 2 Clinical exam and findings: A 54-year-old with left wrist mass at the dorsal aspect of the wrist. Patients stated that the pain began in 2019. Patient experienced pain in the wrist, thumb, and index and middle fingers. Aggravating factors were pushing in wrist extension and twisting. Patient was occasionally experiencing cracking in the wrist. Patient denied numbness and tingling Carpal boss palpated at the base of left third metacarpal that was tender to touch. Patient had been using Exos brace, voltaren gel and biofreeze for 2 weeks with some relief. MRI of the left wrist demonstrated prominent dorsal carpal boss at the third CMC joint with mild subchondral marrow edema and irregularity in the distal capitate and base of third metacarpal in this location.
2.4 Subject 3 Clinical exam and findings: A 42-year-old professional boxer, presented with an old second metacarpal bone fracture with malunion, but with normal functionality and ROM of the fingers. The patient had persistent aching pain at the midshaft of the metacarpal with palpable and visible bone deformity (carpal boss). They stated a prior surgery with metal screws and bone grafting that was performed 15 years ago and mainly complained of pain while punching and pain after boxing. The carpal boss was removed from the 2nd CMC joint which was stabilized with the OSSIO bone nail.

Table 1
Location of carpal boss at initial clinic visit.

Subject	CMC2	CMC3	CMC4	CMC5
1	yes	yes	yes	
2		yes		
3	yes			
4	yes			
5		yes		
Counts	3	3	1	0

4. Diagnostic assessment

3.1 Carpal boss was palpable in all patients on exam and tender to touch.
3.2 Subject 2. Carpal boss was tender to touch and palpable at the base of the left third metacarpal on the dorsum of the hand (Fig. 1).
3.3 Subject 3 pre-op CT imaging showed old fracture of the second metacarpal shaft with CMC carpal boss.

5. Therapeutic intervention

4.1 A total of 10 OSSIOfiber® trimmable fixation nails (Fig. 2) were used in 7 joints. The skin is incised over the carpal boss and the CMC joint capsule is opened. A rongeur is used to remove the boss. Cartilage from the joint surfaces is removed to promote fusion of the joint. Two K-wires are placed to stabilize the CMC joint using fluoroscopy intraoperatively. Using a cannulated drill over the K-wires creates a channel for the insertion of the OSSIO nail. Once inserted, the OSSIO bone nail is trimmed so that it is flushed with the bone surface at the point of entry.

6. Follow-up and outcomes

5.1 Radiographic Outcomes: There is evidence of CMC joint fusion at three months for all five subjects and seven treated joints based on radiographic evidence.
5.2 In Subject 2 (Fig. 3a), is a three month post operative x-ray in which white arrows indicate a shadow outline of a trimmable nail bridging the patient's third carpometacarpal joint (Fig. 3b). is an x-ray of the patient's left third carpometacarpal joint at six months post operatively with white arrows indicating the outline of the OSSIOfiber trimmable nail.
5.3 In Subject 3 (Fig. 4a–b), are 6-month post-operative x-ray images and show the OSSIO nail outline on the second CMC joint.
5.4 Pain Scores: All subjects were pain free at 6 weeks post operation. Mild pain returned in one subject (Subject 3) by the six months visit which may be attributed to a small chip of the trapezoid. This could be attributable to the patient returning at four months post op to training and competing as a professional boxer.

Fig. 1. Palpable carpal boss at base of left third metacarpal on initial CT imaging for Subject 2.

Fig. 2. 2.4 × 30 mm bio-integrative, fiber-reinforced fixation device (OSSIOfiber® Solid Core Trimmable Fixation Nail, OSSIO Ltd., Caesarea, Israel) used in this study.

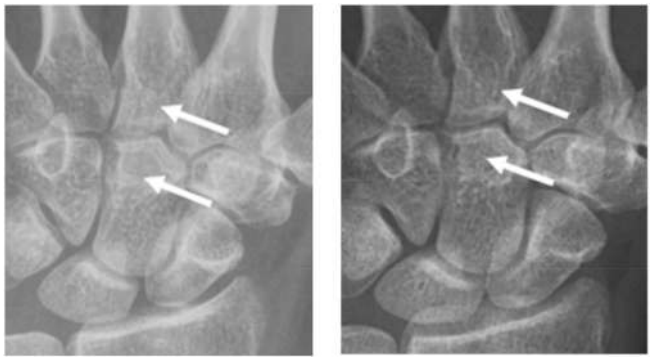

Fig. 3a–b. 3-month Post-operative X-ray, OSSIO outline on third CMC joint for Subject 2, and 6-month Post-operative X-ray, OSSIO outline on third CMC joint for Subject 2 respectively.

Fig. 4a–b. 6-month Post-operative AP and Oblique X-ray, OSSIO outline on second CMC joint for Subject 3.

5.5 Range of Motion: Range of wrist motion was within normal limits for all subjects prior to surgery and again at three months for 4/5 subjects. The one subject with reduced range of motion regained normal range of motion by 6 months. The subject's range of motion was guarded by pain due to development of De Quervain's tenosynovitis.

5.6 Tissue reaction to fixation device: No tissue reaction to the OSSIOfiber® trimmable bone nail was noted in the five subjects.

5.7 Follow-up duration was 6 months for all patients.

7. Discussion

The outcomes observed in our case series of five patients with painful, symptomatic carpal boss highlight a new type of surgical management of carpometacarpal (CMC) instability utilizing the OSSIOfiber® trimmable bone nail. In our study, all seven treated joints demonstrated successful fusion at the three-month follow-up, with no significant adverse events related to the trimmable bone nail noted at six-month follow-up.

Our study involving the CMC joints demonstrates similar applicability of the OSSIO product as has been shown in the foot. Our findings align with previous studies investigating the use of OSSIO products in orthopedic procedures such as correction of hammertoe study.[15,16] In a multicenter clinical and radiographic evaluation of 25 patients undergoing proximal interphalangeal arthrodesis for hammertoe deformity using the OSSIOfiber® implant demonstrated favorable radiographic fusion rates at 12-, 26-, and 52-weeks post-insertion, with no device-related complications reported.[16] In the further follow-up study, the bio-integrative nature of the implant facilitated safe integration within the bone tissue, without adverse effects observed at the one-year follow-up in patients who received the OSSIOfiber implant for correction of hammertoe deformity.[15]

While our study is a small case series, it provides valuable insights into the potential benefits of using a bio-integrative device for CMC joint stabilization or effective management in small joints. Traditional materials used for joint stabilization may pose limitations such as loosening of the joint, reaction to material, risk of breakage, and the need for hardware removal, particularly in the pediatric population.[17] Our study shows that the OSSIO product is sufficient to the traditional devices used for joint stabilization with the benefit of integration as the OSSIO product allows bone to return to the native physiology after implant resorption.

Despite our study limitations, including its retrospective nature, limited follow-up, and small sample size, the absence of inflammation and joint loosening observed with the use of the OSSIO trimmable nail highlights its potential clinical significance. Utilizing a fiber-reinforced bio-integrative implant, such as the OSSIOfiber® trimmable bone nail, represents a promising approach for CMC joint stabilization.

Conflict of interest

The authors of the manuscript have no conflicts of interest to disclose.

Financial support and sponsorship

There was no outside funding provided in the creation of this case series.

Informed consent

The subjects of the study were informed of their inclusion in the above study and provided consent for their use of their information. This study falls under Baptist Health of South Florida's IRB 18772777.

Statements and declarations

Ms. Claire Callan, Dr. Elizabeth Anne Ouellette, Ms. Marla Geltner, and Ms. Anna-Lena Makowski declare they have no financial or non-financial interests to disclose.

This research was approved by Baptist Health of South Florida Institutional Review Board.

There was no source of funding for the study.

Ethical statement

We confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies and in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

All procedures were performed in compliance with relevant laws and institutional guidelines and have been approved by IRB 18772777. Date of IRB approval August 4th, 2022.

CRediT authorship contribution statement

Claire Callan: Conceptualization, Methodology, Investigation, Data curation, Writing (original), Writing – review & editing. **Elizabeth Anne Ouellette:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision. **Marla Geltner:** Methodology, Investigation. **Anna-Lena Makowski:** Conceptualization, Methodology, Investigation, Data curation, Writing (original), Writing – review & editing, Investigation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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