

Short Term Results Of The Ascension® Nugrip™ Cmc Implant For Thumb Carpometacarpal Osteoarthritis

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Abstract

Introduction

Osteoarthritis of the first carpometacarpal joint can cause pain, weakness and deformity resulting in marked disability. Different surgical treatments have been described and compared in previous studies. We evaluated the short term outcomes of the Nugrip™ CMC Implant.

Methods

Ten patients with CMC-1 osteoarthritis were treated with the Nugrip™ CMC implant. Mean follow-up periode was 9.5 months. For subjective assessment the Disabilities of the Arm, Shoulder, and Hand [DASH] questionnaire was used pre and postoperative. Pain was assessed using a visual analogue scale [VAS] pre and postoperative. Furthermore, patients were asked postoperative to judge satisfaction and functionality using a VAS [0=very satisfied; 10=not at all]. Postoperative objective assessment consisted of range of motion [ROM] of the thumb, tip pinch and handgrip strength. All measurements were compared with the contralateral side.

Results

Seven out of ten joints were placed in the dominant side. We observed three complications; one dislocation needed additional soft tissue stabilization and re-implantation of a larger Nugrip prosthesis. A second patient had a remaining symptomatic osteophyt, which needed resection. The third patient had implant malposition resulting in dysfunction and subsequent removal of the prosthesis. This patient was not assessed during the last follow up.

The average score on the DASH pre- and postoperative was 41 and 23, respectively. The mean visual analogue score for pain was 6 and 3. VAS for postoperative functionality and satisfaction was 4 and 3, respectively [n=9].

The average grip strength with the Jamar-meter [n=8] on the operated side was 18.4 kg, on the contralateral nonoperative side 22.7. Tip pinch strength using a pinch gauge was on the operated side 5.7 kg, on the contralateral side 6.4 kg.

The radial abduction in the carpometacarpal joint [CMC-1] on the operated side was 49°, on the contralateral side 55°.

Conclusion

The short term results of the Nugrip™ CMC Implant are satisfactory however the procedure has some pitfalls. Instability is in our opinion a contraindication and resection of osteophytes especially on the ulnar site is mandatory.

INTRODUCTION

Osteoarthritis of the first carpometacarpal joint is a common problem, often bilateral and especially affecting postmenopausal women (7,10,11). A radiographic study from Sodha et al revealed that 57% of 615 people with a radius fracture showed evidence of osteoarthritis at the trapeziometacarpal joint and increasing with age. The

prevalence of grade-III trapeziometacarpal arthrosis was much greater in women than in men at all age levels. This could suggest that this is a normal part of the aging process (13).

Osteoarthritis in the carpometacarpal joint of the thumb [CMC-1] can cause pain, weakness and deformity resulting

in marked disability (11,16,17). The most commonly used conservative treatment modalities are NSAID's, corticosteroid injections and splints (10,18). The result of conservative treatment is often satisfactory and surgical treatment should only be reserved for resistant symptomatic cases.

A variety of surgical techniques have been described in which pain relief and to restore function are the main goals of treatment. Resection arthroplasty and soft tissue procedures have been described thoroughly and recommended based on the severity of CMC-1 osteoarthritis (11,16,17).

Joint Arthroplasty has been performed for 45 years using various types of implant designs and materials, such as silicone, ceramic, polyethylene, and metal (1-3,10,12,15). The aim is to preserve the length of the thumb, which is important for maintaining balance of the soft tissues resulting in better strength and function. In this way, ulnar and axial displacement and metacarpal angulation can be significantly reduced compared with trapezectomy modalities (9).

In this study we evaluate the short term outcomes of the Ascension® Nugrip™ CMC Implant. This is a pyrocarbon hemiprosthesis for the treatment of osteoarthritis in the first carpometacarpal joint.

PATIENTS AND METHODS

Patients were enrolled in this study if they were diagnosed with symptomatic primary or secondary first carpometacarpal joint osteoarthritis based on clinical and radiologic changes and were treated with the Nugrip CMC Implant.

For subjective assessment pre- and postoperative, the Disabilities of the Arm, Shoulder, and Hand [DASH] questionnaire was used. Pain was registered using a visual analogue scale [VAS; 0= no pain, 10=unbearable pain] both pre- and post-operative. Furthermore, patients were asked to judge both functionality and satisfaction postoperative using a visual analogue scale [VAS: 0= very satisfied 10=not satisfied at all]

Objective assessments consisted of interphalangeal joint flexion/extension; metacarpophalangeal joint flexion/extension; and carpometacarpal joint flexion/extension and abduction and adduction. Complementary distance between thumb and palm of the

hand and thumb and pink finger [of 1st and 5th finger] was measured.

Handgrip strength was measured using a hydraulic hand dynamometer [Baseline ®, Irvington, NY]. Tip pinch strength [STPS] was measured between thumb and indexfinger using a pinch gauge [Baseline ®, Irvington, NY]. For both instruments the average of three measurements was used. Sensibility of the nervus radialis superficialis was tested. All measurements were also performed on the contralateral nonoperative side.

An independent hand therapist carried out all ROM and strength measurements.

A total of 10 patients were included in this study [2 men and 8 women]. Out of ten hands seven were dominant. The mean age was 56 years [range 50-72 years]. According to the radiographic criteria of Eaton and Glickel, 1987 (4): preoperatively 2 thumbs had stage II osteoarthritis; 8 had stage III.

Mean follow-up period was 9.5 months [range 5-16 months].

SURGICAL TECHNIQUE

A single surgeon performed all implantations of the Nugrip CMC 1 implant in this group of patients. Axillary block anesthesia was used, and surgery was performed under tourniquet control. All patients received intravenous antibiotics prophylaxis [2 grams Kefzol;Cefazoline, EuroCept bv].

First, a lazy-S incision is made over the CMC joint in line with the dorsal compartment tendons. Great care must be taken to avoid injury to the superficial radial nerve. Then the interval between the abductor pollicis longus [APL] and extensor pollicis brevis [EPB] is opened. This gives a clear view of the CMC joint capsule. A longitudinal incision is made, and by elevating the capsular periosteal flaps anteriorly and posteriorly there is a good exposure of the CMC joint. Additional dissection up the distal radial and ulnar sides of the metacarpal shaft is necessary to release portions of the adductor and opponens muscles, allowing dorsal subluxation of the metacarpal from the trapezium. Using Hohmann retractors placed underneath metacarpal gives an elevation of the base for further preparation. The Starter Awl [Ascension Orthopedics®, Austin, Texas] is inserted intramedullary into the central dorsal third of the first metacarpal. The Alignment Awl is inserted in the shaft of the metacarpal, with the External Alignment Guide

attached [Illustration 1]. The last one should be parallel to the dorsal surface of the metacarpal. External Alignment guide is replaced for the Vertical Cutting Guide. Approximately 3-5 mm of bone is resected; osteotomy is made at junction of metacarpal base an articular surface. After resection thorough palpation for existence of osteophytes is indicated, and remaining osteofyts should be removed thoroughly. Once the resection is complete, the Nugrip Sizing Template can be placed between metacarpal and trapezium for estimating joint space. Replacement of Hohmann retractors on the volar aspect of the trapezium gives a clear view of the distal surface; templating of the trapezium is performed. A solid rim of cortical bone should surround Template for proper stabilization of the implant. K-wire is inserted into center of the Trapezium end the Template is removed. Trapezial cup is prepared using an Axial Cannulated Cutter The trapezial cup may be safely deepened to a level equal with the distal third of the trapezium [Illustration 2-3]. Surface of the cup is being smoothened with the Nugrip Finishing Shaper Broaching of the metacarpal bone is the last step of this procedure. Insert the trial and check the stability of the implant; thumb adduction with simultaneous thumb MP and IP joint flexion.

During implantation of permanent Nugrip implant ensure axial rotation; confirm the dorsal surface of implant stem is parallel to dorsal surface of the metacarpal.

The capsule and skin were closed in layers.

Postoperative conventional x-rays were made [Illustration 4]. The thumb was immobilized for 4 weeks in a plaster, with the thumb in abduction. After four weeks a removable protective splint replaced it, and active physiotherapy was started.

RESULTS

Ten patients were operated in our centre. There were three complications and all needed re-intervention. In one patient there was a displacement of the implant the day after surgery and needed an additional surgical soft tissue stabilization and re-implantation of a larger Nugrip prosthesis. One patient had persisting pain due to a remaining osteophyt which needed additional resection. The third patient had a malposition of the Nugrip™ CMC Implant resulting in persisting pain which resolved after removal of the implant.

The mean preoperative DASH score was 41 [0=no disability, 100=maximum disability]. At follow up the mean DASH score was 23. Results are shown in Figure 5.

The mean visual analogue score for pain preoperative was 6 [range: 1.5 -9.5]. At postoperative follow-up the mean VAS for pain was 3 [range 0.0-8.5], this was an improvement.

The mean VAS for functionality and satisfaction postoperative were respectively 4 and 3 [all shown in Figure 6].

The average grip strength measured on the operated side was 18.4 kg [range 8.3-50.0], contralateral side 22.7 [range 5.0-50.0]. The Tip pinch strength [STPS] using a pinch gauge was on the operated side 5.7 kg [range 4.5-8.0], on the contralateral side 6.4 kg [3.0-11.5] [shown in Table I]. Sensibility of the nervus radialis superficialis was tested in all cases and there were no disorders found.

The radial abduction in the carpometacarpal joint of the thumb on the operated side was 49° [range 28-68], on the contralateral side 55° [range 34-72] [Table II].

The thumb could reach the fifth finger and the palm off the hand for both operated and contralateral side in all patients.

Measurements in interphalangeal and metacarpophalangeal joints are shown in Table III.

DISCUSSION

The current study demonstrates that the Nugrip joint prosthesis as a treatment for thumb basal joint osteoarthritis provides significant pain relief and improvement in the DASH score. Patients were satisfied with the end result. There were three complications and all needed re-intervention; in one patient there was a dislocation of the implant, one patient had persisting pain due to a remaining osteophyt. In one patient there was a malposition of the prothesis which was removed. Instability and remaining osteophyts are in our hands the main pitfalls of this procedure.

Osteoarthritis at the base of the thumb can result in considerable disability. If conservative treatment fails surgical treatment can be a viable option. Wajon et al reviewed this topic in 2005 and 2009, which was later on updated by Vermeulen et al 2011. Wajon et al included all studies which reported clinically relevant outcomes regardless of methodological quality. The articles needed to compare at least two surgical procedures. There were no strict inclusion and exclusion criteria. Seven surgical procedures were identified [trapeziectomy with ligament reconstruction and tendon interposition [LRTI], trapeziectomy, trapeziectomy with ligament reconstruction,

trapeziectomy with interpositional arthroplasty, Artelon joint resurfacing, arthrodesis and joint replacement]. Of participants who underwent trapeziectomy with ligament reconstruction and tendon interposition, 22% had adverse effects [including scar tenderness, tendon adhesion or rupture, sensory change, or Complex Regional Pain Syndrome (Type 1)] compared to 10% who underwent trapeziectomy. Trapeziectomy with ligament reconstruction and tendon interposition is therefore associated with 12% more adverse effects. Despite the diversity in study designs, materials, and methods, the conclusion was that none of the techniques were superior to the others.

The literature regarding total trapeziometacarpal joint arthroplasty is limited. The de la Caffiniere prosthesis, which is a cemented total joint prosthesis developed in the late 1970s, is probably the most widely used and studied design (8,16). This prosthesis has demonstrated a tendency to aseptic loosening in active patients younger than 60 years. Aggressive reaming of the trapezium and use of cement, which might compromise the blood circulation of the trapezium, are mentioned as a possible cause. The Ascension Nugrip Implant preserves the trapezium and has a press fit stabilization in the first metacarpal bone which might avoid loosening in the long term.

Ulrich-Vinther et al compared the Elektra joint prosthesis with tendon interposition arthroplasty. The study demonstrated a quickly restored pain-free, stable motion at the basal joint of the thumb with improved strength equal to the asymptomatic contralateral thumb. The authors concluded that the improvements in the outcome parameters seem to have a more rapid onset in patients with a joint prosthesis than in patients with a tendon interposition arthroplasty. Hernandez et al on the other hand describe poor outcomes at a mean follow-up of 29 months. In nine out of nineteen cases there was trapezial pain with radiographic osteolysis and positive isotope scans. Three patients underwent surgical revision of the prosthesis. The early onset of these symptoms is suggested to be a failure of the osseointegration.

Kaszap et al describe poor outcomes of the Moje thumb carpometacarpal joint arthroplasty. In 83% of the cases migration was seen in at least one component of the implant on radiographs, and in 92% tilting of the prosthesis. Pain was one of the most invalidating factors. The exact mechanism of failure is not clear, but the mechanical characteristics of the implant, its surface properties, and the geometrical design need to be considered. As an example the

circular design of the stem could potentiate the risk of rotational shift. Hansen et al describe the same outcomes, and pointed out the high loosening rate of the Moje Prosthesis.

James et al describe a Hemiarthroplasty for treatment of trapeziometacarpal osteoarthritis with good results. Although the methodological quality is not optimal, but pain relief was significantly changed and improved function was measured using the Buck-Gramcko score. Also survivorship analysis found 94% of these prosthesis were functional at mean follow-up of 72.1 months.

Considering the literature on the arthroplasty for treatment of the trapeziometacarpal joint, the hemiarthroplasty might have better results but are less stable and might fail due to progressing osteoarthritis of de trapezium. Our choice for the Nugrip arthroplasty was based on the fact that it is an hemiarthroplasty, made of Pyrocarbon. The Pyrocarbon resembles bone closely which might minimize osteointegration of the Trapezium. By making a ball and socket stability is added. By close follow-up in the future we will investigate the hypothesis. Care must be taken in patients with instability and proper placement is essential.

Due to the lack of high quality methodological research on the use of total joint prosthesis and hemiarthroplasty in advanced stages of OA is necessary, RCT's of prostheses compared to trapeziectomy, mentioned in the reviews as one of the best treatments, with long follow-up. Vermeulen et al also suggests that, due to the small differences in techniques, researchers should focus on developing more sensitive outcome measures that are indicative of the specific changes in hand function after CMC OA.

Table 1

Comparison of Grip strength and Scoring Tip Pinch Strength between operated and contralateral side

Patient	Operated side GS ¹	Contralateral GS	Operated side STPS ²	Contralateral STPS
1	12	18	6	6
2	14.5	22	5	7
3	10.3	8.6	5	3
4	12	5	4.5	4.5
5	26	22	5.5	6
6	8.3	24	6.3	3
7	12	32	5.2	11.5
8	50	50	8	10
Mean	19.54	22.70	5.69	6.38
9 ³	10	25	1.5	5.5

Outcome in kilograms

In this table results of patient with fractured metacarpal (and prosthesis) are excluded

¹ GS = Grip Strength

² STPS = Scoring Tip Pinch Strength

³ Patient with malposition of Nugrip CMC Implant

Table 2

Range of motion in carpometacarpal joint of the thumb in operated and contralateral side

Patient	Operated side extension-0-flexion CMC ¹		Contralateral side extension-0-flexion CMC		Operated side adduction-0-abduction CMC		Contralateral side adduction-0-abduction CMC	
1	14	0	10	16	0	12	0	40
2	0	0	16	0	0	14	0	60
3	30	0	28	46	0	0	0	52
4	0	10	30	0	0	30	0	28
5	0	0	28	0	0	32	0	64
6	0	0	10	0	0	10	0	38
7	0	0	30	0	0	20	0	68
8	0	0	28	6	0	18	0	45
Median	0	0	28	0	0	16	0	48.5
9 ²	0	0	10	0	0	20	0	30

Outcome in degrees
In this table results of patient with fractured metacarpal (and prothesis) are excluded
¹ CMC = Carpometacarpal joint of the thumb
² Patient with malposition of Nugrip CMC Implant

Table 3

Measurements range of motion in interphalangeal and metacarpophalangeal joint of the thumb

Patient	Operated side extension-0-flexion IP ¹		Contralateral side extension-0-flexion IP		Operated side extension-0-flexion MCP ²		Contralateral side extension-0-flexion MCP	
1	0	0	30	0	0	0	64	0
2	0	0	52	0	0	0	60	0
3	18	0	42	30	0	0	64	0
4	0	0	46	0	0	0	64	0
5	20	0	56	20	0	58	76	18
6	0	0	44	0	0	64	72	0
7	16	0	46	20	0	54	82	0
8	10	0	48	10	0	54	68	0
Median	5	0	46	5	0	53	66	0
9 ³	0	0	30	30	0	40	82	0

Outcome in degrees
In this table results of patient with fractured metacarpal (and prothesis) are excluded
¹ IP = Interphalangeal joint of the thumb
² MCP = Metacarpophalangeal joint of the thumb
³ Patient with malposition of Nugrip CMC Implant

Figure 6

Comparison of VAS for pain pre- and postoperative, and postoperative for functionality and satisfaction

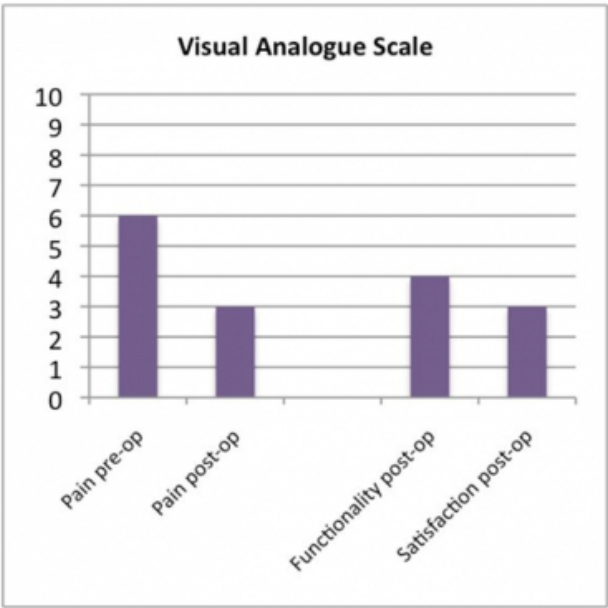


Illustration 1

The Alignment Awl inserted intramedullar with the External Alignment Guide attached

Figure 5

DASH score pre- and postoperative

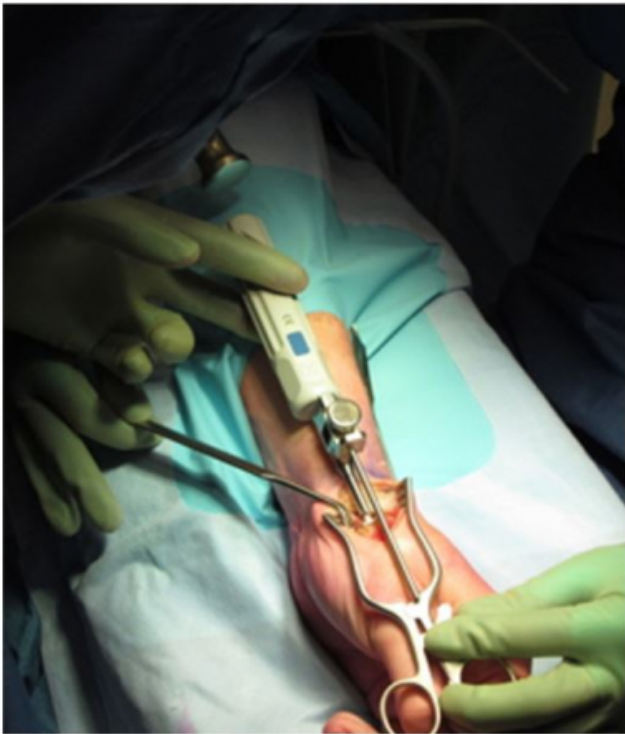
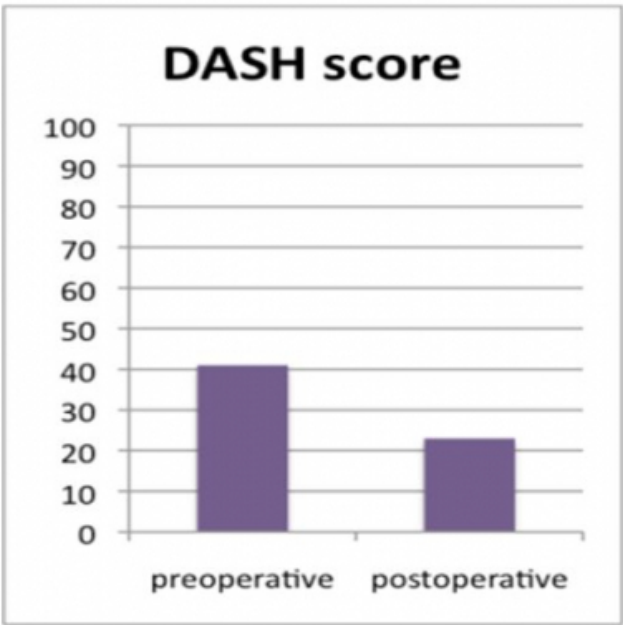


Illustration 2 and 3

Preparing of the trapezium using an Axial Cannulated Cutter, with result

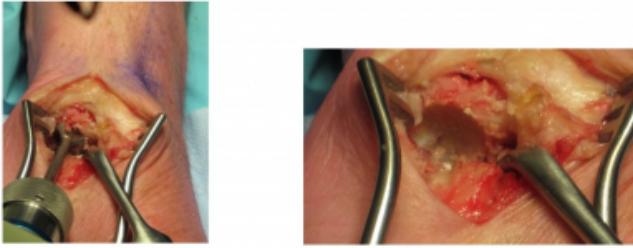


Illustration 4

Conventional X-ray postoperative after inserting Nugrip



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