CHAPTER 2

SUBJECTIVE AND RADIOGRAPHIC OUTCOMES OF PATIENTS AFTER FIRST METATARSOPHALANGEAL JOINT HEMI-IMPLANTATION

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INTRODUCTION

Hallux rigidus is a progressive degenerative disease of the first metatarsophalangeal joint that has been reported annually to affect up to 10% of those over the age of 50 (1). Whether it results primarily or secondarily (i.e., from trauma/injury, biomechanics), hallux rigidus can become very debilitating, affecting even simple activities of daily living. Patients often present with pain and/or stiffness in their great toe joint that is worse with ambulation or activity. Radiographically, one can observe joint space narrowing, flattening of the first metatarsal head, and osteophytic formation at the base of the proximal phalanx and at the metatarsal head. Conservative treatment options include shoe modifications or insoles, nonsteroidal anti-inflammatory drugs, steroid injections, physical therapy, and rest. When conservative options fail, surgical treatment should be considered and includes a cheilectomy, phalangeal and metatarsal osteotomies, joint arthroplasty, hemi- or total joint implants, or fusion of the great toe joint (2). When determining the appropriate procedure for the patient, it is necessary to keep certain things in mind, such as the stage of the deformity, which side of the joint is affected, the age and activity level of the patient, and any other underlying medical comorbidities.

Although joint fusion remains the current gold standard of treatment for end-stage hallux rigidus, joint implants have gained popularity in recent years among foot and ankle surgeons for the use of earlier staged hallux rigidus. The goal of an implant arthroplasty is to relieve pain and restore motion and length of the great toe joint.

To our knowledge, there have not been any reports on the use of the Osteomed hemi-implant. Therefore, the purpose of our study was to observe the clinical, radiographic, and subjective outcomes after utilizing the Osteomed hemi-implant in our patient population.

MATERIALS AND METHODS

Institutional review board approval was obtained for the retrospective chart review. Inclusion criteria included all adult patients who underwent surgical correction for hallux limitus/rigidus utilizing the Osteomed hemi-implant between March 2007 and May 2013 at Scripps Green. All procedures were performed by one surgeon (GDC).

Evaluation

All patients were included for the clinical evaluation portion of the study, regardless of any concomitant procedures they received. Clinical evaluation included the postoperative course and any noted complications, including device removal rate.

For the radiographic analysis, only patients with preoperative and postoperative weight-bearing films were included. Radiographic evaluation involved comparing pre- and postoperative measurements, including hallux shortening and Seiberg's index, along with any noted changes around the implant, including hypertrophic bone formation, lucency around the implant (suggesting loosening or backing out of the device), and cortical breach of the implant.

Lastly, all patients were sent a follow-up subjective questionnaire (the Modified Maryland Foot Score), which asked questions regarding their physical limitations and satisfaction with the procedure. At the end of the questionnaire, patients were also asked whether or not they would undergo the same operation again. The questionnaires were sent through the mail, along with a letter of intent and a consent form. All patients who returned the questionnaires were included and their information was kept confidential.

Statistical Analysis

Statistical analysis for the radiographic measurements was carried out using the Student's *t*-test. Differences of $P < 0.01$ from preoperative to postoperative measures were considered statistically significant.

RESULTS

Between March 2007 and May 2013, a total of 106 patients (37 male, 69 female; 128 feet) underwent surgical correction for their hallux limitus/rigidus deformity utilizing the Osteomed hemi-implant. The average age at the time of surgery was 60.1 years (range 41-84 years). Twenty-two patients had bilateral implants performed, and 41 patients

had other concomitant procedures, including Watermann-Green osteotomies (13 patients), correction of digital contracture(s) (16 patients), and tailor's bunionectomies (3 patients).

Clinical Evaluation

All 106 patients were included in the clinical evaluation. The average follow-up was 15 months from the time of surgery. The most common postoperative complication was transfer capsulitis and/or the progression of hammertoe contractures of the lesser digits (21 patients). Of these 21 patients, 5 patients went on to have surgical correction for their hammertoe deformities. Fourteen patients had superficial wounds and/or clinical signs of localized infection around the incision. All of these patients were treated prophylactically with a short course of oral antibiotics and no further complications were reported. Nine patients developed a fracture along one of the lesser metatarsals, with 7 of these being stress fractures along the second metatarsal. Of the 128 implants placed, only 2 were removed, secondary to the presence of continued pain at the first metatarsophalangeal joint. At the time of the implant explantation, one patient underwent a Keller arthroplasty with the use of GraftJacket and the other patient underwent a Mayo arthroplasty.

Radiographic Evaluation

Eighty-three patients met the criteria for radiographic analysis. Preoperative and postoperative radiographic results are detailed in Table 1. The average hallux length, measured by the length of the bisection of the proximal phalanx, was 29.4 mm, preoperatively. The average length of the hallux postoperatively was 27.4 mm, for an average hallux shortening distance of 2.0 mm, which was statistically significant. The average preoperative Seiberg's index value was 2.2°. Postoperatively, this value was 1.7° for a difference of 0.5°, which was also statistically significant.

Other radiographic changes noted postoperatively included lucency around the implant and/or gapping between the implant and the proximal phalanx base (12 patients), heterotopic bone regrowth at the great toe joint (10 patients), and asymmetric placement and/or cortical breach of the implant (2 patients).

Patient Questionnaire

Nineteen patients (18%) filled out and returned the patient subjective questionnaire (Modified Maryland Foot Score); however, 7 questionnaires were not filled out completely and were, therefore, not included in the calculation of the total Modified Maryland Foot Score (Mod-MFS). They were, however, included when calculating the subcategories of the Mod-MFS. If a patient gave multiple answers for one question, the questionnaire was included, but the lowest answer was recorded. The breakdown of the Mod-MFS is shown in Figure 1. Out of a possible 100 points, the patients averaged a total score of 81, postoperatively (range 40-100 points). Breaking the questionnaire down into its subcategories, the average pain score was 36.3 (of a possible 45 points), the average gait score was 19.8 (of 22 points), the average cosmesis score was 8.1 (of 10 points), the average activity score was 15.3 (of 18 points), and the average satisfaction score was 3.9 (of 5 points).

The satisfaction part of the questionnaire was answered by 18 patients. Thirteen of the 18 patients were "very satisfied" or "satisfied" with the procedure, 3 patients were "neither satisfied or dissatisfied" and 2 patients were "very dissatisfied." Seventeen patients answered whether or not they would undergo the procedure again. Ten of the seventeen patients stated that they would definitely undergo the procedure again, 5 patients said they would maybe undergo the procedure again, and 2 patients said they would definitely not undergo the procedure again. (Figure 1)

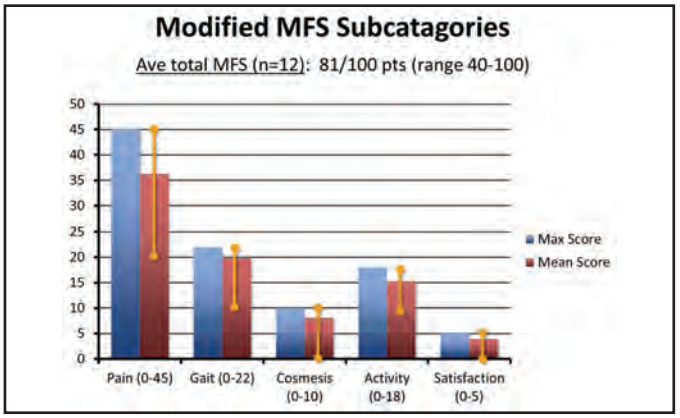

Figure 1. Breakdown of the Modified Maryland Foot Score patient subjective questionnaire.

Table 1. Preoperative and postoperative measurements after the insertion of the Osteomed hemi-implant

XR measurement	Before	After	Change	*P*
Hallux length	29.4 mm	27.4 mm	2.0 mm	< 0.01
Seiberg's index	2.2°	1.7°	0.5°	< 0.01

DISCUSSION

The use of an implant for hallux rigidus was first introduced in 1951 when Endler used a hemi-implant in the base of the proximal phalanx (3). Over the years, several different joint spacers have been developed, each trying to improve on the previous implants. Unfortunately, there is a lack of well-designed prospective studies or long-term outcomes after the insertion of many of these implants.

The most commonly reported complications after the insertion of the more recent metallic hemi-implants is metatarsalgia, subsidency and loosening of the implant, or recurrence of osteophytes around the joint. Konkel et al reported good patient outcomes after the insertion of two different hemi-implants. They reported a postoperative AOFAS score of 86 after the insertion of the Swanson titanium implant with an 85% patient satisfaction rating and a postoperative AOFAS score of 89 after the insertion of the Futura implant with 88% of their patients reporting a good to excellent result, postoperatively (4, 5).

Our study results are comparable to those reported on other similar metal hemi-implants in terms of clinical and radiographic outcomes. The most common complications in our study were transfer capsulitis, clinically, and lucency around the implant, radiographically. We only had to remove two implants. Our subjective scores were lower than those previous described on the other reported hemi-implants; although, we did use a different outcomes measure. Our mean postoperative Mod-MFS was 81 and our patient satisfaction rate was 72%. Unfortunately, we had very low patient participation with only 18% of our patients returning the questionnaire.

There are a few studies available comparing the different treatment options for end-stage hallux rigidus. In 2007, Raikin et al performed a retrospective study on 46 patients who underwent either a fusion or a hemi-arthroplasty (BioPro implant) for grade III or grade IV hallux rigidus. Although the mean follow-up time period for the hemi-arthroplasty group was significantly longer than a fusion (79.4 months versus 30.0 months), the authors found that those who underwent a fusion had a greater mean postoperative AOFAS-HMI score, were more satisfied with their procedure, and had lower pain scores. Furthermore, there were 5 revisional procedures in the hemiarthroplasty group, 4 of which went onto a fusion; whereas, there were no failed fusions to date (6).

In 2012, Kim et al performed a retrospective study, in which they evaluated 158 patients who underwent surgical correction for end-stage hallux rigidus. In the end, they found no difference in average postoperative ACFAS or AOFAS scores between those who underwent a first metatarsophalangeal joint fusion, a Keller arthroplasty, or a hemi-implant inserted in the proximal phalangeal base (7). Last year, Erdil et al compared a first metatarsophalangeal joint fusion, hemiarthroplasty, and a total joint implant for advanced hallux rigidus. They found no functional difference, postoperatively, between the 2 implant groups, but a significantly lower functional score was found in the fusion group, related to the loss of motion at the great toe joint. The pain scores significantly improved in all groups, but a significantly greater improvement was noted in the fusion group compared to both implant groups (8).

As one can see, there still exists controversy as to what is the best treatment option for patients with hallux limitus/rigidus. Although, a fusion of the first metatarsophalangeal joint remains the gold standard for end-stage hallux rigidus, there does appear to be a place for the joint implant in patients who are not good candidates for a fusion or those who wish to keep motion of the joint.

The present study demonstrated fair short-term clinical, radiographic, and subjective outcomes after the insertion of the Osteomed hemi-implant for patients with hallux limitus/rigidus. The most common postoperative complication was transfer capsulitis of the lesser digits, revealing the presence of altered biomechanics after implant insertion. Lucency around the implant was also observed in a number of radiographs, though this had no correlation to removal of the implant. Further research is needed in order to better analyze the biomechanical effects of the first metatarsophalangeal joint implant. In addition, more long-term follow-up studies need to be performed in order to better evaluate the longevity of the implant. (Figure 2)

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Maryland Foot Score

Patient Name _____ Age _____ Sex _____ Date of Exam _____

1. PAIN
   a. None, including with sports 45
   b. Slight, no change in ADL's or work ability 40
   c. Mild, minimal change in ADL's or work 30
   d. Moderate, significant decrease in ADL's taken ASA . . . 20
   e. Marked, during minimal ADL's eg. bathroom, simple housework. Stronger, more frequent analgesics 10
   f. Disabled, unable to work or shop 0

2. FUNCTION
   a. GAIT
      (1) **Distance walked**
         unlimited 10
         slight limitation 8
         moderate limitation (2-3 blocks) 5
         severe limitation (1 block) 2
         indoors only 0
      (2) **Stability**
         normal 4
         weak feeling – no true giving way 3
         occasional giving away (1-2 mos.) 2
         frequent giving away 1
         orthotic device used 0
      (3) **Support**
         none 4
         cane 3
         crutches 1
         wheel chair 0
      (4) **Limp**
         none 4
         slight 3
         moderate 2
         severe 1
         unable to walk 0

3. COSMESIS
   a. Normal 10
   b. Mild Deformity 8
   c. Moderate 5
   d. Severe 0
   e. Multiple deformities 0

Date of Injury _____

Foot: R L Both

Comments: _____

_____

_____

b. FUNCTIONAL ACTIVITIES
   (1) **Shoes**
      any type 10
      minor concession 9
      flat, laced 7
      with orthotics 5
      space shoes 2
      unable to wear shoes 0
   (2) **Stairs**
      normally 4
      with bannister 3
      any method 2
      unable 0
   (3) **Terrain**
      any surface 4
      problems on hills, uneven surfaces 2
      problems on flat surfaces 0
   (4) **Motion**

	5 Normal	4 Slight	2 Marked	0 Ankylosed
Ankle D. flex P. flex				
Subtal Invers. Evers.				
Midft. Abduct. Adduct.				
MTP D. flex P. flex				

TOTAL POINTS _____ **100/Max.**

Satisfaction of OsteoMed Phalangeal Hemi-Implant
(circle one answer below)

Very satisfied
Satisfied
Neither satisfied or dissatisfied
Very dissatisfied

Would you undergo the procedure again?
(circle one answer below)

Yes, definitely
Maybe
No, definitely not

Figure 2. The Modified Maryland Foot Score Questionnaire.