Medical Policy

Partial or Total Replacement Of First Metatarsophalangeal Joint

Effective Date: November 2009;

Subject: Partial or Total Replacement of First Metatarsophalangeal (MTP) Joint

Overview: Underlying causes of disease or disorder to the MTP joint include osteoarthritis, rheumatoid arthritis, and others. These diseases and disorders can cause painful stiffness or deformation of the big toe. If patients do not experience relief after conservative therapies, there are a number of established surgical interventions. Partial joint implants can be surgically attached to either the metatarsal or phalangeal end of the joint. A full replacement connects both ends of the joint.

Policy and Coverage Criteria:

NOTE: Prior Authorization is not required

Harvard Pilgrim covers both metatarsal and phalangeal hemiarthroplasty of the Hallux and full MTP joint replacement (arthroplasty).

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Surgical treatment may be considered for patients with hallux valgus or hallux rigidus with severe symptoms when conservative treatment is not effective. The simplest surgical procedure consists of shaving off the bony prominence interfering with joint movement (i.e., cheilectomy). When conservative medical management and less invasive procedures have failed, procedures involving joint destruction may be considered. Joint destructive procedures include resection arthroplasty (i.e., removal of the medial eminence on the metatarsal head and removal of part of the proximal phalanx, leaving a flexible joint [e.g., Keller's arthroplasty], arthrodesis (i.e. excision of the metatarsal head along with part of the proximal phalanx, and fusion of the joint), and implant arthroplasty (i.e., partial or total joint replacement with an artificial implant).

MTP joint replacement is carried out under general or regional anaesthesia using tourniquet control. An incision is made over the joint and the capsule is exposed by dividing tissue and retracting tendon. The joint surfaces are excised and the medullary canals of the first metatarsal and proximal phalanx are reamed to accommodate the prosthetic joint implant. A preliminary reduction with a trial implant is done to ensure a snug fit and the implant components are then placed in each canal. The joint capsule is closed and a flexible splint is used postoperatively to maintain the correct position (NICE, 2005).

In a partial joint replacement (hemiarthroplasty), doctors traditionally implant a metal cap on phangeal side of the joint. There are also implants available that are installed on the metatarsal side of the joint (HemiCAP; Arthrosurface, Franklin, MA).

2. Literature Review:

Harb et al (2015) conducted a systematic review to assess clinical and adiological outcomes following surgery for adolescent hallux valgus (AHV). The authors identified 9 studies including 140 patients. The results showed a significant improvement in the intermetatarsal angle, hallux valgus angle, and distal metatarsal articular angle. Surgical interventions for AHV showed excellent clinical and radiological outcomes and high patient satisfaction.
A retrospective study by Erkocak et al. (2013) evaluated an MTP implant for treatment of hallux rigidus. Pain scores and average range of motion improved in follow up. Follow up ranged from 25 to 62 months. The authors noted the preservation of joint movement and improved pain relief are advantages of the procedure. Hasselman and Shields (2008) reported on 25 of the first 30 patients they treated with hemiarthroplasty of the first metatarsophalangeal joint using the HemiCAP prosthesis. Mean follow-up was 20 months. The mean postoperative increase in range of motion of the join was 42 degrees. The mean American Orthopaedic Foot and Ankle Society and 36-item Short-Form Health Survey Questionnaire scores were 82.1 and 96.1, respectively. The authors found that the short term results are very promising and that future treatment options are maintained because of minimal bone resection at the time of implantation. Conversion to arthrodesis or resection arthroplasty could be performed in the future should the need arise.

Aslan et al. (2012) discussed early results of the HemiCAP implant and found the data to be promising. The authors noted further long-term studies are needed to review the stability of the implant and other treatment innovations.

Perler et al. (2013) reviewed surgical alternatives to arthrodesis for great toe osteoarthritis. In their assessment of partial and total joint replacement and resurfacing implants, the authors acknowledge the need for fusion alternatives to help restore normal foot function, eliminate pain, and improve patients quality of life. Cook et al. (2009) conducted a meta-analysis to evaluate the MTP arthroplasty in terms of patient satisfaction. The analysis included 47 studies with a mean follow-up of 61.48 months. The mean patient age was 54.98 years. Overall patient satisfaction was 85.7%. The authors stated that the results should be carefully considered given the high degree of heterogeneity among the studies and that adoption of standardized outcome measures for future studies would improve the accuracy of pooled data.

Kissel et al. (2008) conducted a prospective case series to evaluate outcomes of hemiarthroplasty using the Biopro cobalt chromium hemi-implant in 30 consecutive patients with hallux rigidus resistant to conservative treatment. Of 30 patients, 23 completed the 12-month follow-up. Average ACFAS Universal Foot and Ankle Score was 80.4, compared to a preoperative score of 41.2. Statistically significant increases in average dorsiflexion and plantarflexion were observed postoperatively compared to preoperative measurements. The authors noted that this was a pilot study to evaluate the role of hemi-implant arthroplasty in addressing various amounts of double-side joint disease of the first MTP.

Sorbie and Saunders (2008) evaluated outcomes of 19 patients (23 implants) with hallux rigidus treated with hemiarthroplasty using Trihedron cobalt chrome implants between June 2000 and Oct 2001. At an average follow-up of 68 months, the average AOFAS score was 88 (range 75-100) compared to a preoperative average score of 57 (range 39-80). Mild occasional discomfort remained in 5 patients. One patient later required hallux valgus correction. Eighteen of 19 patients experienced increased ROM, although a normal range may not have been achieved.

Konkel at al. (2008) conducted a retrospective review to evaluate mid-term results of the Future hemi-great toe implant in 11 patients (13 toes) with hallux rigidus. At an average follow-up of 87 months, pain was absent in 7 toes, mild and occasional in five, and moderate and daily in one. Range of motion averaged 17 degrees of plantar flexion (range 10-30), 47 degrees of dorsiflexion (range 30-100), and total range of motion averaged 64 degrees (range 30-100). Six patients had some recurrence of the dorsal osteophyte, and three of the six recurrent dorsal bunion were associated with limited dorsiflexion and recurrent mild aching. Mild lucency was seen at the base of the implant in 10 of 11 patients, but the lucency did not extend down the stem of the implant.

Pulavarti et al. (2005) reviewed functional results at a minimum follow-up of 36 months in 32 patients (36 implants) who received the Bio-Action great toe implant for symptomatic advanced degenerative changes in the first MTP joint. The MTP scoring system developed by Kitaoka et al. was used to evaluate outcomes. Significant improvement in the hallux MTP scale and range of motion achieved after the procedure was reported and 77% of patients considered the results to be good or excellent. The authors stated that the main problems associated with implant arthroplasty of the MTP joint are a lack of standard outcome measures, incremental design changes and limited reports on long-term follow-up. They emphasized the need for a universal scoring system and a large, multicenter prospective trial to further prove the usefulness of a total hallux MTP joint system.

In a retrospective case series, Rairkin et al. (2006) compared the long-term outcomes of metallic hemiarthroplasty to outcomes of arthrodesis for treatment of severe arthritis of the first MTP joint. A series of patients were treated with a metallic hemiarthroplasty (n=21 feet; 20 patients) or an arthrodesis (n=27 feet; 26 patients) between 1999 and 2005. All hemiarthroplasties were performed by a single surgeon, and involved a cheilectomy of the metatarsal head, removal of a small portion from the base of the proximal phalanx, including the articular cartilage, and implantation of a BioPro implant. All arthrodeses were performed by another surgeon, and included
resection of the articular cartilage from both sides of the joint to achieve flat surfaces of exposed cancellous bone, followed by placement of two screws to achieve rigid internal fixation. Patients were assessed clinically, radiographically, and with a questionnaire, by an independent observer. Postoperative satisfaction and function were graded using the American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scoring system.

Of the 20 patients (21 feet) treated with hemiarthroplasty, 17 (18 feet) were available for evaluation at a mean follow-up of 79.2 months (range 68-85.7 months). Five (24%) of the 21 joints required subsequent surgical treatment, at an average of 13 months, because of failure of the hemiarthroplasty. One of these patients was treated with revision hemiarthroplasty, and four were treated with arthrodesis. Eight of the feet in which the hemiprosthesis survived had evidence of plantar cutout of the prosthetic stem on the final follow-up radiograph. The satisfaction ratings in the hemiarthroplasty group at final follow-up were: good or excellent, 12 feet; fair, 2 feet; and poor or a failure, 7 feet. All 27 arthrodesis patients achieved fusion, and no revisions were required. Two patients required hardware removal, which was performed as an office procedure. At a mean final follow-up of 30 months, the satisfaction ratings in the arthrodesis group were: good or excellent, 22 feet; fair, 4 feet; and poor, one foot. The mean pain score was significantly better in the arthrodesis group, than in the hemiarthroplasty group. The mean AOFAS-HMI score was also significantly higher at final follow-up in the arthrodesis group, increasing from 36.1 of 100 points preoperatively, to 83.8 at final follow-up, compared to an increase from 35.6 of 100 points preoperatively, to 71.8, for the 16 feet (15 patients) with a surviving hemiprosthesi.

4. Governmental/Regulatory Agencies:
FDA: The FDA issued 510(k) approval (K031859) for the HemiCAP great toe resurfacing hemiarthroplasty implant on February 18, 2004. It is a single-use implant device to be used with bone cement in the first metatarsal joint for treating degenerative and post-traumatic arthritis, hallux valgus or hallus limitus, hallux rigidus, and unstable or painful metatarsophalangeal (MTP) joint in the presence of good bone stock.

CMS: There is no National Coverage Determination for the HemiCAP great toe resurfacing hemiarthroplasty implant or other MTP joint arthroplasty implant.

NICE: Current evidence on the safety and efficacy of metatarsophalangeal joint replacement of the hallux appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance (2005)
http://www.nice.org.uk/guidance/ipg140

Codes:
HCPCS Codes:
L8641: Metatarsal joint implant
L8642: Hallux implant

CPT codes:
28291 –Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28296 - Hallux Valgus correction with metatarsal osteotomy
26535 - Arthroplasty, interphalangeal joint; each joint
26536 - Arthroplasty, interphalangeal joint; with prosthetic implant, each joint
28899 - Unlisted procedure; foot or toes

References:


Summary of Changes:

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