Clinical Policy Bulletin: Metatarsal Phalangeal Joint Replacement

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Policy

Aetna considers total prosthetic replacement arthroplasty with silastic implants and hemiarthroplasty medically necessary for persons with disabling arthritis of the first metatarsal phalangeal joint (hallux rigidus). Metatarsal phalangeal joint replacement for other indications, and for joints other than the first metatarsal phalangeal joint (e.g., tarsal metatarsal joint) is considered experimental and investigational because its value is unproven.

Aetna considers ceramic prostheses (e.g., the Moje implant) experimental and investigational for replacement of the first metatarsal phalangeal joint and for other indications because their long-term effectiveness has not been established.

Aetna considers modular implants (e.g., the METIS® prosthesis and the ToeFit-Plus™ prosthesis) experimental and investigational for replacement of the first metatarsal phalangeal joint and for other indications because their long-term effectiveness has not been established.

Aetna considers interpositional arthroplasty with biologic spacers (e.g., the InterPhlex interdigital implant) and total prosthetic replacement arthroplasty using total metallic implants experimental and investigational for hallux rigidus, degenerative arthritis, and other indications involving the metatarsal phalangeal joints because their effectiveness has not been established.

See also CPB 0629 - Bunionectomy.

Background

Most clinical presentations of the hallux (big toe) concern the metatarsal phalangeal joint (MPJ). The underlying causes of disease/disorder of the MPJ
include osteoarthritis, rheumatoid arthritis, disease of the hallux sesamoids and post-traumatic degeneration. Both types of arthritis often affect the first MPJ located at the base of the big toe. The MPJ may become stiff (hallux rigidus), or deformed (hallux valgus). Hallux rigidus is characterized by pain as well as a reduction in the range of motion (ROM), especially dorsiflexion, at the first MPJ. Hallux valgus is classified as an abnormal deviation of the great toe towards the midline of the foot. Disease/disorder of the MPJ affects shoe wear, ambulation, and other activities of daily living. Although the literature addressing treatments of conditions that affect the hallux often focuses on surgical interventions, the use of conservative therapies is emphasized before surgery is considered. Conservative treatments include exercise, physiotherapy, supportive shoes worn alone or worn with soft/semi-rigid orthoses, non-steroidal anti-inflammatory drugs, and steroid injections. Many surgical procedures have been described for the treatment of congenital and acquired conditions of the big toe. They include arthrodesis (fusion of the joint), arthroplasty, cheilectomy (trimming of the joint), Keller procedure (simple excision of the joint), osteotomy, and plantar release. Metatarsal phalangeal arthrodesis remains the gold standard for arthritis and salvage of the painful first MPJ (Weinfeld and Schon, 1998; Giannnini et al, 2004; Sammarco and Nichols, 2005; Kelikian, 2005).

Brage and Ball (2002) stated that when approaching patients with a painful first MPJ that has failed conservative therapies and first-line surgical treatments (cheilectomy or minor bunion procedures), the surgeon should stratify these patients based upon diagnosis, age, and activity level. For the young, active patient, an arthrodesis is the gold standard, and the primary predictors of clinical and radiographical success are proper fusion angle alignment and maintenance or restoration of length. In the elderly, inactive patient, arthrodesis is a safe and reliable treatment option. However, the Keller procedure may be preferable because it provides excellent early symptomatic relief and has a less debilitating post-operative rehabilitation program. The patients between these two extremes fall into a treatment gray zone. The arthrodesis should again be considered the gold standard because it is reliable and durable with time and activity. However, the authors noted that biologic or prosthetic inter-positional arthroplasty are exciting investigational treatment options for these patients. If a prosthetic implant is to be used, the double-stemmed, hinged silastic implant with protective titanium grommets, or a metallic hemi-arthroplasty prosthesis, appear to be the 2 best choices of implant. With the continuous advances in material engineering and tissue engineering, prosthetic and biologic inter-positional arthroplasties hold the greatest promise for the painful first MPJ in the future. These treatment modalities allow restoration of alignment and maintenance of motion, length, and strength, which are fundamental in attaining a good clinical result. The authors stated that when the optimal material is developed (whether it is prosthetic, biologic, or a combination of both), these treatment advantages will be realized without the attendant complications associated with the use of the current implants. The observations of Brage and Ball (2002) were in agreement with those of Sizensky (2004).

Coughlin and Schurnas (2004) reported their experience with cheilectomy or MPJ arthrodesis in the treatment of hallux rigidus. Of the original 114 patients with a diagnosis of hallux rigidus, 110 returned for the final evaluation. Eighty patients (93 feet) had undergone a cheilectomy, and 30 patients (34 feet) had had an
arthrodesis. The mean durations of follow-up were 9.6 and 6.7 years following cheilectomies and arthrodeses, respectively. These authors reported that 97% of patients (107/110) had a good or excellent subjective result, and 92% of cheilectomy (86/93) were successful in terms of pain relief and function. Cheilectomy was used with predictable success to treat grade-1, grade-2 and selected grade-3 cases. Patients with grade-4 hallux rigidus or grade-3 hallux rigidus with less than 50% of the metatarsal head cartilage remaining at the time of surgery should be treated with arthrodesis.

A systematic evidence review of treatments for hallux rigidis by Yee and Lau (2008) found that the consistently favorable results reported in several level IV studies constituted fair evidence (grade B recommendation) to support the use of cheilectomy in persons with grade I and II hallux rigidis. The authors noted that 2 separate studies observed poor results in a small subset of patients with advanced degeneration of the MPJ. The authors concluded that, based on this evidence, cheilectomy can not be recommended for grade III hallux rigidus.

Taylor et al (2004) stated that arthrodesis has emerged as the primary salvage procedure for severe osteoarthritis of the first MPJ. These investigators reported that 43 patients underwent arthrodesis of the first MPJ with stabilization provided by either 2 crossed lag-screws or a dorsal plate and screws. First MPJ arthrodesis was the primary procedure for 46 of the 54 treated feet. At a mean of 21.7 months (median of 13.5 months), 34 of the 43 patients completed a brief telephone survey about surgical outcomes. Radiographical measurements of inter-metatarsal, hallux valgus, inclination, and dorsiflexion angles were made pre-operatively and post-operatively. Mean time to fusion was 7.3 weeks; arthrodesis was successful for 50 of 52 feet (radiographs were missing for 2 of the 54 feet treated). Internal fixation devices were removed from 5 feet. Thirty of the 34 patients (88.2%) rated their result as excellent or good; the other 4 (11.8%) rated their result as poor.

A systematic evidence review by Yee and Lau (2008) found that the consistently favorable results in many level II and IV studies constitute fair evidence (grade B recommendation) to support the use of arthrodesis for the treatment of stage III hallux rigidus.

Although joint replacement remains the ultimate solution for hip osteoarthritis, and may be a viable option in ankle osteoarthritis, replacement of the MPJ has not been established as a standard of care for osteoarthritis of the hallux. Despite its initial success in relieving symptoms, the use of total joint replacements of the first MPJ with a flexible hinged silicone prosthesis for replacement arthroplasty was initially abandoned because of the high and increasing rate of failure of the implant, as demonstrated radiographically (Granberry et al, 1991). These first generation silastic implants failed because of the high shear forces concentrated at the prosthetic hinge.

To address this, new systems were redesigned for insertion with titanium grommets to reduce the stress applied to the silastic in order to increase the survival of the arthroplasty (Yee and Lau, 2008). Sebold et al (1996) investigated the use of double-stem silicone implants protected by titanium grommets. These were placed in the hallux metatarso-phalangeal joints of 32 patients (47 feet). All patients had a painful destroyed joint and most were women. Three patients (6 feet) were lost to follow-up. Nineteen patients had a diagnosis of rheumatoid
arthritis (25 feet) and 10 had degenerative joint disease (16 feet). The average age for the group was 57 years and the average follow-up was 51 months (range of 34 to 76 months). Twenty patients (30 feet) were completely satisfied with their result. Eight patients (10 feet), all with rheumatoid arthritis, had some minor post-operative complaints, usually involving the lateral toes. Two patients (3 feet) in this group had no pain, but would have preferred more hallux motion. One patient with rheumatoid arthritis (1 foot) had a poor result due to implant removal for deep sepsis. Radiographical analysis of these patients showed no evidence of implant fracture and the implant composite appeared to be well-tolerated by the surrounding bone in which it was placed. The investigators reported that, when compared with another, similar group of patients in whom grommets were not used, this implant appeared to be much more stable, as there was significantly less evidence of radiolucency seen around those implants protected by the grommets. The investigators stated that the titanium grommets may protect the silicone implant and may help provide a longer life for the silicone implant.

In a systematic evidence review of treatments for hallux rigidus, Yee and Lau (2008) stated that, despite these improvements, concerns persist regarding the potential effects of silicone debris leading to foreign-body reaction, synovitis, and bone erosion in the hallux. In addition, the systemic effects of silicone microfragments invading the lymphoreticular system are still unknown. The authors concluded that conflicting evidence weakly supports total prosthetic replacement arthroplasty with silastic implants with hallux rigidus (grade C recommendation).

Other MPJ prostheses include the titanium hemi-great toe implant (Leavitt et al, 1991), the 2-component first MPJ implant (Gerbert et al, 1995), and the Moje press-fit ceramic implant (Malviya et al, 2004). Malviya et al reviewed their results with the Moje press-fit ceramic implant. This study included 7 procedures in 6 patients with a mean age of 60.2 years followed for a mean of 35 months (a range of 24 to 43 months). There was a significant (p < 0.001) improvement of the visual analog score from 7-8 to 1-2 and of the Foot Function Index from 75.6 to 8.6. A mean post-operative dorsiflexion of 29.2 degrees and plantar flexion of 12.1 degrees were recorded. Apart from slight cortical recession in 1 case, probably related to overuse, there was little evidence of osteolysis or loosening of implants and no major complication has been noted in any of the patients. The authors stated that the press-fit design appears to have overcome the disadvantages of the previous screw-fit prosthesis that had been reported to have complications related to metallosis around the titanium screw.

The Clinical Practice Guideline First Metatarsophalangeal Joint Disorders Panel (Vanore et al, 2003) noted that total joint replacement systems have been designed for the first MPJ generally as 2-component non-constrained articulations in an attempt to allow motion in more than 1 plane. Materials used for opposing articular surfaces are chosen for their low coefficient of friction and for their minimum wear characteristics. Numerous implant systems have been developed during the years, and several are still used clinically, although long-term clinical usefulness has yet to be established. The panel stated that judicious use and strict criteria are recommended to avoid complications and problematic revisions.
The National Institute for Health and Clinical Excellence (NICE, 2005a) released an assessment on MPJ replacement of the hallux. It concluded that available evidence on the safety and effectiveness of MPJ replacement of the hallux appears adequate to support the use of this procedure, but there is limited evidence of the durability of this procedure. The NICE assessment stated that clinicians should ensure that patients fully understand the uncertainties about the place of this procedure in relation to alternative treatment options such as arthrodesis (NICE, 2005a). The assessment stated that patient selection is important, and should take into consideration the likely intensity and duration of use of the joint based on the patient's activities and aspirations. This report also stated that further research will be useful in establishing the long-term outcomes of different types of prostheses. These conclusions were based on a review of the available evidence (NICE, 2005b). The main outcome measures reported were pain relief and patient satisfaction. Three studies reported that 73 % (8/11), 79 % (46/58) and 100 % (7/7) of joints with implants were pain-free after mean follow-ups of 17 months, 12 years, and 35 months, respectively. Another study including 86 implants reported a statistically significant improvement in pain scores after the procedure. Two further studies reported pain relief in 66 % (59/90) of implants and 94 % (30/32) of patients (mean follow-ups of 3 years and 8 years, respectively). Four studies reported that between 74 % (29/39) and 88 % (7/8) of patients were completely satisfied with the procedure (mean follow-ups of 12 months and 17 months, respectively). Although most of the specialist advisors to NICE stated that this was an established technique, these advisors noted that there is limited evidence on the durability of the newer implants. The specialist advisors also stated that potential adverse events included persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas, and transfer metatarsalgia. Some of these complications may require removal of the joint. Radiological follow-up may show fracture of prostheses or immobility of joints in the long-term. However, the influence of these changes on symptom relief remains unclear.

On the other hand, some recent reviews did not find MPJ replacement to be a standard treatment for diseases/disorders of the hallux (Fuhrmann et al, 2003; Giannnini et al, 2004; Ferrari et al, 2004; Wulker, 2004; Keiserman et al, 2005; Esway and Conti, 2005). Fuhrmann et al (2003) reported their experience with replacement of the first MPJ. After a 3-year follow-up, most patients who had an MPJ replacement were extremely satisfied with the outcome. Plantar pressure distribution revealed a marked improvement. However, recovery of metatarsophalangeal (MTP) dorsiflexion was limited and joint stability worsened. Radiologically, 1/3 of the prostheses showed radiolucent lines indicating loosening of the implant. These researchers stated that MPJ replacement offers distinct advantages in the treatment of end-stage hallux rigidus, but more research is needed on implant design and osseous fixation.

A review on surgical interventions for hallux rigidus (Giannnini et al, 2004) did not list MPJ replacement as one of the options, which include arthrodesis, cheilectomy, Keller procedure, osteotomy, plantar release, and arthroplasty with the use of a spacer. Additionally, a Cochrane review on interventions for treating hallux valgus (Ferrari et al, 2004) did not mention the use of MPJ replacement. Furthermore, Wulker (2004) stated that conservative treatments for hallux rigidus
mainly consist of local anti-inflammatory applications and orthopedic appliances to decrease load at the MPJ. With progression of the arthrosis, joint-preserving procedures such as cheilectomy are used. In complete destruction of the joint space, arthrodesis is the technique of choice in the mostly active, younger patients. The author stated that resection arthroplasty is mainly used in the elderly, less active patients, and the results of first MPJ replacement are inferior to arthrodesis.

Keiserman et al (2005) noted that many surgical procedures are available for the treatment of hallux rigidus. The choice depends on the severity of the disease, activity level of patient, and expectations about the surgery. These investigators said that cheilectomy is recommended for early disease and may be associated with an osteotomy of the proximal phalanx. For active patients who have severe hallux rigidus, arthrodesis and biological inter-position arthroplasties have shown good results. These investigators stated that Keller arthroplasty is reserved for patients with low functional demand; and prosthetic replacements are not recommended at this time. In addition, Esway and Conti (2005) stated that replacement of the hallux MPJ does not have the same success as hip and knee arthroplasties. Silastic joint implants have a high patient satisfactory rate; however they have caused many complications, including silicone synovitis and lymph node inflammation. Metal and polyethylene hemi-arthroplasties and total toe replacements appear to be more promising although results are preliminary. Problems with these implants seem to be related to soft tissue instability of the joint; patients who have hallux rigidus have more success than patients who have hallux valgus or rheumatoid arthritis. Severe complications can be treated with removal and synovectomy or arthrodesis, depending on the length and alignment of the foot, as well as the functional demands of the patients. These researchers further stated that it would be beneficial to have more data on these implants so that improvements can be made in design and patient selection.

Silastic hemiarthroplasty was initially abandoned as a treatment for hallux rigidus because of their failure in terms of poor durability, foreign body reaction and dislodgement of components (Shankar, 1995; Rahman and Fagg, 1993). The metallic hemiarthroplasty was developed in response to these failures of silastic implants (Townley and Taranow, 1994). The procedure involves the resection of the proximal portion of the proximal phalanx in addition to the resection remodeling of the metatarsal head (Townley and Taranow, 1994). The metallic prosthesis is then implanted to replace the articulating surface of the proximal phalanx. Current metallic hemiarthroplasty has not been proven to offer significant benefits compared with other surgical alternatives.

Available published peer-reviewed evidence for metallic hemiarthroplasty consists primarily of retrospective case series (Townley and Taranow, 1994; Taranow et al, 2005). In the only prospective study of metallic hemiarthroplasty for hallux rigidus published to date, Roukis et al (2003) reported similar short-term outcomes with metallic hemiarthroplasty and periarticular osteotomy. The investigators compared metallic hemiarthroplasty to periarticular osteotomy in 44 patients (47 feet) with hallux rigidus. A subjective evaluation, physical examination, and radiographical analysis were performed pre-operatively and at a 1-year follow-up. Twenty patients (20 feet) underwent a peri-articular osteotomy, with 16 patients (16 feet) returning. Seven patients (9 feet) underwent metallic hemiarthroplasty, with all
patients returning. The subjective evaluation was based on a modified American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal-Interphalangeal 100-point scale. The physical examination included first MPJ ROM. Radiographical analysis included the metatarsal protrusion distance, transverse plane angulation of the second digit, lateral talo-first metatarsal angle, sagittal plane relationship of the first and second metatarsals, and hallux equinus angle. Statistically significant differences between pre-operative and post-operative values were found for the periarticular osteotomy group for the metatarsal protrusion distance ($p = 0.000$), transverse plane angulation of the second digit ($p = 0.000$), and lateral talo-first metatarsal angle ($p = 0.015$). No other statistically significant differences between the pre-operative and post-operative values for either procedure group were found to exist. The investigators noted that there were equally significant improvements in subjective scores and a high percentage of patient satisfaction in both groups. However, both procedures resulted in only minimal increases in first MPJ ROM.

Raikin et al (2007) reported better long-term outcomes with arthrodesis than with metallic hemiarthroplasty in hallux rigidus. Patients with hallux rigidus were treated with either a metallic hemiarthroplasty or an arthrodesis between 1999 and 2005. Post-operative satisfaction and function were graded with use of the American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scoring system, and pain was scored with use of a visual analog scale. The investigators reported that 21 hemiarthroplasties and 27 arthrodeses were performed in 46 patients. Five (24 %) of the hemiarthroplasties failed; 1 of them was revised, and 4 were converted to an arthrodesis. Eight of the feet in which the hemiprosthesis had survived had evidence of plantar cut-out of the prosthetic stem on the final follow-up radiographs. At the time of final follow-up (at a mean of 79.4 months), the satisfaction ratings in the hemiarthroplasty group were good or excellent for 12 feet, fair for 2, and poor or a failure for 7. The mean pain score was 2.4 of 10. All 27 of the arthrodeses achieved fusion, and no revisions were required. At the time of final follow-up (at a mean of 30 months), the satisfaction ratings in this group were good or excellent for 22 feet, fair for 4, and poor for 1. The mean pain score was 0.7 of 10. Two patients required hardware removal, which was performed as an office procedure with the use of local anesthesia. The AOFAS-HMI and visual analog pain scores and satisfaction were significantly better in the arthrodesis group. The investigators reported that arthrodesis is more predictable than a metallic hemiarthroplasty for alleviating symptoms and restoring function in patients with severe hallux rigidus.

A systematic evidence review by Yee and Lau (2008) found that, except for a study co-authored by the developer of the hemiarthroplasty (Townley and Taranow, 1994), the use of hemiarthroplasty in the management of hallux rigidus is supported by conflicting or poor quality evidence (grade C recommendation). The long-term consequences for hemiarthroplasties that have not failed but are malpositioned, subsided or surrounded by radiolucencies remains uncertain. The authors stated that further studies designed to yield level I or II evidence are warranted to address these concerns.

In a randomized controlled clinical study, results of arthrodesis were also found to be superior than total joint replacement with metallic implants. Gibson et al (2005) reported on the results of a randomized controlled trial to evaluate clinical
outcomes after MPJ arthrodesis and replacement arthroplasty in end-stage hallux rigidus. Between November, 1998, and January 2001, 63 patients between the ages of 34 and 77 years, with unilateral or bilateral MPJ arthritis were recruited and randomly selected to have either MPJ arthrodesis or arthroplasty. Twenty-two patients (38 toes) had arthrodesis and 27 patients (39 toes) had arthroplasty. A single surgeon performed all surgery. The primary outcome measure determining successful surgery was a decrease in pain as measured on a visual analog scale (VAS). Functional outcome was assessed at 6 months and 1 and 2 years. The investigators reported that, at 24 months, pain improved in both groups (p < 0.001), but there were significantly greater improvements after arthrodesis (p = 0.01). All 38 arthrodeses united at a mean dorsiflexion angle of 26 degrees, with few complications. In contrast, in the arthroplasty group, 6 of the 39 inserted implants had to be removed because of phalangeal component loosening. In the remainder the ROM gained was poor, and the patients tended to bear weight on the outer border of their foot. The investigators concluded that outcomes after arthrodesis were better than those after arthroplasty. The investigators reported that the results were partially attributable to an unacceptably high incidence of loosening of the phalangeal components, which resulted in removal of the implants. The investigators noted, however, even when data from the failures were excluded, arthrodesis was clearly preferred by most patients.

A systematic review of the evidence for treatment of hallux rigidus by Yee and Lau (2008) found that given the unfavorable results in multiple studies with different implants, total prosthetic replacement arthroplasty with metallic implants “cannot be recommended at this time for the management of hallux rigidus.” The authors stated that the results of the prospective, randomized trial by Gibson et al (2005) constitute a grade B recommendation of arthrodesis instead of arthroplasty. The authors stated, however, that more level I or II evidence is warranted to confirm these findings.

Deheer (2006) argued against first MPJ implant arthroplasty. The author noted that intermediate- and long-term studies raise concerns about implant failure and longevity. Other causes for concern are silicone-induced synovitis and lymphadenopathy. Furthermore, the lack of any significant long-term results and the documented metallic breakdown from 2-piece metallic implants make their use in hallux rigidus questionable. Meanwhile, a comparative study showed the superiority of arthrodesis to implant arthroplasty. Also, alternatives to joint-destructive procedures are emerging. These include arthrodiastasis and the osteochondral autograft transfer procedure. The author concluded that this evidence proves that implant arthroplasty is not the best treatment for patients with hallux rigidus or other first MPJ pathology.

Interpositional arthroplasty combines a standard resection arthroplasty with the insertion of a biologic spacer into the joint to avoid some of the difficulties associated with an isolated resection arthroplasty. Various tissues, including tendons, have been utilized in the interpositional graft. Theoretically, this procedure necessitates less bone resection from the proximal phalanx and better maintains joint stability and motion (Yee and Lau, 2008).

Hamilton et al (1997) reported on their experience with 30 patients (37 feet) with severe hallux rigidus who underwent interpositional arthroplasty over a 10-year
period. The authors reported that pain and function were significantly improved. The American Orthopaedic Foot and Ankle Society (AOFAS) scores improved from an average of 23 pre-operatively to 37 post-operatively. Average dorsiflexion improved from 10 to 50 degrees. Transfer metatarsalgia was not seen. All patients had at least 4/5 plantarflexion strength and averaged 50 degrees of dorsiflexion. The authors concluded that, in patients with severe hallux rigidus and nearly equal length of first and second metatarsals, capsular interposition arthroplasty offers a surgical option that relieves pain without sacrificing motion or strength.

Kennedy et al (2006) examined 18 patients with severe articular cartilage loss who received 21 interposition arthroplasties. The patients a mean age was 56 years. They had a mean follow-up of 38 months. All patients had substantial loss of articular cartilage when examined intra-operatively. Patients were evaluated using the AFOAS and Short Form-36 scores. All 18 patients had pain relief, and 17 of 18 patients said they would have the procedure again. The mean post-operative increase in ROM of the first MPJ was 37 degrees. The mean AFOAS and Short Form-36 scores were 78.4 and 96.3, respectively. The complication rate was 6 %.

Lau and Daniels (2001) conducted a retrospective review of 19 patients (24 feet) with grade 2 osteoarthritis and 11 patients (11 feet) with grade 3 osteoarthritis. The patients with grade 2 osteoarthritis were managed with a cheilectomy and the patients with grade 3 osteoarthritis with an interpositional arthroplasty. All patients were individually assessed with a subjective questionnaire, physical examination, AOFAS hallux scale, SF-36 and pedobarographic analysis. Cheilectomy patients (51.9 years) were younger than interpositional arthroplasty (59 years). Follow-up between the interpositional arthroplasties (2.0 years) and cheilectomies (2.1 years) were comparable. Post-operative motion, VAS and SF-36 scores were comparable between groups. Cheilectomies had a higher mean AOFAS score (77.3) than interpositional arthroplasties (71.6). Weakness of the great toe was reported in 72.7 % of interpositional arthroplasty patients compared to only 16.7 % of patients with a cheilectomy. Patient satisfaction was 87.5 % in cheilectomies and 72.7 % in interpositional arthroplasties. Pedobarographic analysis demonstrated a decreased load under the great toe with increased weight transfer to the lesser metatarsal heads in all patients. The weight transfer to the lesser metatarsal heads was greatest in patients with interpositional arthroplasty. The authors concluded that management of moderate hallux rigidus with a cheilectomy and phalangeal osteotomy is a reliable method of relieving pain and improving function. Management of severe osteoarthritis of the joint with an interpositional arthroplasty should be considered a salvage procedure with less reliable results.

Other studies published of interpositional arthroplasty using a biologic spacer have also been level IV evidence, including Barca (1997) (12 patients followed for an average of 21 months) as well as Coughlin and Shurnas (2003) (7 patients followed for an average of 41 months). In a systematic evidence review of treatments for hallux rigidus, Yee and Lau (2008) concluded that considering the limited quantity and quality of the data, there is insufficient evidence (grade I recommendation) to recommend interpositional arthroplasty for the treatment of hallux rigidus.
The Moje ceramic toe implant is made of zirconium oxide and was developed in 1994 by Dieter Werner (an orthopedic surgeon) and Hans Jurgen Moje (a ceramic engineer). The original implant was screw-fit but complications of osteolysis and metallosis led to the replacement of the design with the press-fit one. The press-fit implant is a 2-component ceramic prosthesis coated with apatite and fosterite crystals (Bioverit). It relies mainly on interference fit coupled with osseo-integration encouraged by the Bioverit coating. The coating forms a closed contact with the substrate and possesses a good adhesive strength (Malviya et al, 2004).

In a single-surgeon series study, Barwick and Talkhani (2008) evaluated the clinical outcome of the Moje arthroplasty using objective and subjective assessment tools. A retrospective outcome study of 24 implants was performed in 22 patients undergoing first MPJ replacement for osteoarthritis from 2004 to 2006. Each patient underwent clinical assessment using the AOFAS for the hallux and a patient outcome satisfaction questionnaire. All pre- and post-operative radiographs were reviewed. Average follow-up was 26 months with a median AOFAS score of 80 out of a maximum 100. The revision rate at 3 years was 12.5%. Only 63% of patients were "very satisfied" with the overall outcome from the procedure. AOFAS for the hallux correlated strongly with patient satisfaction. Radiographical mal-alignment in 4 patients was significantly associated with lower AOFAS (p = 0.01). The authors concluded that the Moje ceramic prosthesis offers less reliable outcomes than the "gold standard" arthrodesis and caution is advised regarding its use for osteoarthritis of the first MPJ.

McGraw et al (2010) assessed the mid-term clinical and radiographical results of the Moje hallux MPJ replacement. These investigators described their single-surgeon experience of 63 components in 48 patients at a mean follow-up of 44 months. Patient satisfaction was assessed by questionnaire and radiographical assessment performed immediately post-operatively and at the latest follow-up. Mean AOFAS hallux score increased from 56 to 72 (p < 0.01) and mean satisfaction score was 7.6 (scale 1 to 10). A total of 67% of subjects reported minimal or no pain. Five implants have been removed (8%), 4 because of pain associated with implant loosening and subsidence, and 1 because of deep infection. Fifty-seven percent of metatarsal and 56% of phalangeal components had subsided and radiographical evidence of loosening in 58% of X-rays analyzed at latest follow-up was found. Prosthetic subsidence was associated with greater margin of uncovered bone under the prosthesis (p = 0.05 for metatarsal, p = 0.03 for proximal phalanx component) and longer follow-up (p < 0.001). The authors concluded that in spite of the good clinical outcome at the mid-term stage with 91% implant survival, given the widespread loosening and subsidence encountered in this study, the long-term outcome following this procedure is uncertain.

In a case series study, Brewster and colleagues (2010) reported the functional results of the Moje first MPJ replacements performed between February 2001 and November 2006. All patients who underwent Moje arthroplasty under the care of a single surgeon were included; outcome scores and complications were recorded annually. A total of 32 joints in 29 consecutive patients were followed for a mean duration of 34 (range of 6 to 74) months, and the mean patient age at the time of operation was 56 (range of 38 to 79) years. Hallux rigidus was the primary
diagnosis in 28 (87.5 %) of the cases. The mean AOFAS-HMI score at final follow-up was 74/100 (range 9 to 100), with 13 (40.63 %) joints rated good-to-excellent. Two (6.25 %) joints were revised to arthrodesis at a mean of 52 (range of 41 to 63) months following the arthroplasty procedure, and the overall prevalence of post-operative complications was 6 (18.75 %). Based on these results, the authors concluded that first MPJ joint replacement with the Moje device remains promising, but still has room for improvement before the results match those obtained with larger joint (knee, hip) arthroplasty. Thus, more studies including larger number of patients with longer follow-up are needed to evaluate the long-term results of the Moje ceramic prosthesis for MPJ replacements. Furthermore, Gutteck and colleagues (2011) stated that the high loosening rate of the Moje prosthesis in the treatment of hallux rigidus caused disappointing medium-term results. Arthrodesis using an iliac crest bone graft is the standard salvage procedure.

Metatarsophalangeal implants have been proposed as treatment for disorders affecting joints other than the first MTP joint, for other toe joints (e.g., interphalangeal joints), and for the tarsal metatarsal (TMT) joint. However, there is insufficient evidence regarding the use of MTP implants for these indications. Nagy et al (2014) noted that ceramic first MPJ replacement has been reported for treatment of hallux rigidus (HR), but there are no published mid- or long-term studies available. These investigators presented their mid-term results using a 2nd-generation ceramic first MPJ implant. A retrospective review of clinical data and radiographs was performed for 31 feet (24 women; mean age at surgery was 55 ± 6 years) who had first MPJ replacement with a 2nd-generation ceramic prosthesis (primary, 29 feet; revision, 2 feet). Mean follow-up was 81 ± 27 months after surgery. Mean first MP passive ROM was 32 ± 17 degrees (dorsiflexion and plantarflexion). Mean AOFAS score was 72 ± 19 points and Foot Function Index was 27 ± 26 points (all 31 feet). Clinical rating for 29 feet that had surgery as a primary procedure was excellent in 5 feet (17 %), good in 8 feet (28 %), fair in 3 feet (10 %), and poor in 13 feet (45 %). Patients were satisfied with the outcome in 24 feet (77 %). Follow-up radiographs showed that radiolucency, change in angulation, sinking, and mal-alignment of the metatarsal or proximal phalanx components were common. Complications included 1 superficial wound infection, and revision was performed in 5 feet (16 %) because of loosening, sinking, subluxation, pain, or fractured prosthesis. Implant survival was 92 % at 5 years, 85 % at 7 years, and 68 % at 9 years. The authors concluded that these findings of 2nd-generation ceramic first MPJ replacement in this series demonstrated poor clinical and radiological results with a high revision rate.

The ToeFit-Plus is a modular implant system for the hemi-arthroplasty or total replacement of the first MPJ. The non-cemented implant is fixed in the host bone by means of a self-tapping threaded taper.

Erkocak et al (2013) stated that although MTP arthrodesis has been advocated by many authors, implant arthroplasty appears to be successful option in advanced HR. These investigators evaluated the early results of the ToeFit-Plus prosthesis for the treatment of HR. Between December 2007 and January 2011, a total of 26 toes of 24 patients with MTP arthritis of the great toe were treated with ToeFit-Plus implant. The average follow-up time was 29.9 (range of 25 to 62) months. All
patients were evaluated clinically and radiographically. Post-operative satisfaction and function were scored according to the AOFAS score. Pain was assessed with the use of a VAS. Mean pre-operative AOFAS score improved from 42.7 (range of 36 to 59) to 88.5 (range of 59 to 98) at the final follow-up ($p < 0.01$). Pre-operative average VAS pain scores improved from 7.4 pre-operatively to 1.9 at the final follow-up ($p < 0.01$). The average MTP joint ROM improved from 25.9 degrees pre-operatively to 53.8 degrees at the final follow-up. No radiologic loosening was found, but radiolucency was observed in 2 patients with this implant. No revision was required for any of the patients during the follow-up period. The authors concluded that this total first MTP joint prosthesis yielded good functional outcome and high patient satisfaction level with low early complication rate. Salvage arthrodesis remains an option if future revisions are indicated. These preliminary findings need to be validated by well-designed studies with larger sample size and longer follow-up.

In a retrospective study, Kolodziej and colleagues (2013) evaluated functional and radiographic results of the first MPJ replacement with use of unconstrained, modular, 3- component, porous titanium and hydroxyapatite coated, press-fit METIS® prosthesis. According to author's knowledge, results of this type of prosthesis have never been published before. A total of 25 prostheses were implanted in 24 patients (were 20 females and 4 males) between February 2009 and May 2011; AOFAS-HMI was used to assess functional results. Patients were also asked if they would undergo procedure again or recommend it to other people. Weight-bearing radiographs were made at final follow-up and analyzed for presence of osteolysis and radiolucency. In 8 patients total joint replacement was introduced as a salvage treatment after failure of previous surgery like Keller resection arthroplasty, failed arthrodesis, avascular necrosis and post-operative arthritis. The reasons for prosthetic replacement were HR ($n = 11$), rheumatoid arthritis ($n = 4$) and gout ($n = 1$). Additional procedures were performed in 3 cases (Akin phalangeal osteotomy in 2 cases and fifth metatarsal osteotomy in 1 case). The mean age at the operation was 56 years. The average follow-up period was 18 months (range of 12 to 36 months). The median post-operative value of AOFAS-HMI scores was 88 points (range of 75 to 95 points). First metatarsophalangeal joint motion (dorsiflexion plus plantarflexion) was classified according to AOFAS-HMI ranges as: moderately restricted (between 30 to 70 degrees) in 19 patients 80 % (20 prosthesis) and severely restricted (less than 30 degrees) in 5 patients (20 %). Overall, 15 (64 %) patients were completely satisfied, 5 (20 %) reported moderate satisfaction and 4 (16 %) were totally disappointed and would not undergo this procedure again. A limited hallux dorsiflexion was the main dissatisfaction reason. Partial radiolucent line was seen in 1 patient (4 %). There were 2 serious complications. In 1 patient, with rheumatoid arthritis, deep infection occurred 12 months after prosthesis implantation. In the second case phalangeal implant was revised due to misalignment. The authors concluded that the METIS® MPJ replacement allowed alleviate of pain relating to HR and partial restoration of joint movement, even in patients after failures of primary MPJ surgery. AOFAS-HMI results were better than previously reported in the literature in assessment of the first MPJ replacement. These preliminary findings need to be validated by well-designed studies.
Duncan et al (2014) investigated the outcomes of first MP replacement for HR using the Smith & Nephew ToeFit-Plus™ implant. These investigators assessed the outcomes of 69 first MPJ replacements using the AOFAS score pre-operatively and annually post-operatively, with retrospective radiologic review. All operations were performed by the same surgeon within 2 centers. A total of 69 arthroplasties were performed within the study period (57 patients). The median AOFAS score at 1 year was 100 (interquartile range [IQR] 100 to 100), at 2 years was 100 (IQR 95 to 100), at 3 years was 100 (IQR 87.5 to 100), and at 4 years, it was 100 (IQR 91.25 to 100). Radiolucencies around the phalangeal component were seen in 23 cases; however, this was symptomatic in only 2 patients, who required revision surgery. The authors concluded that these early results showed that first MPJ replacement surgery with the ToeFit-Plus™ prosthesis resulted in significant improvements in the AOFAS scores for most patients; however, longer term follow-up is needed to monitor the clinical effect of radiolucency around the phalangeal component.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

28293

Other CPT codes related to the CPB:

26535
26536

HCPCS codes covered if selection criteria are met:

L8641 Metatarsal joint implant
L8642 Hallux implant

Other HCPCS codes related to the CPB:

L8658 Interphalangeal joint spacer, silicone or equal, each

ICD-9 codes covered if selection criteria are met:

735.2 Hallux rigidus

Other ICD-9 codes related to the CPB:

714.0 - 714.9 Rheumatoid arthritis and other inflammatory polyarthropathies
715.17, Osteoarthrosis of ankle and foot
715.27,
715.37,
715.97
The above policy is based on the following references:

11. Brage ME, Ball ST. Surgical options for salvage of end-stage hallux rigidus.
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