Implants for Metatarsal Joint Pain

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DESCRIPTION

Osteoarthritis of the forefoot most frequently affects the metatarsophalangeal (MTP) joint and may be the result of repetitive trauma (including microtrauma), severe bunion deformities (hallux valgus), hallux limitus, hallux rigidus or recurrent hallux deformity following surgery and can result in disabling pain. Individuals with hallux rigidus have joint pain and restricted motion at the first MTP joint. The first MTP plays a functional role during gait.

Hallux valgus is a condition in which the great toe (hallux) is bent outward (toward the midline of the foot) so that it overlaps the second toe and may or may not be accompanied by a bunion. Conservative treatment options for hallux valgus include changing to footwear that fits properly and does not compress the toes, padding to provide a “bunion-shield”, orthotics which take pressure off the bunion, reduction of inflammation with icing and medications to treat pain and inflammation. In more severe cases, surgical removal of the bunion and arthrodesis may be considered. Arthrodesis results in the permanent loss of joint motion thus effecting an individual’s gait.

Hallux limitus is a term used to describe loss of motion in the MTP joint. Hallux rigidus, a state in which the ability to move the MPT is lost or severely restricted, is considered by many to be the end (severe) stage of hallux limitus. Hallux rigidus usually involves erosion of the MTP joint cartilage and the development of osteoarthritis. Hallux rigidus usually develops in adults between the ages of 30 and 60 years. Additionally, bone spurs, or overgrowth, may develop with hallux rigidus and act as a mechanical block to motion and cause pain. Conservative treatment options for hallux limitus and rigidus may include methods to reduce inflammation and pain, including rest, anti-inflammatory medications, and icing.

Treatment

Treatment may include debridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Debridement involves the removal of the synovial membrane, osteophytes, loose articular debris, and diseased cartilage and can produce symptomatic relief. Subchondral abrasion techniques attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect.

Early-stage osteoarthritis of the first MTP joint is typically treated with conservative management, including pain medication and change in footwear. Failure of conservative management in patients with advanced osteoarthritis of the MTP joint may be treated surgically.

Cheilectomy (removal of bone osteophytes) may be considered as a treatment option to reduce pain and improve range of motion in individuals with mild to moderate hallux rigidus who failed to benefit from conservative treatment. Cheilectomy offers the advantages of being joint sparing, preserving joint motion and maintaining joint stability. Interpositional spacers with autograft or allograft have been used as temporary measures to relieve pain, as well.

Advanced stages of hallux rigidus with severe joint damage, are often treated by arthrodesis (joint fusion). With arthrodesis, the damaged cartilage is removed, and the two bones are fixed together with screws and/or plates which allow the bones to fuse together. Arthrodesis offers the advantage of being a permanent correction with elimination of the arthritis and pain. However, the trade-off is that the procedure results in the permanent restriction of movement of the MTP joint.

Although partial or total joint replacement have been explored for MTP osteoarthritis, complications from bone loss, loosening, wear debris, implant fragmentation, and transfer metatarsalgia are not uncommon. Also, since the conversion of a failed joint replacement to arthrodesis has greater complications and worse functional results than a primary arthrodesis (joint fusion), MTP arthrodesis is considered the most reliable and primary surgical option. Arthrodesis can lead to a pain-free foot, but the loss of mobility in the MTP joint alters gait, may restrict participation in running and other sports, and limits

footwear options, leading to patient dissatisfaction. Transfer of stress and arthritis in an adjacent joint may also develop over time.

Early-Stage First Metatarsophalangeal Osteoarthritis

Clinical Context and Therapy Purpose

The purpose of an implant in patients who first metatarsophalangeal (MTP) joint osteoarthritis (OA) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does a synthetic cartilage implant in patients who have first MTP OA improve the net health outcome?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with early-stage first MTP OA.

Interventions

The therapy being considered is the metatarasal joint implants.

Comparators

The following therapies are currently being used:

- Conservative nonoperative treatment which would include modification of footwear and non-steroidal anti-inflammatory drugs (NSAIDS)
- Cheilectomy
- Arthrodesis

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;

Outcomes

The general outcomes of interest are symptoms, typically measured with a visual analog score (VAS) for pain. Functional outcomes and quality of life are measured with the Foot and Ankle Ability Measure (FAAM). The FAAM is a validated measure of sports activities and activities of daily living (ADL), with a minimal clinically important difference defined as 9 points for sports and 8 points for ADL subscales. Adverse events from the implantation procedure would be measured within 30 days, while dislocation and wear would be monitored at 5 to 10 years.

A beneficial outcome of the implant would be a reduction in pain and improvement in function.

A harmful outcome of the implant would be an increase in pain and a reduction in function.

Review of Evidence
(2020) Silva and colleagues stated that historical results of arthroplasty of the 1st MTP (1 MTP) joint are relatively poor; however, improvements in the understanding of the normal foot biomechanics, implant materials and design currently make arthroplasty a reasonable option in appropriately selected patients. These investigators compared the clinical and radiographic results of 1 MTP arthrodesis and arthroplasty in the treatment of HR and presented a rationale for patient selection for arthroplasty. A total of 36 patients (38 feet) with HR submitted to surgery (12 arthrodesis and 26 arthroplasties) were prospectively included in the study. Pain was assessed using the VAS and the functional status was assessed using the AOFAS-HMI scale. Complications and radiographic results were also analyzed, and survival rates were calculated for both procedures. All of the patients reported significant improvement in pain and functional status following surgery. Patients submitted to arthroplasty had better functional results on the AOFAS-HMI scale (89.7 versus 65.7 points; $p < 0.001$) and better pain relief (VAS 1.6 versus 3.9 points; $p = 0.002$) when compared with the group submitted to arthrodesis. There was 1 case of infection in the arthroplasty group and 2 cases of pseudarthrosis in the arthrodesis group. The authors concluded that arthrodesis provided pain relief and satisfactory results but altered the biomechanics of gait. Like arthrodesis, arthroplasty improved pain significantly, being a more physiological alternative to preserve the biomechanics of the foot. These researchers stated that while the 2 surgical methods yielded good clinical results, selected patients submitted to arthroplasty had better clinical scores and lower revision rates.

(2020) Smyth et al. conducted a systematic review of PVA implants in patients with hallux rigidus. The authors identified 7 publications, 6 of which were related to the key randomized controlled trials. The systematic review noted the lack of information independent of the original RCT as a primary limitation. They concluded that a moderate recommendation can be given for use of a polyvinyl alcohol implant in the short-term, but long-term data is lacking.

(2017) Stone and colleagues stated that the optimal operative management of HR is still a matter for debate among surgeons. Despite arthrodesis widely considered to be the gold standard treatment, many surgeons advocate arthroplasty as a suitable alternative. There are, however, few long-term or high-quality studies evaluating these modalities. These researchers presented the 15-year follow-up of a randomized controlled trial (RCT). These data were the follow-up to the original study published in 2005. In the original study, 63 patients (77 toes) were recruited to and randomized to have either metatarsophalangeal joint (MTPJ) arthrodesis or arthroplasty. The primary outcome

measure was a decrease in pain on a (VAS at 24 months. In the present study, data were available for all surviving patients (52 patients, 66 toes). Data were collected in the form of satisfaction scores, VAS for pain, the VAS foot and ankle and survivorship data. The results of the original study demonstrated that pain relief was greater following arthrodesis at 2 years. At 15 years, patients with an arthrodesis experienced less pain and were more satisfied compared to those with an arthroplasty. No functional differences were seen between these 2 groups. There were more revisions in the arthroplasty group. The authors concluded that despite the hope of better function, less pain, and greater satisfaction from MTPJ replacement, this was not found in the authors'' patient population. The long-term results of this study showed that arthrodesis out-performed arthroplasty. If an arthroplasty failed, then salvage was likely to be technically difficult, with significant potential for complications. Level of Evidence = I.

(2017) Stevens et al. conducted a systematic review of surgery for hallux rigidus including total joint replacement and arthrodesis of the first metatarsophalangeal joint. Thirty-three studies with 741 arthrodeses and 555 total joint replacements were included in the qualitative analysis. Six different prostheses were used for total joint replacement, and various fixation techniques were used for arthrodesis. The results of 6 arthrodesis studies and 7 total joint replacement studies were pooled in the quantitative analysis. Pooled results showed superiority of arthrodesis compared with total joint replacement for improving clinical outcome (by 43.8 versus 37.7 points on the AOFAS-HMI score) and reducing pain (a decrease of 6.56 versus 4.65 points on the VAS pain score). It was found that fewer intervention-related complications (23.1% versus 26.3%) and revisions (3.9% versus 11%) were reported after arthrodesis as compared with total joint replacement, with pain and nonunion and prosthetic loosening being the most commonly reported complications after arthrodesis and total joint replacement, respectively. The authors concluded that the systematic review indicates that arthrodesis is superior for improving clinical outcome and reducing pain and is less often accompanied by intervention-related complications and revisions, compared with total joint replacement in patients with symptomatic hallux rigidus; however, prospective, randomized controlled trials are needed to verify this conclusion.

(2014) Nagy et al. 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, sinkage, 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, sinkage, 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.

Advanced First Metatarsophalangeal Osteoarthritis

Clinical Context and Therapy Purpose
The purpose of an implant for the metatarsal joint in patients who have advanced first MTP OA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the synthetic cartilage implant in patients who have advanced first MTP OA improve the net health outcome?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with advanced MTP OA.

Interventions
The therapy being considered is the implants for metatarsal joint pain.

Comparators
The following therapies are currently being used:

- Conservative nonoperative treatment which would include modification of footwear and NSAIDS.
- Cheilectomy
- Arthrodesis

Outcomes
The general outcomes of interest are symptoms, typically measured with a VAS for pain. Functional outcomes and quality of life are assessed with the FAAM. Adverse events from the implantation procedure would be measured within 30 days while harms from dislocation and wear would be measured at 5 to 10 years.

A beneficial outcome of the implant would be a reduction in pain and improvement in function.

A harmful outcome of the implant would be an increase in pain and a reduction in function.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;

Review of Evidence
(2020) Clough and Ring noted that arthroplasty for end-stage HR is controversial. Arthrodesis remains the gold standard for surgical treatment, although is not without its complications, with rates of up to 10 % for nonunion, 14 % for re-operation and 10 % for metatarsalgia. These researchers analyzed the outcome of a double-stemmed silastic implant (Wright-Medical, Memphis, TN) for patients with end-stage HR. They carried out a retrospective review of 108 consecutive implants in 76 patients, between January 2005 and December 2016, with a minimum follow-up of 2 years. The mean age of the patients at the time of surgery was 61.6 years (42 to 84). There were 104 women and 4 men. Clinical, radiological, patient reported outcome measures (PROMS) data, a VAS for pain, and satisfaction scores were collected. The survivorship at a mean follow-up of 5.3 years (2.1 to 14.1) was 97.2 %. The mean Manchester Oxford Foot and Ankle Questionnaire (MOXFQ) scores improved from 78.1 to 11.0, and VAS scores for pain from 7/10 to 1.3/10. The rate of satisfaction was 90.6 %; 3 implants (2.8 %) required revision; 1 for infection, 1-month post-operatively, and 2 for stem breakage at 10.4 and 13.3 years post-operatively. There was a 1.9 % re-operation rate other than revision, 23.1 % of patients developed a minor complication, and 21.1 % of patients had non-progressive and asymptomatic cysts on radiological review. The authors reported a 97.2% survivorship at a mean follow-up of 5.3 years with this implant. These investigators did not find progressive osteolysis, as has been previously reported. These results suggested that this double-stemmed silastic implant provided a predictable and reliable alternative with comparable outcomes to arthrodesis for the treatment of end-stage HR.

(2020) Smyth et al. conducted a systematic review of PVA implants in patients with hallux rigidus. The authors identified 7 publications, 6 of which were related to the key randomized controlled trial described below, and the final publication was a case series by Cassenelli et al. (2019) which is also included below. The systematic review noted the lack of information independent of the original RCT as a primary limitation. They concluded that a moderate recommendation can be given for use of a polyvinyl alcohol implant in the short-term, but long-term data are lacking.

Section Summary: Advanced First Metatarsophalangeal Osteoarthritis
Results at 2 years from the pivotal non-inferiority trial showed pain scores that were slightly worse compared to patients treated with arthrodesis and similar outcomes between the groups for ADL and sports. In a non-inferiority trial, some benefit should be

observed to justify the non-inferiority margin. However, the benefit of Cartiva with respect to increased range of motion does not appear to translate to improved ADL, sports activities, or patient report of well-being compared to arthrodesis. In addition, the Cartiva group showed a higher rate of adverse outcomes (Moderate Difficulty, Extreme Difficulty, and Unable to Do) compared to the arthrodesis group for walking for 15 min (16% vs. 0%), Up Stairs (6% vs. 0%) and Squats (19% vs. 8%). Some bias in favor of the novel motion preserving implant was also possible, as suggested by the high dropout rate in the arthrodesis group after randomization. Five-year follow-up of both the randomized and run-in patients who received an implant was reported in 2018 for 135 of 152 patients. At this time point, 15% of implants had been removed with conversion to arthrodesis. There are additional safety signals in an independent study by Cassinelli et al. (2019) and An et al. (2019). In that report, 30% of patients underwent magnetic resonance imaging due to pain, 20% had additional surgery and 38% were unsatisfied or very unsatisfied. A retrospective comparative observational study found few differences in either safety or efficacy between arthrodesis and Cartiva with a limited mean follow-up of 33 months. Further long-term study of potential adverse events with this novel technology is needed. In addition, comparison to arthrodesis at long-term follow-up is needed to determine whether the implant improves function. Corroboration of long-term results in an independent RCT is also needed to determine the effect of the implant on health outcomes.

Miscellaneous: Bioabsorbable poly-L-D-lactic acid RegJoint Inter-Positional Implant

(2021) Partio and colleagues noted that inter-positional arthroplasty was developed to retain foot function and to relieve pain due to the arthritis of the first MTP joint. The bioabsorbable poly-L-D-lactic acid RegJoint inter-positional implant provides temporary support to the joint, and the implant is subsequently replaced by the patient's own tissue. In this study, these researchers retrospectively examined the results of the poly-L-D-lactic acid inter-positional arthroplasty in a 9-year follow-up study among patients with hallux valgus with end-stage arthrosis or HR. A total of 18 patients and 21 joints underwent inter-positional arthroplasty using the poly-L-D-lactic acid implant between February 1997 and October 2002 at Tampere University Hospital. Of these, 15 (83.3 %) (21 joints) patients were compliant with clinical examination and radiographic examination in long-term (average of 9.4 years) follow-up. The mean age of the patients was 48.3 (from 28 to 67) years at the time of the operation; 6 patients underwent the operation due to arthritic hallux valgus and 9 patients due HR. The mean Ankle Society Hallux Metatarsophalangeal-Interphalangeal Scale and VAS for pain scores improved after the operation in all patients. The decrease of pain (VAS) after the operation was statistically significant (77.5 versus 10.0; $p < 0.001$). Post-operative complications were observed in 3 (14.3 %) joints of 2 HR patients. For these patients, surgery had only temporarily relieved the pain, and they underwent re-operation with arthrodesis. The authors concluded that inter-positional arthroplasty using a poly-L-D-lactic acid implant yielded good results. This study indicated that the poly-L-D-lactic acid inter-positional implant may be a good alternative for arthrodesis for treatment of end-stage degeneration of the

1MTP joint. Moreover, these researchers stated that inter-positional arthroplasty using a bioabsorbable PLDLA implant should be examined in a prospective RCT setting. The authors stated that this study had several drawbacks. First, it was a retrospective study. Second, the sample size (n = 15 patients with 21 MTP joints) was small. Third, the lack of pre-operative evaluation with patient-reported outcome measures.

Miscellaneous: The Cartiva Implant

(2021) Joo et al. conducted a retrospective review of 181 patients who underwent arthrodesis (n=122) or Cartiva implant (n=59) at their institution. At baseline, patients receiving Cartiva had higher physical function scores (47.1) than those undergoing arthrodesis (43.9: p<.01), and this difference remained significant at the mean final follow up of 33 months (51.4 vs. 45.9; p<.01). Pain interference scores were similar between groups at baseline (57.4 vs. 55.6; p=.07) and remained similar at final follow up (46.9 vs. 48.2; p=.49). Significant pain was reported by 4 patients (10%) in the Cartiva group and 5 patients (8%) in the arthrodesis group at final follow-up (p=.76). Complications occurred in 3 (2.4%) patients in the arthrodesis group and 2 (3%) in the Cartiva group (p=.72).

(2019) Cassinelli et al. conducted a retrospective review of early outcomes and complications from the Cartiva implant for the treatment of hallux rigidus at their institution. Sixty consecutive patients treated between August 2016 and April 2018 with a mean of 15 months of follow-up (range 2 to 30) were included. Out of 60 patients (64 implants), 30% of patients underwent magnetic resonance imaging (MRI) due to pain, 20% had additional surgery and 38% were unsatisfied or very unsatisfied. Magnetic resonance imaging showed residual capsular inflammation, bone marrow edema, and degenerative changes/edema of the phalanx or metatarsal. A limitation of these results is that 45% of patients underwent additional procedures at the time of implantation and 23% had prior surgery of the hallux. Therefore, these results are not representative of isolated implant procedures, but may be indicative of results outside of the investigational setting.

(2019) In a subsequent report, An et al. provided further detail on the 16 of 60 (27%) treated patients from their institution who were evaluated for persistent pain following Cartiva implantation. There was a reduction of joint space on plain radiographs, MRI showed a reduction in implant diameter from 10 mm to 9.7 (standard deviation [SD] 0.4) mm and bony channel widening to 11.2 (SD 0.8) mm. Peri-implant fluid suggested instability at the implant-bone interface. There was also evidence of subsidence, with the implant below the subchondral bone of the metatarsal head, and persistent edema was observed in all 16 cases. Radiographic findings from another series of 27 consecutive patients by Shi et al (2019) also suggested subsidence of the implant into the soft medullary canal. An analysis of the Manufacturer and User Facility Device Experience (MAUDE) also found subsidence to be a concern with 16 voluntary reports between July 2016 and October 2019. It has been noted that the implants in the reports by Cassinelli et al. and An et al. were initially seated 2 to 2.5 mm above the adjacent bone, rather than the

0.5 to 1.5 mm that is recommended by the manufacturer. Further study is needed to clarify these issues.

(2018) Glazebrook et al. reported a reduction in operative and recovery time with the implant compared to arthrodesis. Additional analysis of data (2017) from the pivotal trial did not identify any factors (e.g., hallux rigidus grade, preoperative pain, duration of symptoms, body mass index) that affected the success of the procedure. The analysis raised questions whether Coughlin grade (symptoms, radiographic measures, range of motion), is the most appropriate method to identify patients for the procedure, leading the investigators to recommend using only clinical signs and symptoms to guide treatment.

(2016) The U.S. Food and Drug Administration (FDA) approval of the Cartiva synthetic cartilage implant was based on an unmasked, multicenter, noninferiority trial (Cartiva MOTION) that compared the implant with arthrodesis of the first MTP joint (see Table 1). This study was published by Baumhauer et al. The primary outcome was a composite of a 30% or greater difference in VAS scores for pain, maintenance of function on the FAAM ADL subscale, and absence of major safety events at 2 years. The primary effectiveness endpoint was achieved by 80% of patients in both groups, and the implant met the 15% noninferiority margin ($p<.0075$).

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Dates	Participants	Active Intervention	Comparator Intervention
Baumhauer et al. (2016); MOTION	US, Canada, EU	2009-2012	197 patients with advanced hallux rigidus (Coughlin grade 2, 3, or 4 with VAS $\geq$ 40/100. Patients were excluded if they had lesions > 10 mm in size, hallux varus to any degree, or hallux valgus > 20	132 patients received the Cartiva cartilage implant	65 patients underwent arthrodesis

RCT: Randomized controlled trial; VAS: visual analog score

VAS pain scores decreased significantly in both groups but were consistently lower in the arthrodesis group from 6 weeks through 2 years. Nearly all patients (97%) who underwent fusion had 30% or greater relief in pain compared with 89% of patients who received the implant. Maintenance of function, as measured by the FAAM ADL subscale, was observed in 98.3% of patients who received the implant and in 97.6% of

patients who underwent fusion. Fourteen (9.2%) implants were removed and converted to arthrodesis, while in the arthrodesis group 6 (12%) patients had removal of screws or screws and plates. As expected, dorsiflexion was significantly better in the implant group (29) than in the fusion group (15; p<.001). Radiographic measurements showed 4 (8%) occurrences of mal-union or non-union in the fusion group and no device displacement, fragmentation, or avascular necrosis with the implant. Some instances of radiolucency, bony reactions, and heterotopic ossification were observed, but these events did not correlate with individual patient success.

A selection of results from the FAAM ADL questionnaire, which is made up of 21 related questions, were reported on the FDA's Summary of Safety and Effectiveness (see Table). Only the "Up on Toes" was superior in the Cartiva group. Of concern is the greater difficulty of the Cartiva group (Moderate Difficulty, Extreme Difficulty, and Unable to Do) compared to the arthrodesis group for walking for 15 min (16% vs. 0%), Up Stairs (6% vs. 0%) and Squats (19% vs. 8%).

Foot and Ankle Ability Measure (FAAM) Activities of Daily Living Questionnaire Excerpt

Outcomes	Group	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to Do
Daily Activities	Arthrodesis	94%	6%	0%	0%	0%
	Cartiva	88%	10%	0%	2%	0%
Walk 15 Min	Arthrodesis	85%	13%	0%	0%	0%
	Cartiva	67%	17%	9%	5%	2%
Upstairs	Arthrodesis	87%	13%	0%	0%	0%
	Cartiva	83%	10%	4%	2%	0%
Up on Toes	Arthrodesis	36%	28%	17%	9%	11%
	Cartiva	37%	33%	15%	7%	9%
Squat	Arthrodesis	70%	21%	6%	2%	0%
	Cartiva	57%	18%	11%	6%	2%

Limitations in relevance and design and conduct are shown in the Tables below.

Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Baumhauer et al (2016) MOTION				2. Range of motion is an intermediate measure.	1,2. Follow-up in this publication was for 2 years, but the Cartiva group will be followed for 5 years.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Baumhauer et al. (2016);, MOTION				1. Withdrawals after randomization were higher in the control group (15/65 vs. 2/132), suggesting possible bias in expectations and subjective outcome assessments in favor of the novel joint		

				preserving procedure. A modified intention-to-treat analysis was requested by the U.S. Food and Drug Administration to adjust for the difference in study withdrawals. The modified intention-to-treat analysis included 130 patients in the Cartiva group and 50 patients in the fusion group.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

An FDA regulated safety and efficacy follow-up study was required through 5 years. The patients in the follow-up study included the randomized and nonrandomized run-in group who received the implant for a total of 152 patients (see Table) but did not include the arthrodesis group. By year 5, 15.1% of the implant group had undergone removal and conversion to arthrodesis (see Table). The overall Kaplan-Meier synthetic cartilage implant survivorship at 5.8 years of follow-up was 84.9%. Of the patients who retained the implant, 97.2% reported a clinically significant improvement in pain, 90.5% reported

a clinically significant improvement in FAAM ADL, and 93.3% reported a clinically significant improvement in FAAM sports. Independent radiographic review found no evidence of avascular necrosis, device migration, or fragmentation. Because there was no follow-up of the arthrodesis arm from the randomized trial, conclusions about the comparative effectiveness of the 2 treatment options are limited

The pivotal trial compared the implant with arthrodesis and showed patient-reported pain scores to be slightly worse than arthrodesis with similar outcomes between the two groups on scores for activities of daily living and sports. Five-year follow-up was reported in 2017 for about 20% of the original cohort, which showed no evidence of implant degradation or reduction in pain and function. Continued Food and Drug Administration approval depends on a 5-year follow-up of the complete cohort and will provide needed information on implant durability. There is a high possibility of bias in favor of the novel device. Corroboration of long-term results in an independent study would provide greater confidence in the findings of the pivotal trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous: The HemiCAP Implant
(2019) A product brief by the ECRI Institute includes the following information:

The HemiCAP implant has limited evidence from two small comparative studies and 11 small case series at high risk of bias suggests that HemiCAP reduced pain in patients with hallux rigidus. Although two of these studies were comparative, they reported on too few patients and are at too high a risk of bias to determine whether HemiCAP works as well as arthrodesis or TJR. Randomized controlled trials (RCTs) are needed to assess HemiCAP's impact on pain, patient functional status, quality of life, and adverse events compared with that of other treatments, but none are ongoing.

- HemiCAP versus TJR: Two small retrospective cohort studies reporting on 83 patients found that both treatments reduced pain with no statistical difference in pain reduction (measured with visual analog scale [VAS]) between treatment groups at 29.9-month follow-up.
- HemiCAP versus arthrodesis: One retrospective cohort study reported greater pain reduction in patients treated with arthrodesis (n = 12) than in those treated with hemi-arthroplasty (n = 14) through two-year follow-up.
- HemiCAP: Eleven case series (five prospective and six retrospective reporting on 237 patients) assessed HemiCAP in patients with hallux rigidus and reported on one or more of the following: VAS scores improved from 7.0 to 8.4 preoperatively to 1.21 to 3.5 postoperatively. Authors reported statistically significant improvements in the American Orthopedics Foot and Ankle Society pain score, Short-Form (SF)-36 quality of life measure, and Foot and Ankle Disability Index. Patient satisfaction and retreatment rates varied widely.

The evidence limitations included the studies are at high risk of bias due to three or more of the following: single-center focus, small sample size, retrospective design, and/or lack of randomization, controls, and blinding. No studies assessed HemiCAP for treating

bunions (hallux valgus). RCTs comparing HemiCAP with arthrodesis or TJR and reporting on patient-oriented outcomes (e.g., pain, patient functional status, quality of life, adverse events) at more than one year follow-up are needed to assess HemiCAP's comparative safety and effectiveness.

Miscellaneous: The METIS Prosthesis

(2017) Dygrynova and associates evaluated the results of cheilectomy and TJR in patients with hallux rigidus. Minimum duration of follow-up was 18 months. The study included 59 patients who underwent surgery due to hallux rigidus between January 2013 and December 2014; 37 patients underwent cheilectomy and 22 patients had total joint arthroplasty using the METIS. The outcomes were assessed by comparing pre-operative and post-operative ROM, VAS, AOFAS-HMI and patients' satisfaction with operative treatment. Pre-operative and post-operative outcomes were compared for the individual types of surgery using the repeated measures ANOVA. The level of statistical significance was set at $p < 0.01$. The mean age was 47.9 ± 7.0 years in patients who underwent cheilectomy and 62.5 ± 5.5 years in patients after TJR METIS. There was a significant decrease ($p < 0.001$) in the VAS pain score and a significant improvement in dorsiflexion, ROM, AOFAS-HMI scores in both the treatment groups. In both the groups more than 75 % of patients reported good or excellent subjective results. The authors stated that these findings were in agreement with findings of other studies assessing the results of cheilectomy and TJR surgery in patients with hallux rigidus. Direct comparison of the VAS pain score, AOFAS-HMI and ROM across studies was difficult because of variability in the evaluation systems. They stated that cheilectomy is mostly recommended for young active patients with mild osteoarthritis. Moreover, it is also possible to use minimally invasive surgery with early and reliable outcomes. These investigators performed cheilectomy also in younger patients with moderate osteoarthritis in order to extend the period of clinically acceptable results and thereby to postpone the TJR indication. They stated that TJR (similarly to arthrodesis of the 1st MTP joint) is a procedure performed in elderly patients with low physical activity and more advanced deformities. The authors concluded that both the reported methods offer reliable and valuable short-term clinical outcomes with relatively low complication rate. They stated that cheilectomy is undoubtedly more appropriate for younger patients with mild or moderate arthritic changes. Although it did not appear to alter the natural progression of the disease process, it provided satisfactory pain relief, motion improvement and overall patient gait comfort for patients in a short-term period. They stated that TJR appeared to be a better solution for less active older patients to whom it provides a loadable, painless, and moving joint. This was a small study ($n = 22$ for the total joint replacement group) with short-term follow-up (18 months).

(2015) In a prospective study, Silva and colleagues evaluated the preliminary results from the METIS-Newdeal metatarsophalangeal prosthesis for treating hallux rigidus grade III/IV. A total of 8 metatarsophalangeal prostheses that were placed in 6 patients between November 2007 and July 2009 were included in this report. The patients' mean age was 55 years and the mean follow-up after the surgery was 50 weeks. The results were evaluated using the AOFAS-MTP score and x-ray images as controls. The AOFAS-MTP

score increased significantly from 42p before the surgery to 82p after the surgery (↑ 1.95x), mainly due to improvement in the functional level. No intercurrences were identified radiologically. Among the 5 patients who underwent operations, only 1 expressed dissatisfaction with the surgery: this was expressed after early infection appeared at the surgical site, and it was the only post-operative complication found. The authors concluded that total metatarsophalangeal arthroplasty using METIS-Newdeal presented promising short-term results. However, they stated that evaluations on a larger number of cases with a longer follow-up are needed in order to draw more consistent conclusions.

(2013) In a retrospective study, Kolodziej and colleagues 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 ware 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.

Miscellaneous: The Moje Implant

(2010) McGraw et al 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.

(2010) In a case series study, Brewster and colleagues 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.

(2008) In a single-surgeon series study, Barwick and Talkhani 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.

There is an unacceptably high incidence of failure of the press fit Moje implant.

Miscellaneous: OsteoMed ReFlexion 1st MTP Implant System
(2021) Akoh et al completed a case series large database analysis on adverse events involving hallux metatarsophalangeal joint implants: Analysis of the United States Food and Drug Administration data from 2010 to 2018 and found the following information: Among 64 reported hallux MTPJ implant adverse events, the most common modes of adverse events were component loosening (34%), infection (14.1%), component fracture (9.4%), inflammation (9.4%), and allergic reaction (7.8%). Regarding implant type, Cartiva SCI had the highest percentage of adverse events (23.4%), followed by Arthrosurface ToeMotion (20.3%), Ascension MGT (12.5%), Arthrosurface HemiCAP® (10.9%), Futura primus (9.4%), and Osteomed Reflexion (6.3%). There was an increase in reported adverse events after 2016. The MAUDE database does not report the total incidence of implant insertion.

They reported the study of the MAUDE database demonstrated that component loosening, and infection are the most common modes of adverse events for hallux MTPJ implants. Cartiva accounted for one-fourth of the implant-related adverse events during our study period, followed by ToeMotion, and Ascension MGT implants. Continued reporting of adverse events will improve our understanding on short and long-term complications of various hallux MTPJ implants.

Silicone Implants
(2019) Majeed, H. completed a systematic f the available literature on the outcomes of silastic implants including very early reported studies. The review included an initial search revealed 522 articles from the searched databases. Twenty-eight articles were selected for final inclusion, which were most relevant to the use of silastic implants. There was only one prospective study whilst all the others were retrospective studies. Twenty-eight studies had a total of 2354 feet with silastic replacements in 1884 patients. The studies took place, and their outcome results were collected between 1968 and 2003. The average age of patients was 53 years among all the studies, the youngest patient being 15 years old and the oldest 82 years old in different studies. The average follow-up was 85.3 months. Among all the studies there were a total of 5.3% (124 feet) failed prostheses. Improvement in pain was reported in 76.6% (1804 feet). The average rate of patient satisfaction was 84%. There was a reported incidence of 3.6% (85 feet) of superficial infection, early inflammation of the wound and synovitis. Incidence of deep infection was 1.7% (40 feet). Radiological lucencies, cyst formation, bone resorption and osteophytes formation, of varying degree, were reported in 18.2% cases (429 feet). Implant fracture and fragmentation occurred in 4.3% cases (101 feet). Eighty-four implants (3.6%) required removal due to infection, fracture or persistent pain after surgery. The length of time from surgery to implant failure or removal was found to be highly variable among different studies.

The strengths include a detailed analysis of the currently reported and historical studies utilizing appropriate critical appraisal tools. The author believes that the results of this review will provide surgeons with a detailed account of the results and initial complications related to the design of the implants and a forward direction to conduct future studies. The weaknesses of this review include the fact that the available studies provided are only Level-IV evidence. Furthermore, these studies were analyzed by only one author. However, with the use of relevant research tools, sufficient data were extracted and have been presented in a logical manner.

The available studies have shown that the silastic joint replacement can be a good alternative to arthrodesis in older and less active patients who wish to preserve the movements of their first metatarsophalangeal joint. Several historical studies have reported high satisfaction rates and subjective and objective improvements for treating hallux rigidus with the use of previous generations of silastic implants but were fraught with implant-related complications, in particular with the use of single-stemmed implants. Most of the available studies have smaller patient populations, shorter follow-up and flaws in study designs with a few reporting long-term results of the older implants for relatively larger numbers of patients. There is a lack of long-term follow-up of the current implants in the literature. Some of the implants in current use have no published results. More long-term prospective and randomized controlled studies with larger patient cohorts are needed to build a robust evidence base for the use of current generation of silastic implants as an alternative to the traditional arthrodesis procedure.

Miscellaneous: Toefit-Plus

(2021) Bartak and colleagues compared long-term success rate of MTP joint replacement for HR. These investigators provided long-term results of MTP joint replacement with the use of the ToeFit Plus System. This study consisted of 19 total joint replacements and 12 hemi-arthroplasties in 18 and 11 patients, respectively, and they were carried out between 2005 and 2009. The average follow-up period was 12.2 years (range of 9.8 to 13.7, SD 1.1) for the total arthroplasty group and 11.1 years (range of 9.5 to 13.9, SD 1.7) for hemi-arthroplasty group. In all followed-up patients, AOFAS score was calculated along with the ROM assessment. Average AOFAS score improved from 37 pre-operatively to 79 at the time of last follow-up in total arthroplasty group and from 45 to 86 in the hemi-arthroplasty group, with consideration to the statistically considerable difference of both groups. The total ROM improved on average from 14° to the current 32° in patients with total arthroplasty and from 15° to 32° with hemi-arthroplasty. The total number of cases that required surgical revision was 7 (37 %) in total arthroplasty group and 2 (17 %) in hemi-arthroplasty group. The authors concluded that due to the high percentage of failure that was shown in the long-term results, these investigators no longer use the ToeFit Plus System.

(2017) Gupta and Masud stated that HR is osteoarthritis (OA) affecting the MTPJ of the 1st toe. Patients often complain of pain and stiffness with pain being aggravated by walking, particularly during toe-off in the gait cycle. Osteoarthritis of the MTPJ is

commonly treated with arthrodesis or resection arthroplasty. Metallic replacement of this joint is used sometimes but is not widely accepted. The use of silastic joints has problems with synovitis and implant failure. These investigators used titanium implants, which can be screwed into the metatarsal and phalanx, allowing good fixation without the use of bone cement. Release of the tight plantar capsule and tissues is necessary to achieve better ROM and correct implant positioning. In this study, a total of 55 cases of OA of the 1st MTPJ were treated surgically with Toefit-Plus joint replacement. The implant consists of both metatarsal and phalangal components and a fixed-bearing polyethylene insert. All patients had a release of tight soft tissues on the plantar side. Follow-up occurred at 84 to 144 months after surgery (mean of 134 months), and the results showed increasing numbers of implant failures and revisions (21 %) of Toefit-Plus implants; 47 patients were available for review; 24 (51 %) out of 47 patients reported satisfactory results with Toefit-Plus arthroplasty; 10 of these patients (21 %) had removal of implants and further surgical procedures were needed due to implant failure; 11 (23 %) out of 47 patients still complained of pain despite having joint replacement with the Toefit-Plus implant. There was a high rate of complications with the Toefit-Plus implant resulting in revision surgery. Patients should have the risks associated with arthroplasty clearly explained, including the risk of revision, and the option of arthrodesis should be discussed when planning surgery. The authors conclude that further trials and re-design of implants may help to improve results; they would not recommend the Toefit-Plus implant due to poor results seen in 1/3 of patients.

(2016) Mermerkaya and Adli evaluated the short- to mid-term outcomes of metatarsal head-resurfacing hemi-arthroplasty and total MTPJ arthroplasty (total joint replacement [TJR]) as surgical treatments for advanced-stage HR. From 2012 to 2014, all data from patients who underwent surgery for the treatment of grades 2 to 3 HR were retrospectively reviewed, and 45 patients were included in this study. Of these patients, 26 underwent metatarsal head-resurfacing hemi-arthroplasty (Group I) and 19 underwent TJR (Group II). All patients were clinically graded prior to surgery and at their final follow-up visits using the AOFAS-HMI scale, VAS, and the 1st MTPJ ROM score. Metatarsal head resurfacing was performed on 26 patients; 2 patients underwent bilateral procedures, yielding a total of 28 cases in Group I; TJR was performed on 19 patients in Group II. Of the 26 Group I patients, 12 (46.2 %) were men and 14 (53.8 %) were women, with a mean age of 56.3 ± 4.5 years (range of 47 to 63 years); the mean follow-up duration was 29.9 ± 5.2 months. Of the 19 Group II patients, 8 (42.1 %) were men and 11 (57.9 %) were women, with a mean age of 57.1 ± 5.8 years (range of 45 to 66 years); the mean follow-up duration was 27.1 ± 7.5 months. Significant improvements were evident in the AOFAS scores, and the VAS scores decreased, in both groups. No significant difference was evident between groups I and II. The authors concluded that after failure of conservative treatment in patients with moderate-to-severe HR, both MTPJ hemi-arthroplasty and TJR were associated with effective recovery of toe function and MTPJ ROM, as well as good short- to mid-term functional outcomes.

This study was limited by its observational and retrospective design and relatively small sample size (n = 45). Another drawback was that all procedures were performed by 2

surgeons, using a standardized technique, in 2 centers. Furthermore, these investigators did not evaluate patient satisfaction (e.g., by using the Medical Health Outcomes Short-Form 36-item survey instrument). The authors stated that a prospective, multi-center randomized trial is needed. Comparative studies of the long-term outcomes of various surgical techniques, with larger case series of similar patients, are needed. If conservative treatment failed in patients with moderate-to-severe HR, 1st-MTPJ hemi-arthroplasty and TJR effectively permit recovery of toe function and 1st-MTPJ ROM, in addition to affording good short- to mid-term functional outcomes. There is a high rate of complications with the Toefit-Plus™ implant resulting in revision surgery.

Summary of Evidence

Bioabsorbable, ceramic, modular, molded cylindrical, or silicone implants often fail because of loosening, dislocation, implant fragmentation and bone loss. After implant failure, salvage therapy with arthrodesis (fusion) often results in a poorer functional outcome than primary fusion. Because of this, primary first MTP arthrodesis has been considered the most reliable surgical option for advanced osteoarthritis of the great toe. The implants have been proposed as an alternative to fusion for hallux limitus or hallux rigidus in the first MTP joint to reduce pain, improve function and maintain joint motion, but allow for the option of fusion if needed.

For individuals who have early-stage first MTP joint OA who receive a joint implant, the evidence is lacking. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal study was performed in patients with Coughlin stage 2, 3, or 4 hallux rigidus. No evidence was identified in patients with stage 0 to early-stage 2 hallux rigidus. (Review of Evidence No studies were identified on the use of synthetic cartilage implants for early-stage first MTP OA.)

For individuals who have advanced first MTP joint OA a multitude of great toe implants have been studied over the years to maintain toe motion. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Arthrodesis is the established treatment for advanced arthritis of the great toe, although the lack of mobility can negatively impact sports and choice of footwear and is not a preferred option of patients. While some results suggested that an arthroplasty/implant provided a predictable and reliable alternative with comparable outcomes to arthrodesis for the treatment of end-stage HR.

Based on the published data on these devices, the short- and long-term benefits and hazards are not yet fully understood; additional data from prospective, randomized controlled studies with medium- to long-term follow-up are needed to better understand the benefits and risks related to use of implants for MTP joint disorders. Uncontrolled studies suggest that surgical treatment of hallux rigidus with cheilectomy or arthrodesis provides long-term relief of pain and improved function. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

Regulatory Status
Numerous prostheses fabricated from various components including metal (e.g., Titanium), acrylic, silastic, and metal alloys, have received FDA approval as Class II devices through the 510(k) process.

Implant	Manufacturer	Description	Approval
AnaToemic® 1st MTP Hemi Implant	Arthrex	The AnaToemic® Phalangeal Hemi-Prosthesis, also known as, Arthrex metatarsal phalangeal joint implant, is a press-fit cobalt chrome implant where it is an ideal option in these cases where a joint sparing procedure is preferable to arthrodesis and an immediate gain in ROM is desired.	Approved in 2007 as that is intended to be used in patients with hallux limitus, hallux valgus, hallux rigidus, arthritic degradation of the metatarso-phalangeal joint, degenerative arthritis, rheumatoid arthritis and bunion deformity associated with arthritis of the metatarsal -phalangeal joint.
Bioabsorbable Poly-L-D-Lactic Acid RegJoint™ Inter-Positional	Scaffdex	The implant provides temporary support to the joint, and the implant is subsequently replaced by the patient's own tissue.	_____ _____
Cartiva Synthetic Cartilage	Wright Medical	The Cartiva implant is an 8- to 10-mm polyvinyl alcohol (PVA) disc that is implanted with a slight (1- to 1.5-mm) protrusion to act as a spacer for the first MTP joint. It comes with dedicated reusable	Approved in 2016 and is indicated for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

		instrumentation, which includes a drill bit, introducer, and placer.	Lesions greater than 10 mm in size and insufficient quality or quantity of bone are contraindications. Continued approval depends on a study evaluating long-term safety and effectiveness. The post-approval study will follow the subjects treated with Cartiva® Synthetic Cartilage Implant for 5 years. The post-approval study will follow the subjects treated with Cartiva Synthetic Cartilage Implant for 5 years. FDA product code: PNW.
GAIT Implant	Sgarlato® Labs Inc	The GAIT Implant is designed for replacement of the first metatarsophalangeal joint. The prosthesis is constructed of medical grade silicone elastomer and is available in three sizes: small, medium and large.	The GAIT implant was approved by the FDA in 2019. It is reserved for Class 3 type degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of the joint cartilage, bony spurring surrounding the joint space and a painful ROM of the first MTP joint, both with rotation and walking. The implant is meant to augment the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal head in the transverse, sagittal and frontal plane.
HemiCAP® Toe Contoured Articular Prosthetic Implant	Arthrosurface, Inc.	The implant consists of a metallic articular resurfacing component mounted on a taper post.	The HemiCAP® implant was approved by the FDA in 2013. The system is intended to be implanted with bone cement to treat stiffness, instability, or pain associated with arthritis in the first MTP joint (hallux rigidus) or to treat bunions (hallux valgus).

			Metatarsal head resurfacing (hemi-arthroplasty) is intended as an alternative to joint fusion (arthrodesis), total joint replacement (TJR), or bone spur removal.
METIS® Prosthesis	_____	The prosthesis consists of three components: metatarsal (cobalt-chromium alloy), phalangeal (titanium), and a third-generation interposition component composed of polyethylene. Metatarsal and phalangeal components are coated with hydroxyapatite. The design seeks to preserve the normal anatomy of the MTP joint, preserving the sesamoid bones and their tendinous insertions, with an expected range of motion of about 85°.	_____
Moje Ceramic Implant	Orthosonics, Ltd.	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	The Moje implant has not received FDA approval.

		screw-fit but complications of osteolysis and metallosis led to the replacement of the design with a press-fit version. 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.	
Primus Great Toe Implant	_____	The Primus Flexible Great Toe has a silicone polymer and is designed for MTP joint replacement.	The Primus Great Toe Implant was approved by the FDA in 2013.
ReFlexion 1st MTP Implant System	OsteoMed	This three-piece implant system designed for the reconstruction of the 1st MTP, resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, or revision of previous arthroplasty. The cone in cone implant secures bone to implant seating.	The implant was approved by the FDA in 2008 indicated for use as a hemi-arthroplasty implant for the MTP joint for degenerative and post-traumatic arthritis in the presence of good bone stock and integrity of the phalangeal base, along with hallux litmus, hallux valgus, hallux rigidus and an unstable to painful MTP joint.

Swanson Flexible Hinge Toe	Wright Medical® Technology Inc	The Swanson Flexible Hinge Toe is a double-stemmed flexibe hinge implant designed to restore function to the MTP joints which are disabled by rheumatoid, degenerative, or post traumatic arthritis. Sizes available include 0 – 7.	The first generation was approved by the FDA in 1998. Subsequent generation would be dependent on the current FDA approvals.
Toefit-Plus™	Smith & Nephew	The prosthesis can be used for hemi or total arthroplasty. is composed of a tapered, threaded, conical titanium core, which avoids any need for cement. On the metatarsal side, a cobalt chrome metatarsal head is tapped into the titanium core and to accommodate the proximal phalanx, a polyethylene phalangeal plate is clipped to the core.	_____

PRIOR APPROVAL

Not applicable.

POLICY

The use of metatarsophalangeal implants is considered **investigational** as a treatment for all indications, including but not limited to, metatarsophalangeal joint disorders (hallux limitus or hallux rigidus) to include the following implants because the evidence is

insufficient to determine the technology results in an improvement in the net health outcomes:

- AnaToemic 1st MTP Hemi Implant
- Bioabsorbable poly-L-D-lactic Acid RegJoint Inter-Positional Implant
- Cartiva Implant
- GAIT Implant
- HemiCAP® Toe Contoured Articular Prosthetic Implant
- METIS Prosthesis
- Moje Implant
- (OsteoMed) ReFlexion 1st MTP Implant System
- Primus Great Toe Implant
- Swanson Flexible Hinge Toe
- ToeFit-Plus Prosthesis

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 28291 Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
- L8641 Metatarsal joint implant
- L8642 Hallux implant
- L8699 Prosthetic Implant, not otherwise specified

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POLICY HISTORY

Date	Reason	Action
December 2022	Annual Review	Policy Renewed
December 2021	Annual Review	Policy Revised
December 2020	Annual Review	Policy Revised
December 2019	Annual Review	Policy Revised
December 2019		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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