Anthem

Medical Policy

Subject: Extraosseous Subtalar Joint Implantation and Subtalar Arthroereisis
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Description/Scope

This document addresses the use of extraosseous subtalar joint implantation and subtalar arthroereisis.

Extraosseous subtalar joint implantation is a minimally invasive surgical procedure performed to stabilize and prevent redislocation of the talotarsal joint for symptoms associated with hyperpronation caused by partial talotarsal joint dislocation or talotarsal joint instability.

Subtalar arthroereisis is a surgical procedure performed to correct excessive talar displacement and calcaneal eversion due to pes planus (flatfoot) by placement of an implant in the sinus tarsi. Subtalar arthroereisis may be performed alone or in combination with other comprehensive surgical procedures for ankle and foot conditions.

Note: Please see the following related document for additional information:

- CG-DME-22 Ankle-Foot & Knee-Ankle-Foot Orthoses

Position Statement

Investigational and Not Medically Necessary:

A. Subtalar arthroereisis is considered **investigational and not medically necessary** for all indications, including but not limited to the treatment of flatfoot conditions, symptomatic flexible flatfoot deformity, and posterior tibial tendon dysfunction.
B. Extraosseous subtalar joint implantation is considered **investigational and not medically necessary** for all indications, including but not limited to, talotarsal joint stabilization.

Rationale

Subtalar Arthroereisis

Subtalar arthroereisis attempts to correct hindfoot valgus and midfoot abduction present in individuals with pes planus, also known as flatfoot, through the insertion of an implant into the sinus tarsi. This prevents excessive eversion of the subtalar joint by improving the position of the talus relative to the calcaneus and navicular. Due to its joint sparing technique, arthroereisis is regarded to be a minimally invasive procedure (Tan, 2021). Subtalar arthroereisis has been suggested both as an isolated procedure and as a component of a more comprehensive surgical procedure. As an isolated procedure, key outcomes of subtalar arthroereisis include short- and long-term improvement in symptoms and other functional outcomes such as walking, in addition to durability and other safety measures of the implant. When used as a component of a more comprehensive surgical procedure, controlled studies are needed to isolate the contribution of the arthroereisis to the overall treatment effect.

Smith and colleagues (2021) performed a systematic review for subtalar arthroereisis that was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The aim of the systematic review was to assess the outcome of arthroereisis for the treatment of symptomatic pediatric flexible pes planus. All articles were assessed against the following inclusion criteria: primary subtalar arthroereisis for symptomatic pediatric flexible pes planus and prospective or retrospective studies. The database search identified 47 articles and review of references identified 4 additional articles. Application of the inclusion criteria resulted in 32 eligible articles. There were 8 studies removed due to exclusion criteria (non-English language, no preoperative data available, no patient-centered outcomes, arthroereisis performed as part of a reconstruction); 24 studies remained in the final review. These consisted of 5 prospective case series, 13 retrospective case series, 3 prospective non-randomized comparative studies and 3 retrospective non-randomized comparative studies. The methodological quality of articles was assessed using an abridged Downs and Black's criteria.

The studied procedures were performed on 2550 feet of at least 1399 individuals. The average age at the time of surgery was 11.62 years (range 5-17 years), within the ideal age range of 9-12 years. The overall complication rate was 7.1% with further surgery required in 3.1% of cases. The authors concluded that arthroereisis produced favorable outcomes and high satisfaction rates with a reasonable risk profile. They noted that established surgical procedures for flexible pes planus are not without risks and include more complicated, lengthier interventions with longer rehabilitation periods. The authors point out that the current literature is limited by the lack of high-quality prospective studies, a paucity of long-term data and heterogeneity of outcome measures between studies. They concluded these factors need to be addressed to truly evaluate whether arthroereisis is an effective treatment for symptomatic pediatric flexible pes planus.

Tan and colleagues (2021) performed a systematic review conducted in accordance with the PRISMA guidelines. The review included 17 publications reporting on procedures done on 1536 feet. The average duration of follow-up of the studies included in the review was noted as 43.52 months. A large number of radiographic parameters were reported by the various studies. To allow for meaningful comparisons between the pre- and post-operative radiographic measures, only radiological outcomes that were reported in 3 or more papers were used for statistical analysis. The studies consistently reported improvement in the radiological outcomes, approximating that of a normal population. Subtalar arthroereisis was shown to restore the collapsed medial longitudinal arch as measured by Meary's and the calcaneal pitch angle. Heel valgus was also significantly reduced, evident by the post-operative lateral talocalcaneal angle.

Five studies reported postoperative subjective self-grading of outcomes. Individuals were considered to have experienced a positive outcome if they rated their experience to be excellent, good or fair. All studies reported an improvement in outcomes post-operatively. It was noted that 187 feet out of 199 (94.0%) had improvement in their grading of outcomes post-operatively. This was statistically significant ($p< 0.001$). Out of 1312 individuals in these studies, 116 individuals reported post-operative complications (8.78%). Incomplete correction of the deformity was reported in 23 individuals who had undergone exosinotarsal arthroereisis with metallic AO screws (1.75%). The incomplete correction was resolved using conservative treatment and orthotic insoles. Another notable

complication was local inflammatory responses to the bioabsorbable implant. This was reported in 21 individuals (1.60%). All individuals with this complication had undergone arthroereisis with a bioabsorbable device. This inflammatory response required revision surgery in 1 individual due to persistent pain. The other individuals with this inflammation were treated with conservative measures such as rest, application of ice, or non-steroidal anti-inflammatory drugs (NSAIDs). The study concluded that subtalar arthroereisis resulted in both pain relief as well as correction of the underlying pes planovalgus deformity. They also assert that the procedure leads to a significantly increased number of positive short- to mid-term outcomes. The authors acknowledge that this review does not address the long-term efficacy of this procedure. They note that “current knowledge is still in its infancy. Further larger scale studies should be done to confirm the results proposed in the review.”

Progressive Collapsing Foot Deformity (formerly known as Adult Flatfoot) Conditions

No randomized controlled trials (RCTs) have evaluated subtalar arthroereisis for treatment of progressive collapsing foot deformity conditions, either as an isolated procedure or as part of a larger surgery. One retrospective comparative study evaluated subtalar arthroereisis as part of a comprehensive surgical procedure. The study, by Walley and colleagues (2018), was a retrospective case-control study comparing outcomes in 15 individuals who had surgical flatfoot correction (such as posterior tibial tendon resection or Achilles’ lengthening) plus an arthroereisis implant, and a matched control group of 30 individuals who had surgery without the implant. Mean duration of follow-up was 4.5 years for the experimental group and 3.4 years for controls for clinical outcome assessment. Clinical outcomes were assessed with the Short Form-36 (SF-36) and a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst pain). At follow-up, SF-36 and VAS scores did not differ significantly between groups. The mean duration of radiographic follow-up was 2.4 years. At last follow-up, the lateral talar-first metatarsal angle improved significantly more in the experimental group than in the control group ($p<0.05$). The study had a small sample size, was non-randomized and retrospective and did not find that subtalar arthroereisis improved clinical outcomes.

In 2021, Silva reported the results of a retrospective comparative study involving 72 subjects with progressive collapsing foot deformity treated with either lateral column lengthening (n=41) or subtalar arthroereisis (n=31). The reported results indicated that both groups demonstrated significant improvement in all their clinical and radiological outcome measures at 6 months and 24 months, except for SF-36 mental function score. The column lengthening group had significantly better results on midfoot American Orthopaedic Foot & Ankle Society (AOFAS) scores at 24 months (90.3 vs. 81.1, $p<0.001$). A significant improvement in Body Mass Index (BMI) was reported in the column lengthening group at 24 months after surgery (29.1 vs. 27.2, $p=0.035$). The subtalar arthroereisis group did not have similar changes. The column lengthening group experienced two complications (4.4%), including one case of sural nerve entrapment and one of wound breakdown requiring surgical debridement. Seven subjects (20.6%) in the subtalar arthroereisis group had to have their implant removed due to midfoot pain. However, deformity correction was maintained at 24 months in all subjects despite implant removal. The authors concluded that lateral column lengthening demonstrated superior outcome scores and lower complication rates at 24 months when compared to subtalar arthroereisis.

A number of case series have been published (Adelman, 2008; Bernasconi, 2022; Brancheau, 2012; Lucaccini, 2008; Needleman, 2006; Ozan, 2015). Most of these case series had small sample sizes. All of these included fewer than 50 individuals and most had fewer than 25 participants.

One of the larger case series was published by Brancheau and colleagues in 2012. This was a retrospective study of 35 individuals (60 feet) treated with the Maxwell-Brancheau Arthroereisis (MBA) implant (Subtalar MBA® Implant System; Integra LifeSciences Corporation, Plainsboro, NJ) in adults and children with flexible flatfoot. The mean age of the participants at the time of surgery was 14.3 (range 5 to 46) years. Adjunct procedures were performed in 48 of the 60 cases (80%) based on the participants’ presenting complaints, diagnostic and intraoperative findings. Pre- and post-operative anteroposterior and lateral foot radiographs were compared at a mean of 36 months postoperatively. The mean changes were reported as statistically significant ($p<0.00001$) differences in five different talar/calcaneal/intermetararsal angles. It was noted, however, that correction of radiographic parameters is not always a reliable predictor of satisfaction with the surgical outcome.

A subgroup of 24 (68.6%) participants responded to a subjective questionnaire at a mean of 33 months postoperatively. The presenting chief complaints were resolved in 23 of 24 individuals (95.8%), and 21 of 24 individuals (87.5%) returned postoperatively to either the same or a greater activity level in sports. When asked to rate their pain, the subgroup reported that 24 of 40 feet (60%) were considered free of pain postoperatively, 13 of 40 feet (32.5%) experienced mild pain, and 3 of 40 feet (7.5%) were moderately painful. A total of 17 (71%) of the subgroup could stand for long periods of time without pain, however, 7 of the subgroup (29%) could not. A substantial number of participants (11.9%) experienced complications including pain and restricted motion of the subtalar joint, the most common complaint requiring implant removal. In addition to lacking a comparison group, the study is limited due to the large proportion of participants lost to follow-up, heterogeneity of the participants based on age (participants of all ages were included) and lack of blinding.

Pediatric Flatfoot Conditions

Metcalfe and colleagues (2012) performed a systematic review of the available literature regarding arthroereisis in children with flexible flatfoot. The literature consisted primarily of case reports and retrospective case series; no RCTs were identified. Methodological variations include device type, inclusion criteria, surgical technique, application of adjunctive procedures and outcome measures. Few studies applied validated clinical or participant-reported outcome measures. While several studies demonstrated significant improvements in radiographic parameters including increased arch height and improved joint congruency following arthroereisis, the precise mechanism by which arthroereisis improves foot alignment remains to be explained. Calcaneal inclination angle demonstrated the least change with only small increases following arthroereisis. The procedure remains associated with a number of complications including sinus tarsi pain, device extrusion, and under-correction. Complication rates were reported to range between 4.8% and 18.6%, with unplanned removal rates between 7.1% and 19.3% across all device types. Satisfaction rates ranged from 79% to 100%.

In 2014, De Pellegrin conducted a case series on pediatric subjects with flexible flatfeet who underwent subtalar extra-articular screw arthroereisis (SESA) insertion with an average follow-up of 4.5 years. For 22 years, data was collected on 485 subjects (732 feet). Authors reported data on 138 subjects (227 feet) who underwent screw removal at an average of 3.1 years post insertion. Of that group, a subsample of 76 subjects (121 feet) were evaluated for outcomes after screw removal (which occurred an average of 2.9 years after the procedure). It is unclear how that subsample was selected. The outcome assessment in the 76-subject subsample included a medical examination of the foot, radiographic measurements (Costa-Bartani angle, talar inclination angle, calcaneal pitch angle), and a footprint analysis. The results showed a significant statistical improvement in the radiographic angles measured pre- and post-operatively for screw insertion ($p<0.001$). These results were maintained after screw removal. Additionally, loss of correction was reported in 9 subjects. It is not clear from the report if loss of correction occurred while the initial screw was in place, after initial screw removal, or after screw replacement. The complication rate in the 398 subjects for whom full data was available was 6.3%, which included joint effusion or hemarthrosis (n=8), contraction of the peroneal muscles (n=14), and stress fractures (n=3). Treatment of complications included early screw removal, screw reimplantation, physical therapy, use of orthoses, and steroid injections. The authors' conclusion was that SESA is an optimal technique for the correction of flexible flatfoot. However, there are several limitations

in this study including lack of a validated evaluation score after surgery, lack of a control group, and others. It should also be noted that a concerning complication rate and lack of long-term follow-up limit the generalizability of these findings.

A study by Chong and colleagues (2015) compared subtalar arthroereisis and lateral column calcaneal lengthening in children (mean age: 12.8 years) with painful flatfeet. A total of 7 individuals and 13 feet were in the arthroereisis group and 8 individuals and 11 feet were in the lateral column lengthening group. Outcomes included five radiographic measures, of which only calcaneal pitch differed significantly between groups at follow-up. Groups did not differ significantly at follow-up in kinematics outcomes (such as ankle and midfoot flexion/extension) or pedobarometry outcomes (such as time spent on the hindfoot). Two complications were identified in each group. The study had a small sample size and did not compare interventions on functional outcomes.

In 2021 Tahririan and colleagues reported the results of a prospective RCT involving 66 juvenile subjects with symptomatic flexible flatfoot unilaterally treated with either lateral calcaneal lengthening (n=31) and subtalar arthroereisis (n=35). Significant improvements were noted in both groups with regard to clinical parameters, with the mean AOFAS score increasing from 68.71 to 87.87 in the calcaneal lengthening group and from 67.28 to 86.14 in the arthroereisis group ($p<0.001$ for both). No significant differences between groups were noted in AOFAS scores ($p=0.431$). With regard to radiographic parameters, significant improvements were reported in both groups for AP Tal-1Met, Lat Tal-1Met, and calcaneal pitch ($p<0.001$ for all). The only difference between groups was calcaneal pitch, which was significantly larger in the calcaneal lengthening group ($p<0.001$). One adverse event was reported in each group, with the 1 calcaneal lengthening subject experiencing graft displacement after 1 month that was resolved with 2 weeks of conservative treatment. One arthroereisis subject reported persistent pain 7 months after surgery, which was resolved with removal of the arthroereisis screw. The authors concluded that both groups had substantial improvement in clinical and radiographic aspects, but that the arthroereisis group experienced more rapid symptom relief and earlier weight-bearing capacity. However, no data was provided supporting either of these conclusions.

Eysel (2022) reported a non-randomized comparative trial of 18 adolescent subjects with 25 symptomatic flexible flat feet (7 bilateral and 11 unilateral) treated with subtalar arthroereisis who were compared to 13 healthy controls (26 feet). Mean follow-up for the arthroereisis group was 3.9 years (range 0.4-8). At mean follow-up of 2.6 years, 13 feet had undergone explantation procedures and the remaining 12 feet retained the arthroereisis implant. The healthy control group was significantly younger and weighed less than the arthroereisis subjects at the time point of analysis. The AOFAS questionnaire was completed by all control and arthroereisis subjects. The arthroereisis group responded individually for each foot if procedures were bilateral. AOFAS scores for the control group were scored at 100 points out of 100 for all feet; in the arthroereisis group mean AOFAS scores improved from 69 points to 94 points. Implant removal had no impact on AOFAS scores. Radiographical measures indicated a significant improvement in lateral TMT angle (-11° to -4°, $p=0.004$), AP TMT angle (-36° to -22°, $p<0.001$), and TMT index (-46° to -26°, $p<0.001$). Interestingly, calcaneal pitch was unchanged after arthroereisis. Dynamic pedobarography was performed by all participants, which demonstrated that the hallux valgus angle was unchanged. However, arch index was reported to be significantly increased after arthroereisis vs. control feet. The authors reported that, “subtalar arthroereisis was able to effectively treat symptomatic flexible flatfeet in this population.” However, the weak study design and low power of this study limit the generalizability.

A 2019 systematic review did not identify any additional controlled studies evaluating subtalar arthroereisis for pediatric flatfoot. Nearly all of the published case series had sample sizes of fewer than 50 individuals each. In 2018, Faldini and colleagues published a retrospective case series in 173 children who had been followed for a mean of 49.5 months. Children had undergone subtalar arthroereisis for flexible flatfoot using polymeric endo-orthotic implants. Outcomes were assessed using the Italian Foot Function Index Questionnaire (FFI) which ranges from 0 to 162 with a lower score indicating a better outcome, and the Self-reported Foot and Ankle Score (SEFAS) which ranges from 0 to 48 with a higher score indicating a better outcome. Baseline FFI and SEFAS scores were not reported. The mean scores at follow-up were within the normal range; the mean FFI was 5.3 in males and 3.7 in females, and the mean SEFAS score was 47 in both males and females. Implant removal surgery was performed in 4 of 173 individuals. Limitations of this study and other series include lack of a control or comparison group and lack of blinding.

A prospective RCT published by Ahmed (2022) involved 35 pediatric subjects with spastic cerebral palsy and flexible flatfoot deformity (57 feet). Subjects were assigned to treatment with either lateral column lengthening (n=19, 29 feet) or subtalar arthroereisis (n=16, 28 feet). Mean follow-up was 15.6 months. The authors reported no statistically significant differences between the two groups with regard to the primary outcome, which was improvement in clinical outcome as measured by a clinical score tool ($p=0.281$). Both groups had statistically significant improvement in most measured angles vs. baseline; the exception being lateral talocalcaneal angle, which favored the arthroereisis group ($p=0.003$). Finally, there were no statistically significant differences reported between groups with regard to complication rates.

A prospective case-controlled study by Herdea (2022) compared 33 subjects with bilateral flexible flatfeet who underwent arthroereisis to 36 age- and sex-matched subjects in a control group with normal feet who underwent no treatment. A titanium implant was inserted for all the arthroereisis procedures with the specific type of implant being based on hospital availability. The follow-up period for this study was a minimum of 2 years and no subjects were lost to follow-up. A quality-of-life assessment was measured using the AOFAS Ankle-Hindfoot Scale. Based on the assessment, the quality of life significantly improved in the study group ($p<0.0001$). The postoperative quality of life does not differ significantly from the control group. Another outcome measured was running time of the subjects. Within the study group, the running time improved significantly postoperatively compared to baseline ($p<0.0001$). However, when compared to the control group, the study group continued to have significantly slower running times ($p=0.01$). Finally, radiographic angles were measured and improved significantly in all planes ($p<0.0001$). The authors noted that quality of life improvement was correlated with the measurements from the talonavicular coverage angle and Meary’s angle. The limitations of this study include small sample size, short follow-up, and significant differences between groups with regard to BMI. Also of note, all the subjects in the study group had flexible flatfeet with a moderate form of Achilles tendon shortening which made them suitable for the arthroereisis surgery.

Elbarbary and colleagues (2022) conducted a prospective study of 23 subjects (46 feet) with cerebral palsy and moderate bilateral flexible planovalgus deformities. A single team operated on all subjects and performed arthroereisis using a cancellous screw. There was a minimum follow-up of 2 years (mean 36.7 months) with clinical and radiological assessments. A total of 10 subjects (20 feet) had no history of surgical interventions and 13 subjects (26 feet) had a history of previous interventions consisting of soft tissue procedures for release of spastic muscles at various joints. There was 1 case of wound infection that resulted in hardware removal 4 months postoperatively. However, that subject maintained clinical and radiologic improvement. Outcomes were measured by the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C), radiographs, and clinical assessment at the last follow-up visit. The OxAFQ-C were completed by the subject or the parent and showed an overall improvement in foot shape, shoe comfort, and walking ability. The radiographic and clinical improvement were both statistically significant, with postoperative lateral talocalcaneal angle improvement with a mean difference of 22.44 degrees compared to baseline ($p=0.028$). Additionally, heel alignment angle also showed an improvement with a mean difference of 15.57 degrees compared to baseline ($p=0.002$). Limitations of the study include small sample size, lack of comparison group, and blinding.

A retrospective cohort study done by Chen (2022) involving 69 subjects (107 feet) with pediatric flexible flatfoot who underwent implantation of the HyProCure® (GraMedica®, Macomb, MI) device with (n=61 feet) or without gastrocnemius recession (n=46 feet).

Subjects were followed for a minimum of 1 year (mean follow-up was 35.9 months). The outcomes assessed were the Maryland Foot Score (MFS), VAS for pain, radiographic data, and complications. At the last follow-up, VAS was improved ($p<0.001$). Regarding MFS results, MFS-Pain, MFS-Function, and MFS-Appearance were all significantly improved ($p<0.001$). Radiographic results indicated significant improvement in talar-second metatarsal angle, Meary's angle, and Pitch angle ($p<0.001$ for all). One subject experienced implant extrusion and 10 subjects experienced tarsal sinus pain. Of the subjects experiencing pain, 7 subjects achieved relief with conservative therapy and 3 subjects underwent device explantation. The authors acknowledged several limitations in the study including recall bias, relatively small sample size, and lack of long-term follow-up. In addition, no comparison between the device alone vs. device with gastrocnemius recession was provided.

García Bistolfi (2022) conducted a retrospective cross-sectional study evaluating percutaneous subtalar arthroereisis with the MBA implant for pediatric subjects with flexible flatfoot. The study consisted of 14 subjects (19 feet) who were followed for a minimum of 24 months (mean 68.26 months). The clinical-functional outcome was measured using the AOFAS Ankle-Hindfoot Scale and showed significant improvement ($p<0.001$). The radiographic outcome measured Kite's angle, talar-first metatarsal angle, talonavicular coverage angle, Meary's angle, internal Moreau-Costa-Bartani's angle, talar declination angle, and the calcaneal pitch. All the radiographic angles showed significant improvement ($p<0.001$ for all) but only two angles (talar declination angle and Kite's angle) reached normal values. VAS was measured pre- and post-operatively and showed significant improvement ($p<0.001$). One subject, who had both feet operated on, complained of persistent pain in both feet but was able to perform activities of daily living and participate in sports without any restrictions. In this study, no implants had to be removed. The retrospective design, lack of a control group, small sample size, and short follow-up were all noted limitations in this study.

It should be noted that most of the literature on subtalar arthroereisis for children with flatfoot conditions have been case series studies with significant methodological limitations (Caravaggi, 2018; Cicchinelli, 2008; Kellermann, 2011; Koning, 2009; Le Gall, 2022; Li, 2021; Nelson, 2004; Riva, 2022; Ruiz-Picazo, 2019; Scharer, 2010; Shi, 2023). Overall, the body of evidence addressing the use of arthroereisis in pediatric individuals is limited by multiple factors, including small sample sizes, short follow-up time, lack of blinding, and others. Additional trials in the form of larger blinded RCTs would be helpful in understanding the benefits and harms of this procedure for the pediatric population.

Talotarsal Stabilization

No RCTs or prospective non-randomized comparative studies have evaluated extraosseous subtalar joint implantation for talotarsal stabilization. Several case series evaluating the HyProCure device have been published (Bresnahan 2013; Graham 2012a; Graham 2012b). The studies by Graham and colleagues were retrospective and the Bresnahan study was prospective. The Graham 2012b study had the largest sample size and longest-follow-up. All are limited by lack of comparison or control groups.

Graham and colleagues (2012a) retrospectively evaluated the long-term functional outcomes in adults (n=83) for treatment of symptoms associated with hyperpronation caused by partial talotarsal joint dislocation or talotarsal joint instability. Data on subjective outcomes of postoperative device performance was collected from a mailed questionnaire to participants. At a mean follow-up period of 51 months, 52% (41 of 78) of responders reported complete alleviation of foot pain and 69% (54 of 78) had no limitations on their foot functional capabilities. The implant was permanently removed from 7 of the 117 treated feet (6% removal rate) due to prolonged pain of the anterior talofibular ligament (4 cases), psychogenic reaction (2 cases), and postoperative infection (1 case). Excluding these explantations, an additional 16 participants underwent revision surgeries. Satisfaction with the appearance of their feet was reported in 80% (62 of 78) of cases. A total of 32% of the cases (35 of 110 feet in whom the implants were not removed) were performed with adjunctive procedures to achieve the desired amount of correction and thus the ability to draw conclusions on the efficacy of the HyProCure device as a standalone procedure is limited.

Bresnahan and colleagues (2013) prospectively reviewed subjective clinical outcomes in a multicenter case series of children and adults using the HyProCure device as a standalone procedure for the treatment of recurrent and/or partial talotarsal joint dislocation. A total of 35 individuals (46 feet) were evaluated using the MFS questionnaire, obtained preoperatively and 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year postoperatively. The mean overall scores showed gradual improvement from a preoperative value of 69.5 (± 19.6) to a postoperative value of 89.2 (± 14.4) at 1 year follow-up. Foot pain decreased by 37%, foot functional activities improved by 14%, and foot appearance improved by 29.5%. The greatest degree of improvement occurred at 4 weeks postoperatively, with gradual improvement continuing to the 1-year follow-up. At 6 months, 4 individuals (6 feet, 13%) showed a failure to improve from preoperative MFS, and at 1 year, 3 individuals (6 feet, 13%) showed no improvement. The HyProCure device was removed from 2 individuals (2 feet, 4%) due to discomfort when walking and during activities and failure of the procedure to relieve symptoms. Limitations of this study include the broad nature of the inclusion and exclusion criteria, including a lack of measurement of certain variables, such as the planar dominance of the recurrent talotarsal deformity, the presence of certain secondary conditions, and the relative activity level, all of which could have affected the subjective outcomes. There was a substantial number of cases lost to follow-up and incomplete data at the 1-year postoperative assessment, as 46 feet in 35 preoperative participants decreased to 30 feet in 21 participants.

Larger, longer-term, randomized and controlled studies are needed to fully evaluate the safety and efficacy of the HyProCure device for the treatment of extraosseous talotarsal joint dislocation.

Other Considerations

The American College of Foot and Ankle Surgeons (ACFAS) published two practice guidelines for the diagnosis and treatment of adult and pediatric flatfoot (Harris, 2004; Piraino, 2020). In adults, the guideline stated:

> Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult-acquired flatfoot deformity]…Use of a subtalar implant alone to address pronation of the foot has limited literature demonstrating its use in the flexible deformity without advanced disease of surrounding soft tissues including tendon and ligament (Piraino, 2020).

In the pediatric population,

> proponents of this procedure (arthroereisis) argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot. Others have expressed concern about placing a permanent foreign body into a mobile segment of a child's foot. The indication for this procedure remains controversial in the surgical community (Harris, 2004).

The American Academy of Orthopaedic Surgeons has not taken a formal position with regard to the use of surgically placed implants as a treatment option for progressive collapsing foot deformity, flexible flatfoot in children, or in combination with other comprehensive surgical procedures for ankle and foot conditions.

Conclusion

In summary, the evidence in the peer-reviewed published literature is insufficient to draw conclusions as to the safety and effectiveness of extraosseous subtalar implants for talotarsal stabilization and subtalar arthroereisis with a surgically placed implant for the treatment of flatfoot deformity and other adult and pediatric ankle and foot conditions. The impact of long-term implantation on the development of osteoarthritis, extrusion, etc. is unclear; especially in juveniles who experience significant skeletal and body mass growth post-procedure. As reported by De Pellegrin and discussed above, arthroereisis in children may result in significant complications for which long-term impact is unclear. Further research is required in the form of prospective controlled studies with long-term follow-up of functional improvement. This is particularly important given that the procedures may be performed in growing children.

Background/Overview

Flatfoot (also known as pes planus) is a common but often complex congenital or acquired condition, with diverse symptoms and varying degrees of deformity and disability, with the common characteristic of partial or total collapse of the arch of the foot. It can broadly be categorized as rigid or flexible. The rigid form is usually pathological, often caused by genetic, neurological, inflammatory, rheumatological, traumatic or osseous abnormalities. Individuals with rigid flatfoot usually present with symptoms that often necessitate surgical management (Tan, 2021). Flexible flatfoot, when the foot is flat when standing or weight-bearing and the arch returns when not standing, is one of the most common types, anatomically described as excessive pronation during weight bearing due to anterior and medial displacement of the talus. Flatfoot disorder is usually diagnosed in children as flexible flatfoot, paralytic flatfoot, or flatfoot associated with generalized ligamentous laxity, as seen in Marfan disease, Ehlers-Danlos Syndrome (EDS), Downs syndrome, cerebral palsy, myelomeningocele, developmental delay, and other syndromes. Flexible flatfoot in adults may be congenital or acquired due to posterior tibial tendon dysfunction (PTTD), which in turn may be caused by trauma, overuse, and inflammatory disorders (such as rheumatoid arthritis), among others. Flatfoot in adults may be known as 'progressive collapsing foot deformity.' Symptoms include pain, with or without a dull aching, throbbing or cramping sensation which in children may be described as "growing pains." In addition, flatfoot may contribute to symptoms of low back pain.

Conservative management of flexible flatfoot deformity includes orthotic therapy or shoe modifications, passive stretching exercises and medications such as nonsteroidal anti-inflammatory drugs. For an individual with more severe flatfoot deformity or ligamentous laxity in which ankle instability, PTTD, or early arthrosis has developed, an ankle-foot orthosis or a more proximal device may be more appropriate. A skeletally mature adolescent may benefit from these types of orthoses as a last line of nonsurgical treatment. Various surgical procedures including hind-, mid-, and forefoot osteotomies, soft tissue medial column reconstruction, and subtalar joint arthrodesis have been used in the treatment of individuals who have failed conservative treatment (Blitz, 2010). Arthroereisis is the limitation of excessive movement across the joint. Subtalar arthroereisis is a surgical procedure designed to correct the excessive talar displacement and calcaneal eversion by placing an implant in the sinus tarsi, a canal located between the talus and the calcaneus. Subtalar arthroereisis has been performed alone or in combination with other surgical procedures of the ankle and foot.

Subtalar arthroereisis has been performed for over 50 years, with a variety of implant designs and compositions. For example, the MBA implant involves a simple and reversible implantation procedure, compared to other devices such as the STA-Peg and Kalix® II device (newdeal® SAS, Integra™, Integra LifeSciences Corp., Plainsboro, NJ). The device received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance in 1996 because it was substantially equivalent to products on the market prior to device regulation. The implant is described as an "internal orthotic" designed for correction of pediatric pes valgus and adult posterior tibial dysfunction deformity. According to the FDA summary, the primary indication for the subtalar MBA device is "as a spacer for stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela." The implant consists of a soft-threaded titanium device that is inserted into the sinus tarsi and does not require bone cement. The aim of the procedure is to restore the arch by blocking the anterior and inferior displacement of the talus and by preventing the foot from pronating, thus allowing normal subtalar joint motion. Tissue grows normally around the implant and aids in holding it in place. The individual can ambulate the day after surgery in a Cam walker for approximately 3 weeks. Thereafter, regular shoes can be worn with an ankle brace for an additional 2 to 3 weeks. In children, insertion of the MBA implant is frequently offered as a stand-alone procedure, while adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities. The MBA Resorb Implant received 510(k) marketing clearance in 2005. This implant employs the same basic mechanical features as the predicate MBA implant, but is composed of a material (poly l-lactic acid) that is reabsorbed by the body.

Incongruence of the talotarsal joint, whether flexible or rigid, is present in pes planovalgus; however, talotarsal dislocation can occur without a flatfoot. The displacement of the talus on the hindfoot bones serves as the apex of the deformity. When conservative care fails, talotarsal stabilization with an extraosseous subtalar joint implant has been proposed as a minimally invasive surgical option to facilitate the natural motion of the joint by placement of the talotarsal fixation device deeply into the sinus tarsi. In 2004, Graham Medical Technologies received 510(k) marketing clearance for the HyProCure Subtalar Implant System/Extra Osseous Fixation Device for treatment of hyperpronated feet.

Definitions

Acquired flatfoot: Flatfoot occurring as a result of fracture or dislocation, tendon disruption, tarsal ligament disruption, tarsal coalition, arthritis, neuroarthropathy, neurologic weakness, or other causes.

Arthroereisis: The limitation of movement across a joint.

Calcaneus: The heel bone.

Flatfoot: See pes planus below.

Flexible flatfoot: A complex genetic or environmentally influenced condition where the medial longitudinal arch of the foot lowers and flattens out upon standing but reappears on toe rise.

Pes planus: A complex genetic or environmentally influenced condition with the common characteristic of partial or total flattening of the arch or instep of the foot; also referred to as flatfoot, fallen arches, pes planovalgus, over-pronation or pronation of feet.

Posterior tibial tendon dysfunction (PTTD): A progressive, painful collapse of the medial longitudinal arch of the foot as a result of degenerative or inflammatory processes, overstretching, or traumatic injury to the posterior tibial tendon; the most common cause of progressive collapsing foot deformity.

Progressive collapsing foot deformity: Formally known as 'adult acquired flatfoot.'

Subtalar joint: Compound joint located below the ankle joint at the meeting point of the talus and the calcaneus.

Talus: One of the foot and ankle bones, located just above the calcaneus.

Tarsus: Also referred to as the ankle. The seven bones (talus, calcaneus, navicular, medial, intermediate and lateral cuneiform, and cuboid) composing the joint between the foot (metatarsus) and leg.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

28899	Unlisted procedure, foot or toes [when specified as subtalar arthroereisis] Note: if CPT code 28585 (Open treatment of talotarsal joint dislocation, includes internal fixation, when performed) is used to describe a subtalar arthroereisis procedure, the service is considered investigational and not medically necessary
0335T	Insertion of sinus tarsi implant
0510T	Removal of sinus tarsi implant
0511T	Removal and reinsertion of sinus tarsi implant

HCPCS

S2117	Arthroereisis, subtalar

ICD-10 Procedure

0SUH0JZ	Supplement right tarsal joint with synthetic substitute, open approach
0SUH3JZ	Supplement right tarsal joint with synthetic substitute, percutaneous approach
0SUH4JZ	Supplement right tarsal joint with synthetic substitute, percutaneous endoscopic approach
0SUJ0JZ	Supplement left tarsal joint with synthetic substitute, open approach
0SUJ3JZ	Supplement left tarsal joint with synthetic substitute, percutaneous approach
0SUJ4JZ	Supplement left tarsal joint with synthetic substitute, percutaneous endoscopic approach

ICD-10 Diagnosis

	All diagnoses

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Disco Subtalar Implant System
Extraosseous Talotarsal Stabilization (EOTTS)
Futura™ Angled Subtalar Implant
Futura™ Conical Subtalar Implant
HyProCure Subtalar Implant System
IFS Subtalar Implant
In2Bones PitStop®
Instratek™ Sub-Talar Lok™ Arthroereisis Implant System
Kalix II
Life Spine Subtalar Implant System
Lundeen Subtalar Implant
Maxwell-Brancheau Arthroereisis (MBA) Implant
MBA Resorb Implant
MC-Subtalar™ II
MetaSurg BioArch Subtalar Implant System
Nexa Orthopedics Subtalar Peg
Normed Vario Subtalar Screw
OsteoMed Talar-Fit™ Subtalar Implant System
OsteoSpring FootJack™ Subtalar Implant System
Smith Subtalar Arthroereisis Implant
STA-Peg
SubFix™ Arthroereisis ImplantSub-Talar Lok™ Arthroereisis Implant System
Subtalar MBA Implant System Talar-Fit Subtalar Arthroereisis Implant System
Talus of Vilex (TOV) Subtalar Implants
Trilliant Twist Subtalar Implant

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale, Background/Overview, Definitions, References, Websites for Additional Information, and Index sections.
Reviewed	08/11/2022	MPTAC review. Updated References and Websites sections.
Reviewed	08/12/2021	MPTAC review. Updated References and Websites sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale and References sections.
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	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; added 0510T, 0511T.
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Reviewed	05/09/2013	MPTAC review. Minor format changes. Updated Background, References, and Websites.
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Reviewed	08/19/2010	MPTAC review. Updated Rationale, Background, Coding, and References. Added Websites for Additional Information.
Reviewed	08/27/2009	MPTAC review. Updated Rationale, Background, References, and Index.
New	08/28/2008	MPTAC review. Initial document development.
