Arthroereisis and Subtalar Implants

Policy MP-079

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Flatfoot (hyperpronation and flattening-out of the longitudinal arch); also known as pes planus or pes planovalgus) is a common deformity among children and adults. Having flat feet means that all of the foot touches the ground, there is no space between the middle of the foot — the arch — and the ground. Another cause of flatfoot can be attributed to posterior tibial tendon dysfunction. Talotarsal joint dislocation causes the middle of the foot to roll inward during walking. The joint between the talus and calcaneus is called the subtalar joint. These deformities can worsen with time causing soft tissues of the foot arch to stretch or tear and become inflamed. Various surgical techniques of subtalar joint arthroereisis have been used in the treatment of patients who have failed conservative approaches. One technique uses a small piece of metal that is screwed into the naturally occurring small channel between the ankle bone and the heel bone to restrict the movement of the subtalar joint. The implant keeps the subtalar joint from moving too much. Some surgeons use bone blocks and bond grafts placed into the sinus tarsi to limit excessive subtalar joint pronation. Others advocate the use of endoprosthetic devices.

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Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans considers subtalar implants experimental and investigational for the treatment of talipes equinovarus deformity (club foot), and flatfoot deformity including congenital and adult-onset (acquired) flatfoot deformity (also known as posterior tibial tendon dysfunction) because their clinical value in the management of these conditions has not been established.

Excluded devices include and are not limited to the following:

- Arthrex ProStop Plus™ (Arthrex, Naples, FL)
- Talex™ Arthroereisis Implant Talus (Vilex, LLC.)
- HyProCure® Subtalar Implant System (Graham Medical Technologies)
- Kalix II
- Life Spine® Subtalar Implant System (Tarsa-Link™)
- Lundeen Subtalar Implant (LSI)
- MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ)
- MBAResorb Implant
- Normed Vario Subtalar Screw
- NuGait ™ Subtalar Implant System
- Osteomed Talar-Fit™
- Sub-Talar Lok™ (Instrateck ™ Inc.)
- Subtalar Peg Implant (Nexa Orthopedics, Inc.)
- SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France)
- TARSA-LINK™ Stand-Alone Wedge Fixation System (Centric Medical)
- Trilliant Surgical Subtalar Implant
- Twist Subtalar Implant
- Wright Medical Smith STA-Peg

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

A 2021 systematic review (Smith et al.) reported on a database search for outcomes of arthroereisis for the treatment of symptomatic pediatric flexible pes planus. The authors found 24 articles that met criteria, which were primarily case series, with 6 comparative studies for a total of 2550 feet operated

on. Postoperative patient-reported outcome measures recorded marked improvement. Patient satisfaction was reported as excellent in 79.9%, and poor in 5.3%. All radiological measurements demonstrated improvement towards the normal range following arthroereisis, as did hindfoot valgus, supination, dorsiflexion and Viladot grade. Complications were reported in 7.1% of cases, with a reoperation rate of 3.1%. Arthroereisis as a treatment for symptomatic pediatric flexible pes planus produces favorable outcomes and high patient satisfaction rates with a reasonable risk profile. The average age at the time of surgery was 11.62 years (range 5–17years), 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. Compared to arthroereisis, 'established' surgical procedures for flexible pes planus are not without risk either, they include more complicated, lengthier interventions and have a longer rehabilitation period. With increasing development and use of resorbable implants, the need for a second procedure to remove the implant, and the pain attributed to it in some cases, should hopefully be negated. Limitations to this review include the lack of high-quality prospective studies, a paucity of long-term data and heterogeneity of utilized outcome measures between studies. In conclusion, the authors found that arthroereisis as a treatment for symptomatic pediatric flexible pes planus demonstrated favorable outcomes and high patient satisfaction rates with a moderate risk profile. Nevertheless, further more robust studies are needed to truly evaluate whether arthroereisis is an effective treatment for symptomatic pediatric flexible pes planus.

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a 2021 systematic review and meta-analysis (Tan et al) analyzed 17 publications reporting on procedures done on 1536 feet. The average duration of follow-up for the studies included in the review was noted as 43.52 months, long-term efficacy of this procedure was not addressed. 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 (STA) 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. 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 and the other individuals with this inflammation were treated with conservative measures. In conclusion, the authors found that STA resulted in both pain relief as well as correction of the underlying pes planovalgus deformity and that the procedure leads to a significantly increased number of positive short- to mid-term outcomes. However, with current knowledge still in its infancy, larger scale studies are needed to confirm the results proposed in the review.

A 2022 systematic review (Smolle et al) analyzed follow-up studies of surgically treated pediatric patients with symptomatic flexible flatfoot (FFF). Although pediatric FFF is a common condition, there

are only a minority of patients that become symptomatic. A PubMed search found original articles published up to July 2021 on the outcome of children aged 6 to 14 with surgically treated FFF and minimum follow-up of at least 4 years. Radiographic and clinical outcomes were analyzed. Of initially 541 entries, 10 could be included in the systematic review, involving 846 pediatric patients with 1,536 symptomatic FFF. Pooled mean radiological (n = 8) and clinical follow-up (n = 10) was 5.3 (range of 0.5 to 15) and 7.0 (range of 4.1 to 15) years, respectively. Surgical procedures included arthroereisis (n = 8), lateral column lengthening (n = 1), and Horseman procedure (n = 1). Overall relative frequency of implant-associated complications and wound-healing problems was 3.2% and 1.3%, as well as 2.8% and 1.6% following subtalar arthroereisis (STA) only. From pre-operative to latest radiological assessment following STA, pooled median decrease in TN coverage angle (TNCA; -9.2°), AP talocalcaneal angle (A-TCA; -6.5°), lateral talocalcaneal angle (L-TCA; -3.5°), talar declination angle (TDA; -14°), Moreau Costa Bertani angle (MCB; -13°), and talo-firstmetatarsal angle (L-T1MA; -10°) was observed, as was an increase in calcaneal pitch (4.5°). The review had several drawbacks such as having all studies meeting the defined inclusion criteria, 3 different surgical procedures were included in this review, with 8 of 10 studies reporting on outcomes following STA, information on clinical and radiological parameters were inconsistently reported by individual studies, and a considerable diversity of participants were included. In conclusion, the authors found that children with symptomatic FFF, who are refractory to conservative treatment, having surgical therapy was associated with a manageable complication profile and eventually resulted in satisfactory long-term clinical as well as radiological outcomes. Even though there are clear correlations between clinical and radiological outcomes following surgery for pediatric FFF, the current pooled results point towards concordant overall improvement in radiological and clinical parameters by surgical therapy. The evidence of studies included herein was low, few provided patient-reported outcome measures and long-term results on definite bony corrections are still missing. Therefore, more homogeneous patient cohorts are needed, allowing for distinct conclusions to be drawn in symptomatic pediatric FFF comparing different therapeutic approaches.

A 2017 comparison study (Wen et al) reviewed the mid-term efficacy of both non-fusion subtalar arthroereisis using a subtalar joint stabilizer (SJS) and Dennyson-Fulford subtalar arthrodesis (D-FSA). The study included 26 children with cerebral palsy and spastic flatfoot (FF), who were surgically treated from January 2011 to December 2014, using the AOFAS and hindfoot (AOFAS-AH) scores of the anteroposterior–talocalcaneal angles (ATAs) and the lateral talar-first metatarsal angles (Meary angles) of the affected foot both pre-and postoperative. Follow-up occurred in the SJS group (n12) for up to 48 months and in the D-FSA group for up to 60 months. One drawback of the study was that the follow-up time was relatively short, therefore, long-term status of the foot line could not be provided. The authors concluded that both procedures had no significant differences in improvement degrees of the AOFAS-AH functional scores, ATAs, and Meary angles, indicating similar outcomes for spastic FF. However, further follow-up studies are needed to gather more detailed data.

A 2020 midterm assessment (Bernasconi et al.) reviewed subtalar arthroereisis for correction of FFF in children. The authors hypothesized that (1) STA provided significant radiographic correction of low longitudinal arch and forefoot abduction in paediatric FFF and that (2) mid-term clinical outcomes were satisfactory and comparable to a normal population. A retrospective comparative study was performed of paediatric patients with symptomatic FFF who underwent STA between 2012 and 2015. Multiple measurements on preoperative and latest follow-up radiographs were recorded by two observers and compared to assess for correction of the FFF. Intra- and inter-observer reliability was also assessed. Ankle and hindfoot range of motion (ROM), AOFAS hindfoot score and VAS-FA score were compared with controls without foot symptoms or deformity. From 70 consecutive feet, 62 (31 patients) treated at 10.5 years of age were identified and compared to 48 controls (24 patients). Mean follow-up was 62

months. Intra- and inter-observer reliability was excellent for all angles (range, 0.81-0.97). Radiographic measurements demonstrated significant improvement after surgery (p<0.001) but significance was not reached in talonavicular coverage angle (p=0.49) and calcaneo-fifth metatarsal angle (p=0.53) on dorsoplantar view. At latest follow-up, patients had less hindfoot inversion than controls (15.1° vs. 19.3°, p=0.03), lower AOFAS scores (94.1 vs. 99.6 points, p=0.01), due to pain (p=0.01) and alignment (p=0.006) subscores. Using the VAS-FA score, patients were found to demonstrate higher pain at rest (p range, 0.02-0.03) and during activity (p=0.009) and felt limited when standing on one leg (p range, 0.01-0.03) and running (p=0.04). No loss of correction was found after removal of the implant. This study demonstrated that STA corrected the low longitudinal arch in symptomatic pediatric FFF but did not correct forefoot abduction in relation to the hindfoot. Mid-term assessment revealed STA provided satisfactory ankle and hindfoot ROM, pain and function levels, but limitations are witnessed compared to unaffected individuals. The limitations of the study included the limited sample size, the retrospective design meant no pre-operative clinical scores were available, the evaluation of STA could have been ideally performed against children treated conservatively as a control group, and finally results from a single-surgeon cohort, as those reported here, may be not always generalizable across different centers. Although we concluded this aspect allowed us to assess a more homogeneous group of patients, we advocate multicentric prospective studies to highlight potential differences among surgeons. We feel these findings show SA corrected the low longitudinal arch in symptomatic pediatric FFF, but did not correct fore-foot abduction in relation to the hind-foot. Mid-term assessment revealed SA provided satisfactory ankle and hind-foot ROM, pain and function levels, but limitations were witnessed compared to unaffected individuals. These researchers felt this aspect should be considered when counselling patients and their parents or care-givers to allow for realistic expectations.

A 2020 prospective randomized controlled trial (Ahmed et al) evaluated and compared the effectiveness of STA and lateral column lengthening in the correction of symptomatic flexible pes planovalgus (PPV) in ambulatory cerebral palsy (CP) patients. The study enrolled 35 patients aged 5–12 years that included 57 feet. Patients were divided into 2 groups: group 1, subtalar arthroereisis group (n=28); group 2, lateral column lengthening group (n=29). The primary outcomes assessed the improvement in clinical outcomes, forefoot abduction and hindfoot valgus. The secondary outcome assessed patient/parent satisfaction and tolerance to brace or shoes which were assessed 12 months after surgery. Patients were assessed clinically and radiologically, both preoperatively and 12 months postoperatively. The follow-up period ranged from 12 to 22 months (average 15.6 months). There was a statistically significant improvement in all outcomes parameters after both procedures when compared to the preoperative parameters. No statistically significant differences were observed between the two groups regarding the outcomes of both procedures except arthroereisis was statistically significant both clinically and radiographically (p=0.026) in the correction of hindfoot valgus. Limitations of this study included the small patient population and short term follow-up. The authors concluded that both procedures are valid options for the surgical management of PPV in ambulatory children with spastic CP. However, further, more robust investigation and long-term outcome studies are needed to demonstrate the efficacy and safety of arthroereisis.

A 2021 retrospective comparative study (Silva et al) reviewed the results of 72 subjects with adult-acquired flatfoot deformity treated with either lateral column lengthening (n=41) or subtalar arthroereisis (n=31). The authors indicated that both groups demonstrated significant improvement in all their clinical and radiological outcome measures at 6 months and 24 months, except for SF36 mental function score. The column lengthening group had significantly better results on midfoot 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 (STA) 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 STA 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. In conclusion, the authors found that lateral column lengthening demonstrated superior outcome scores and lower complication rates at 24 months when compared to STA.

A2021 retrospective single center cohort study (Vogt et al.) reviewed various techniques that were used by either applying expandable sinus tarsi implants or lateral calcaneus stop screws, using three different implants. Studies comparing the outcome of STA with different devices are rare. . 113 STA were performed in 73 consecutive patients (28 females). Mean age at surgery was 10.8 years (range 5–16). Mean follow-up was 29.0 months (range 1–111). In 21 feet the nonabsorbable Kalix® endorthesis and in 56 feet the absorbable Giannini endorthesis were applied. Subtalar extra-articular screw arthroereises (SESA) was conducted in 36 feet. Clinical, radiographic and pedobarographic parameters were analyzed. No intraoperative complications were observed. All three procedures achieved comparable improvements of the clinical, radiographic and pedobarographic parameters. The mean foot function index (FFI) improved from 36.4 (range 12–63) to 22.8 (range 2–55). The mean preoperative calcaneal inclination angle and the lateral talocalcaneal angle improved from 9.5° (range 0–22) and 42.3° (range 21–62) to 12.8° (range 0–26) and 37.6° (range 1556), respectively. Pedobarographically determined values of the arch index, the medial midfoot contact area and the medial forefoot peak pressure decreased. In contrast to SESA (1/36, 3%), a higher incidence of implant-related complications was observed using Kalix® (6/21, 29%) and Giannini (10/56, 8%) sinus tarsi implants. Peroneal muscle contractures only occurred in the SESA group (4/36, 11%). Premature removal due to treatment-related complications was necessary in 6/21 Kalix® implants (29%), 4/56 Giannini implants (7%) and 4/36 SESA implants (11%). Implant choice for treatment of painful FFF in children with STA seems to play a subordinate role. Clinical, radiographic and pedobarographic outcomes are comparable between the applied implants. Surgeons and patients should be aware of the different spectrum of implant-related complications. Treatment can be reliably monitored by radiation-free pedobarography providing dynamic information about the deformity. The authors concluded that this study does not provide a control group to compare the outcome with the natural development of pediatric foot shape over time. Further prospective randomized trials are needed to compare the benefits and disadvantages of the available implants with a long-term follow-up.

In 2022, Wang et al conducted a retrospective study and reviewed the mid-term outcomes of subtalar arthroereisis (STA) using Talar-Fit implant for the treatment of flexible flatfoot (FFF) patients; compared clinical and radiographic outcomes between arthroereisis with and without adjunctive operative procedures to examine the effects of adjuncts on the outcomes; and analyzed the risk factors associated with sinus tarsi pain, which is the most common post-operative complication of arthroereisis. A total of 31 FFF children and adolescents (46 feet) treated with STA using Talar-Fit implant from June 2014 to May 2019 were analyzed. The feet were divided into 4 treatment groups; arthroereisis alone, arthroereisis with gastrocnemius recession, arthroereisis with Kidner procedure, and arthroereisis with gastrocnemius recession and Kidner procedure. Clinical function was evaluated based on the AOFAS (American Orthopaedic Foot and Ankle Society) ankle and hind-foot score. The following angles were measured for radiographic evaluation: talar-first metatarsal angle, calcaneal pitch angle, and talar declination angle on the lateral view; and talar-first metatarsal angle, talocalcaneal angle, and antero-posterior (AP) talonavicular coverage angle on the AP view. The paired Student's t-test was used to compare the pre- and post-operative angular measurements and AOFAS scores. The Wilcoxon rank-sum

test was performed to determine the outcome differences among the 4 treatment groups. Multi-variate logistic regression analysis was used to analyze risk factors for sinus tarsi pain; a "p" value of < 0.05 was considered statistically significant. The mean follow-up of the feet was 32.8 months (range of 10 to 71 months). The mean AOFAS score significantly improved from 55.5 ± 14.5 pre-operatively to 86.3 ± 9.9 ($p < 0.001$). Comparison of radiographic outcomes showed that the lateral talar-first metatarsal angle decreased by a mean of 19.1° ± 11.9° ($p < 0.001$), the calcaneal pitch angle increased by a mean of 5.4° ± 3.4° ($p < 0.001$), the talar declination angle decreased by a mean of 14.8° ± 9.9° ($p < 0.001$), the AP talar-first metatarsal angle decreased by a mean of 15.6° ± 10.3° ($p < 0.001$), the AP talocalcaneal angle decreased by a mean of 7.2° ± 8.3° ($p = 0.001$), and the AP talonavicular coverage angle decreased by a mean of 20.4° ± 9.0° ($p < 0.001$). There were no statistically significant differences with regard to AOFAS score and all angle measurements on both the AP and lateral views among the 4 treatment groups. There was 1 dislocation case caused by a fall 6 weeks after surgery, which was treated non-operatively. The incidence of sinus tarsi pain was 13% and logistic regression analysis indicated that patients with a longer distance from the tail end of the implant to the lateral calcaneal wall had 38.8% greater odds of developing sinus tarsi pain. This study had several limitations including the fact that it was retrospective and may be biased, the evaluation of STA could have been compared with patients treated with non-operative methods, this trial lacked a control group, the researchers only had a small number of feet in each treatment group and finally aside from the factors in their logistic regression model, there may be other significate factors such as the shape and material type of the implant. In conclusion, findings of this study indicated that the mid-term clinical and radiographic results were satisfactory in patients who underwent STA using Talar-Fit implant, alone or in combination with other adjuncts, for the treatment of FFF. Also, the implant position was associated with post-operative sinus tarsi pain. Therefore, further prospective RCTs are needed to confirm these findings.

A 2022 retrospective, cohort study (Bernasconi et al) looked to determine whether STA, as an adjunct procedure, improved radiographic correction of stage IIb adult-acquired flexible flatfoot deformity (AAFD) and then evaluate the STA-related complication rate. The study analyzed 22 feet (21 patients) diagnosed with stage IIb AAFD treated by medializing calcaneal osteotomy (MCO), flexor digitorum longus (FDL) transfer, spring ligament (SL) repair with or without Cotton osteotomy and with or without STA in a single center. A total of 7 measurements were recorded on pre- and post-operative (minimum of 24 weeks) radiographs by 2 observers and repeated twice by 1 observer. Inter- and intra-observer reliabilities were assessed. The association of demographic (gender, side, age, body mass index [BMI]) and surgical variables (Cotton, STA) with radiographic change was tested with univariate analysis followed by a multi-variable regression model. Excellent inter- and intra-observer reliabilities were demonstrated for all measurements (intra-class correlation coefficient [ICC], range of 0.75 to 0.99). Gender, side, Cotton osteotomy, and STA were included in the multi-variable analysis. Regression showed that STA was the only predictor of change in TNCA ($R2 = 0.31$; $p = 0.03$) and in calcaneo-fifth metatarsal angle (CFMA) ($R2 = 0.40$; $p = 0.02$) on dorsoplantar view. STA was associated to a greater change in TNCA by 10.1° and in CFMA by 5°; 4 patients out of 12 STA complained of sinus tarsi pain after STA, and removal of the implant resolved symptoms in 3 of them. In conclusion, the authors found that in this series, STA as an adjunct procedure to MCO, FDL transfer, SL repair in the treatment of stage IIb AAFD led to improvement in correction of forefoot abduction and that STA-related complication and removal rates were 33%. However, further comparative and randomized studies with larger cohorts are needed to confirm these findings.

Another study from 2022 was a non-randomized comparative trial (Eysel et al) comparing 18 adolescent subjects with 25 symptomatic flexible flat feet (7 bilateral and 11 unilateral) treated with subtalar arthroereisis and 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. A few drawbacks of the study included all of the AOFAS questionnaires were answered at different time points (0.4-8 years) after surgery, the time point of follow-up examinations varied considerably, some participants were treated bilaterally and others unilaterally and the control data differed in age and weight. The authors concluded that, “subtalar arthroereisis was able to effectively treat symptomatic flexible flatfeet in this population.” However, further more robust studies are needed to demonstrate the efficacy of subtalar arthroereisis.

In a 2023 prospective 3-year follow-up study, Alund found that "Subtalar arthroereisis seems to be effective in the treatment of Progressive Collapsing Foot Deformity, both as a standalone and an adjunctive procedure. In either case, careful patient selection is needed. When performed in a non-obese patient with a functionally intact PT tendon and a stable medial column, a standalone subtalar arthroereisis may achieve good subjective and functional results from a mid-term perspective. In all other cases, the implant alone will most likely not do the job in terms of maintaining hind- and midfoot balance. If medial column instability is not taken care of, the demands on the sinus tarsi implant will simply be too great. Consequently, the implant fails to keep the arch up, and adjunctive procedures must be performed. More studies need to be conducted in order to further outline the proper technique and correct sizing of the implant. Both are critical for the maintenance of the correction initially achieved and for long-term patient tolerance."

A 2024 study (Sabry and Dreyer) noted that “a 2015 web-based survey revealed surprising data indicating that 33% of American Orthopedic Foot and Ankle Society members who had previously conducted subtalar arthroereisis opted to discontinue the procedure due to its high failure rate and the need for implant removal."

In 2023, Hayes reviewed their health technology assessment on subtalar arthroereisis (SA) for the treatment of adult-acquired flatfoot deformity. The authors concluded that “an overall very-low-quality body of evidence is insufficient to conclude that SA is safe and efficacious for treating AAFD in patients with pain, decreased function, and other symptoms that are refractory to standard medical therapies. The majority of studies are retrospective, and no well-designed, controlled studies are available to compare SA with other surgical procedures. Overall, substantial heterogeneity exists in patient samples, surgical approaches, implant devices, and concomitant procedures. Clinical outcome measures varied from validated questionnaires and scales to patient-reported, subjective results (e.g., patient satisfaction with SA). There is a need for additional well-designed clinical studies to evaluate the long-term efficacy and safety of SA and delineate patient selection criteria”.

Also in 2023, Hayes reviewed their health technology assessment on SA for the treatment of pediatric flatfoot (FF). The authors concluded that “An overall low-quality body of evidence suggests that SA is relatively safe and efficacious for treating idiopathic flexible FF in children with pain, decreased function,

and other symptoms that are refractory to standard medical therapies. However, the majority of studies are retrospective, there are few comparative studies, and no well-designed controlled studies to draw firm conclusions regarding its efficacy and safety. For children with spastic FF, there is a paucity of evidence and the overall quality of the body of evidence is very low. Indications were consistent in studies of idiopathic or spastic FF, but overall substantial heterogeneity exists in surgical approaches, implant devices, and concomitant procedures. Clinical outcome measures varied from validated questionnaires and scales to patient-reported, subjective results (e.g., patient satisfaction with SA). There is a need for additional well-designed clinical studies to evaluate the long-term efficacy and safety of SA and to delineate patient selection criteria".

The American College of Foot and Ankle Surgeons (ACFAS) published a consensus statement in 2020 on the appropriate clinical management of adult-acquired flatfoot deformity (AAFD) also referred to as posterior tibial tendon dysfunction (Piraino et al). The consensus statement noted that subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD and there is limited literature demonstrating the use of a subtalar implant alone to address pronation of the foot in type IIa deformity. Therefore, neither of these are appropriate or inappropriate. The ACFAS also stated that the most identified complication is sinus tarsi pain due to presence of the implant; explantation resolves the pain.

The ACFAS' 2004 guideline on pediatric flatfoot (Harris et al) states "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."

In 2009, NICE (National Institute for Clinical Excellence) provided guidance for interventional procedures on sinus tarsi implant insertion for mobile flatfoot. NICE determined that "Current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit, or research".

Applicable Coding

CPT Codes

Not Covered

0335T Insertion of sinus tarsi implant

0510T Removal of sinus tarsi implant

0511T Removal and reinsertion of sinus tarsi implant

HCPCS Codes

Not Covered

S2117 Arthroereisis, subtalar

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