Subtalar Arthroereisis

Medical Policy #: 07.01.34
Original Effective Date: December 2006
Reviewed: July 2022
Revised: July 2022

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

This policy only applies to subtalar arthroereisis (sinus tarsi implant or stent) surgery.

- Arthroereisis is a surgical procedure that limits movement across a joint. Subtalar arthroereisis also called extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint.
- The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Arthrodesis describes a surgical fusion of a joint so that the bones grow together. Subtalar arthrodesis (joint fusion) surgery is not addressed in this policy.

Clinically Valid

The technology must detect presence or absence of a condition (flat foot), the risk of developing a condition in the future or treatment response (beneficial or adverse).

Clinically Useful
A procedure is clinically useful if it improves the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Flat Foot
Flatfoot (also known as pes planus) is often a complex disorder, with diverse symptoms and varying degrees of deformity and disability. Common characteristics of flatfoot are a partial or total collapse of the arch.

Flexible flatfoot is a common disorder, anatomically described as excessive pronation during weight-bearing due to anterior and medial displacement of the talus. It may be congenital, or it may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, inflammatory disorders, and other factors. Symptoms include dull, aching and throbbing, cramping pain, which in children may be described as growing pains. Additional symptoms include refusal to participate in athletics or walking long distances. Conservative treatments include orthotics or shoe modifications, stretching exercises and medication. Various surgical techniques of subtalar arthroereisis have been used in the treatment of individuals who have failed conservative treatment.

Arthroereisis is the limitation of excessive movement across the joint. Subtalar arthroereisis is 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 for a number of years, with a variety of implant designs and compositions. The value of subtalar arthroereisis in the management and treatment of flatfoot deformity has not been established.

Populations
The relevant population of interest is individuals with flatfoot.

Interventions
The therapy being considered is subtalar arthroereisis (also called extraosseous talotarsal stabilization).

Comparators
Conservative treatments include over the counter (OTC) and prescription drug therapy, physical therapy, orthotics, or shoe modifications. Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis.

Outcomes
The outcomes of interest are symptoms, functional outcomes, and quality of life. The average length of follow-up was 18 to 24 months.

Review of Evidence: Flat Foot: Adults
(2022) Hayes Inc. completed a Health Technology Assessment on subtalar arthroereisis for the treatment of adult populations with flatfoot noting the overall current evidence is very low. There is a need for more well-designed studies to review the long-term benefit and safety criteria as well as to decipher selection criteria.

(2012) Graham et al. published a case series that was not confounded by adjunctive procedures and had a relatively long follow-up This study reported mean 51-month follow-up of talotarsal stabilization in 117 feet using the HyProCure device. Patients who received adjunctive procedures affecting the talotarsal joint were excluded from analysis. Adults who met the inclusion and exclusion criteria were invited to participate in the study. Eighty-three patients gave consent to participate, and 78 completed the Maryland Foot Score Questionnaire. Five patients did not complete the questionnaire because they had 7 (6%) implants removed. There were 16 revision surgeries with HyProCure. Nine of the surgeries called for the repositioning of a partially displaced device, or a change in the size of the device altogether. Of the patients who retained the device, 52% reported complete alleviation of foot pain, 69% had no limitations in their foot functional abilities, and 80% reported complete satisfaction with the appearance of their feet. This case series is notable for its assessment of functional outcomes at medium-term follow-up in patients who did not have adjunct procedures.

Review of Evidence: Flat Foot: Pediatric
(2022) Hayes Inc. completed a Health Technology Assessment on subtalar arthroereisis for the treatment of the pediatric populations with flatfoot noting the overall current evidence is very low. There is a need for more well-designed studies to review the long-term benefit and safety criteria as well as to decipher selection criteria.

(2021) Smith et al. completed a systematic review with a database search for outcomes of arthroereisis for the treatment of symptomatic pediatric flexible pes planus provided 24 articles which were included in this review, with a total of 2550 feet operated on. Post-operative 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. There is still a great deal of negativity and literature highlighting the complications and failures of arthroereisis, especially for older implants. The biggest flaws in the collective literature are the lack of high-quality prospective studies, a paucity of long-term data and the heterogeneity of utilized outcome measures between studies. The authors concluded the review found that arthroereisis as a treatment for symptomatic pediatric flexible pes planus produces favorable outcomes and high patient satisfaction rates with a reasonable risk profile. The studies included in this review are primarily case series, with six comparative studies. 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. There is still a great deal of negativity and literature highlighting the complications and failures of arthroereisis, especially for older implants. Compared to arthroereisis, 'established' surgical procedures for flexible pes planus are not without risk either, 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. The biggest flaws in the collective literature are the lack of high-quality prospective studies, a paucity of long-term data and heterogeneity of utilized outcome measures between studies. These factors need to be addressed to truly evaluate whether arthroereisis is an effective treatment for symptomatic pediatric flexible pes planus.

(2021) Vogt et al. completed a review which noted, various techniques were described either applying expandable sinus tarsi implants or lateral calcaneus stop screws. Studies comparing the outcome of STA with different devices are rare. This retrospective single-center cohort study analyzes the results of STA using three different implants. 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 non-absorbable Kalix® endorthesis and in 56 feet the absorbable Giannini endorthesis were applied. Subtalar extraarticular 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 15–56), 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 author's concluded independent of the type of implant, STA is a reliable surgical treatment for symptomatic FFF in children relieving pain and correcting deformity by dynamic and proprioceptive mechanisms. In contrast to two-dimensional and static radiographs, pedobarography provides additional dynamic information about the deformity and helps to monitor the outcome of STA. Complications related to STA are

rare. Painful peroneal muscle contracture seems to be a SESA-specific functional complication while implant-related complications occur more frequently during treatment with sinus tarsi implants. Surgeons should be aware of the different spectrum of complications when counseling patients about STA. Since all three procedures achieved comparable improvements of the outcome measurements, implant choice for treatment of painful FFF in children with STA seems to play a subordinate role and should be left to the preference of the surgeon.

This review also has several limitations due to its retrospective character and is biased by different cohort sizes, availability of the implants and uneven distribution of the etiologies. Patients were only included until 2013 since due to logistic reason pedobarographic analysis was inconsistently available after 2013. STA implants were used consecutively due to their availability and not during the same period. Time related parameters such as the surgeon's expertise, evolution of implants and improved outcome measures with time might limit comparability of the studied cohorts. The statistical findings of this study should carefully be interpreted. We encourage readers to focus more on the clinical, radiographic and pedobarographic outcomes, rather than statistical comparisons and p-values. The fact that some patients were treated bilaterally, and others unilaterally can limit comparability. Some statistical findings might not be applicable to every patient group. Most patients were immature at the time of implant removal or last follow-up and the study lacks long-term observation after treatment focusing on maintenance of the correction and occurrence of recurrent deformity. Furthermore, this study does not provide a control group to compare the outcome with the natural development of pediatric foot shape over time. Prospective randomized trials are needed to compare the benefits and disadvantages of the available implants with a long-term follow-up.

(2020) Bernasconi et al. completed a midterm assessment of subtalar arthroereisis for correction of flexible flatfeet in children. We 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 (prange, 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.

The authors reported this study showed 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. This aspect should be considered when counselling patients and their parents or caregivers to allow for realistic expectations. The author's also reported limitations. First, the limited sample size. Nonetheless our power analysis suggested the study was sufficiently robust to support the conclusions reached. Secondly, the retrospective design meant no pre-operative clinical scores were available, however the clinical improvement associated with radiographic correction has been successfully documented by other study groups [7,8,11–13] and was not among the aims of our work. Thirdly, the evaluation of STA could have been ideally performed against children treated conservatively as a control group. While agreeing with this concept, we also believe that a comparison with a healthy population provided useful insights to judge the procedure. Fourthly, results from a single-surgeon cohort, as those reported here, may be not always generalizable across different centers. Although we reckon that this aspect allowed us to assess a more homogeneous group of patients, we advocate multicentric prospective studies to highlight potential differences among surgeons.

(2011) Metcalfe et al. published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot. Seventy-six case series (none controlled) or case reports were identified. Ten of the studies (756 feet) provided a clinician-based assessment of the surgical result graded from "excellent to poor" with follow-up between 36 and 240 months. Six studies (212 feet) included estimates of overall patient satisfaction using nonvalidated outcome measures, while 1 study (16 feet) found significant improvement using a validated foot-specific patient outcome measure. Data from 15 studies that reported radiographic values were combined for analysis. Although 8 of 9 radiographic parameters showed statistically significant improvements following arthroereisis procedures, the relation between radiographic and clinical outcomes is uncertain. The procedure was associated with several complications including sinus tarsi pain, device extrusion, and under correction. Complication rates ranged from 4.8% to 18.6%, with unplanned removal rates between 7.1% and 19.3% across all device types. The influence of adjunctive procedures on outcomes was not addressed in this review.

Summary of Evidence: Flat Foot

Currently, updated guidelines and randomized high-quality studies are lacking. There are a few comparative and no randomized, prospective controlled studies that evaluate the safety and efficacy of subtalar arthroereisis in combination with other surgical procedures. The overall quality of the body of evidence is very low. Limitations of the published data is the lack of long-term outcomes, particularly important since the

procedure is often performed in growing children, and the difficulty in separating the effect of this procedure from that of other adjunctive treatments. In addition, some publications report high rates of complications and implant removal. There is a lack of consistency with conservative treatments in the available literature where efficacy is shown with the subtalar arthroereisis procedure. Defining the true treatment population in the treatment of childhood and adult flatfoot lack a clear consensus. The evidence on the use of subtalar arthroereisis for treatment of flat foot in the adult and pediatric populations is insufficient to determine that the technology results in an improvement in the net health outcomes.

Talotarsal Joint Dislocation
Talotarsal joint dislocation means that the joint surfaces of the talus are abnormally aligned on the heel and/or navicular bones. The purpose of subtalar arthroereisis in individuals who have talotarsal joint dislocation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with talotarsal joint dislocation.

Interventions
The therapy being considered is subtalar arthroereisis.

Comparators
Alternative surgical approaches for talotarsal joint dislocation.

Outcomes
The outcomes of interest are symptoms, functional outcomes, and quality of life. The follow-up was up to one year.

Review of Evidence
(2013) Bresnahan et al. reported on a prospective study of talotarsal stabilization using HyProCure in 46 feet of 35 patients diagnosed with recurrent and/or partial talotarsal joint dislocation. No procedures besides insertion of the HyProCure device were performed to address the talotarsal joint dislocation. At 1 year postoperatively, scores on the Maryland Foot Score (on a score out of 100) for 30 patients had improved from 69.53 preoperatively to 89.17 postoperatively. Foot pain decreased by 37.0%, foot functional activities improved by 14.4%, and foot appearance improved by 29.5%. Implants were removed from 2 feet with no unresolved complications.

Summary of Evidence: Talotarsal Joint Dislocation
Currently there are not published control trials comparing talotarsal stabilization with extra-osseous subtalar joint implant and nonsurgical treatment or alternative surgical techniques. Although improvements in pain and function were observed, the current evidence on the use of subtalar arthroereisis for treatment of talotarsal joint dislocation is

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

Practice Guidelines and Positions Statements
American College of Foot and Ankle Surgeons (ACFAS)

- (2020) The ACFAS published a consensus statement on the appropriate clinical management of *adult-acquired flatfoot deformity (AAFD)*. The consensus statement stated the following is neither appropriate nor inappropriate:
    - Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD. There is limited literature demonstrating the use of a subtalar implant alone to address pronation of the foot in type IIa deformity. The ACFAS also stated that the most identified complication is sinus tarsi pain due to presence of the implant; explanation resolves the pain. (*Accessed June 2022*)
- (2004) The ACFAS guideline on *pediatric flatfoot* 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." (*Accessed June 2022*)

National Institute for Clinical Excellence (NICE)
(2009) Guidance from the National Institute for Clinical Excellence concluded provided an interventional procedures guidance on sinus tarsi implant insertion for mobile flatfoot which stated:

- 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. (*Accessed June 2022*)

Regulatory Status
Several implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and are summarized /listed below. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Other subtalar implants include but are not limited to:

- Arthrex Prostop and Arthrex Prostop Plus Subtalar Arthroereisis Implant
- Bioarch Subtalar Arthroereisis Implant
- BioBLOCK Resorbable Subtalar Implant
- BioPro Horizon Subtalar Implant
- Conical Subtalar Implant (CSI)
- Disco Subtalar Implant
- Futura Angled Subtalar Implant
- Futura Conical Subtalar Implant

- HyProCure Subtalar Implant System
- IFS Subtalar Implant
- Kalix II
- Life Spine Subtalar Implant System
- Lundeen Subtalar Implant
- Maxwell-Brancheau arthroereisis (MBA) Implant
- MBA Resorb Implant
- MetaSurg BioArch Subtalar Implant System
- Nexa Orthopedics Subtalar Peg
- Normed Vario Subtalar Screw
- NuGait ™ Subtalar Implant System
- OsteoMed Talar-Fit Subtalar Implant System
- OsteoSpring FootJack Subtalar Implant System
- Smith Subtalar Arthroereisis Implant
- SubFix Arthroereisis Implant
- Sub-Talar Lok Arthroereisis Subtalar Implant System
- Subtalar Maxwell-Brancheau Arthroereisis (MBA®) Implant System
- Talus of Vilex (TOV) Subtalar Implant
- Trilliant Surgical Subtalar Implant
- Twist Subtalar Implant

PRIOR APPROVAL

Not applicable.

POLICY

Subtalar arthroereisis/extra-osseous subtalar joint implant is considered **investigational** for all indications, as the evidence is insufficient in demonstrating an impact on improved net health outcomes.

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.

- 28899 unlisted procedure, foot or toes
- S2117 Arthroereisis, subtalar
- 0335T Insertion of sinus tarsi implant
- 0510T Removal of sinus tarsi implant
- 0511T Removal and reinsertion of sinus tarsi implant

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POLICY HISTORY		
Date	**Reason**	**Action**
July 2022	Annual Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Renewed
August 2015	Annual Review	Policy Revised
September 2014	Annual Review	Policy Revised
October 2013	Interim Review	Policy Revised
May 2013	Annual Review	Policy Renewed
May 2012	Annual Review	Policy Renewed
June 2011	Annual Review	Policy Revised

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

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