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Subtalar Arthroereisis (STA)

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
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Coverage

Subtalar arthroereisis (STA), e.g., subtalar implant or extraosseous talotarsal stabilization (EOTTS), **is considered experimental, investigational and/or unproven** for all indications.

NOTE: This policy does not address subtalar arthrodesis.

Policy Guidelines

- There are no specific CPT codes for subtalar arthroereisis.
- S2117 is the specific HCPCS code for subtalar arthroereisis.
- Effective January 1, 2014 category III code 0335T was created for the insertion of the HyProCure® device.
- Subtalar arthroereisis should not be coded as 28725, which describes joint fusion.
- Other arthrodesis or arthroscopy codes that should not be reported are: 28585, 28735, 28740, 29907.

Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Background

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The Maxwell-Brancheau Arthroereisis implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the Maxwell-Brancheau Arthroereisis implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

Regulatory Status

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, a sampling of which are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation. FDA Product Code: HWC.

Table 1. Representative Subtalar Implant Devices Cleared by the U.S. Food and Drug Administration[a]

Device	Manufacturer	Date Cleared	510(k) Number
Subtalar MBA®	Integra LifeSciences	07/96	K960692
OsteoMed Subtalar Implant System	OsteoMed	08/03	K031155
BioPro Subtalar Implant	BioPro	09/04	K041936
HyProCure Subtalar Implant System	Graham Medical Technologies	09/04	K042030
MBA Resorb Implant	Kinetikos Medical	09/05	K051611
Metasurg Subtalar Implant	Metasurg	05/07	K070441
Subtalar Implant	Biomet Sports Medicine	07/07	K071498
Arthrex ProStop Plus Arthroereisis Subtalar Implant	Arthrex	01/08	K071456

Trilliant Surgical Subtalar Implant	Trilliant Surgical	02/11	K103183
Metasurg Subtalar Implant	Metasurg	08/11	K111265
NuGait™ Subtalar Implant System	Ascension Orthopedic	08/11	K111799
Disco Subtalar Implant	Trilliant Surgical	12/11	K111834
OsteoSpring FootJack Subtalar Implant System	OsteoSpring Medical	12/11	K112658
IFS Subtalar Implant	Internal Fixation Systems	12/11	K113399
The Life Spine Subtalar Implant System	Life Spine	06/16	K160169

[a] FDA 510(k) database search product code HWC (03/08/18).

Rationale

This medical policy was created in 2005 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 17, 2022.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Subtalar Arthroereisis

Clinical Context and Therapy Purpose

The purpose of subtalar arthroereisis in patients who have flatfoot is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does subtalar arthroereisis improve the net health outcome in patients with flatfoot?

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

Populations

The relevant population(s) of interest is individuals with flatfoot.

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.

Interventions

The therapy being considered is subtalar arthroereisis.

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.

Comparators

Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Conservative treatments include orthotics or shoe modifications.

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Literature searches on subtalar arthroereisis have identified few published studies, primarily consisting of single-institution case series and individual case reports, reporting on success rates following this procedure. There is a small controlled trial that has compared subtalar arthroereisis with alternative treatments.

Nonrandomized Clinical Trial

Chong et al. (2015) reported on a small prospective nonrandomized trial that compared subtalar arthroereisis with lateral column calcaneal lengthening for the treatment of 24 painful flatfeet in children. (1) Seven children (13 feet) enrolled at a children's medical center were treated with arthroereisis and 8 children (11 feet) enrolled at another children's hospital were treated with lateral column lengthening. Children who underwent subtalar arthroereisis received a subdermal implant and were placed in below-knee walking casts for 3 weeks. Children treated with lateral column lengthening had an opening wedge osteotomy with the insertion of a wedge of cadaveric bone and were placed in non-weight-bearing casts for 1 month and "walker boots" for another month. Outcomes at a mean of 12.7 months after surgery included radiographs, foot pressure, kinematic analysis and the Oxford Ankle-Foot Questionnaire for Children. The two groups showed similar improvements in the lateral talo-first metatarsal angle and talonavicular coverage and kinematics. Both groups showed statistically significant lateralization of the hindfoot and midfoot center of pressure ($p<0.01$). There were no between-group differences for any clinical or functional outcomes. On within-group comparison, only the subtalar arthroereisis group had a statistically significant reduction in time on the hindfoot ($p=0.01$). Both groups had improvements in the parental and child scores on the Oxford questionnaire, but only the subtalar arthroereisis group had a statistically significant improvement in this small sample. There were 2 complications in each group, with the removal of the hardware in 1 patient and removal of the implant in 2 patients. The improvement in pain and foot position was retained following implant removal.

Case Series and Reports

Metcalfe et al. (2011) published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot. (2) 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 a number of 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 systematic review.

Graham et al. (2012) published a case series that was not confounded by adjunctive procedures and had a relatively long follow-up. (3) 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 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.

Other case series have generally not excluded the use of other adjunctive treatments. For example, Vedantam et al. (1998) reported on a series of 78 children (140 feet) with neuromuscular disease who underwent subtalar arthroereisis with a subtalar arthroereisis-peg. (4) The stem of this implant is placed into the calcaneus with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but five of the children had additional procedures to balance the foot. Satisfactory results were reported in 96.4% of patients, although the contribution of the subtalar arthroereisis-peg cannot be isolated. Nelson et al. (2004) reported on 37 patients (67 feet) who received a Maxwell-Brancheau Arthroereisis (MBA) implant and had an average of 18.4 months of follow-up. (5) While this study reported various improvements in anatomic measurements, there were no data on improvement in symptoms. In another series, Needleman (2006) reported significant improvements in pain and function in 78% of patients (23 patients, 28 feet) with use of a subtalar implant as a component of reconstructive foot and ankle surgery. (6) However, because results were not compared with controls receiving reconstructive surgery without STA, the contribution of the implants to these outcomes is unclear. Also, Needleman (2006) reported an overall complication rate of 46%, with surgical removal of 39% of the implants due to sinus tarsi pain; and that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al. (2008) reported on radiographic outcomes in a retrospective analysis of 28 feet in 20 pediatric patients treated with subtalar arthroereisis combined with gastrocnemius recession or with subtalar arthroereisis combined with gastrocnemius recession and medial column reconstruction. (7) Lucaccini et al. (2008) analyzed clinical and radiographic results of 14 patients (16 feet) with hallux valgus in abnormal pronation syndrome treated with distal osteotomy of the first metatarsal bone and subtalar arthroereisis performed in 1 stage. (8) Scharer et al. (2010) conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the Maxwell-Brancheau Arthroereisis implant to treat painful pediatric flatfoot deformities. (9) The patients' average age at the time of surgery was 12 years (range, 6-

16 years). Additional procedures included 12 (18%) gastrocnemius recessions, 6 (9%) Achilles tendon lengthening and 4 (6%) Kidner procedures. At an average 24-month follow-up (range, 6-61 months), there had been 10 (15%) complications requiring reoperation, including implant migration, undercorrection, overcorrection, and persistent pain. The implants were exchanged for a larger or a smaller implant. None of these case series permitted comparison with nonsurgical interventions or with other surgical interventions.

An example of a case series with longer follow-up is the retrospective study by Brancheau et al. (2012), which reported on a mean 36-month follow-up (range, 18-48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis implant with adjunct procedures. (10) The patients' mean age was 14.3 years (range, 5-46 years). Significant changes were observed in radiographic measures (talocalcaneal angle, calcaneocuboid angle, first to second intermetatarsal angle, calcaneal inclination angle, talar declination angle). Seventeen percent of patients reported that 9 (15%) implants were removed after the initial surgery. Of the 24 (68.6%) patients who answered a subjective questionnaire (in person or by telephone at a mean of 33 months postoperatively), 95.8% reported resolution of the chief presenting complaint, and 79.2% said they were 100% satisfied with their surgical outcome. The contribution of the MBA implant to these results cannot be determined by this study design.

Section Summary: Flatfoot

The evidence evaluating the use of subtalar arthroereisis for treatment of flatfoot consists mainly of single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis with lateral column calcaneal lengthening. The small nonrandomized comparative trial (N=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to subtalar arthroereisis, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of particular importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal.

Talotarsal Joint Dislocation

Clinical Context and Therapy Purpose

The purpose of subtalar arthroereisis in patients who have talotarsal joint dislocation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does subtalar arthroereisis improve the net health outcome in patients with talotarsal joint dislocation?

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

Populations

The relevant population(s) of interest is individuals with talotarsal joint dislocation.

Talotarsal joint dislocation means that the joint surfaces of the talus are abnormally aligned on the heel and/or navicular bones.

Interventions
The therapy being considered is subtalar arthroereisis.

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.

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.

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

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

Bresnahan et al. (2013) 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. (11) 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 89.27 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.

Section Summary: Talotarsal Joint Dislocation
The evidence evaluating the use of subtalar arthroeresis for treatment of talotarsal joint dislocation consists of one prospective single-arm study of talotarsal stabilization using HyProCure. Although improvement in pain and function were observed, the current evidence on the use of subtalar arthroereisis for treatment of talotarsal joint dislocation is insufficient to draw conclusions about treatment efficacy with certitude.

Adverse Events
Complications are frequently reported in the literature. Scher et al. (2007) reported on 2 cases of extensive implant reaction in 2 children 2 years after a subtalar arthroereisis-peg procedure. (12) Due to the commonly seen complication of severe postoperative pain with failure to reconstitute the longitudinal arch on weight-bearing and a residual flatfoot deformity, the authors do not recommend subtalar arthroereisis in the treatment of painful flatfoot in children. In a radiographic study, Saxena and Nguyen (2007) evaluated a bioabsorbable subtalar arthroereisis and found poor outcomes in 3 of 6 patients who met the inclusion criteria and consented to additional imaging. (13) Two patients requested implant removal; a third patient had persistent pain but refused explantation. Radiographic measurement (magnetic resonance imaging or computed tomography) found that these 3 patients had smaller tarsal canal widths than the diameter of the inserted interference screw. The authors noted that the implant length also had to be reduced before implantation.

Cook et al. (2011) conducted a retrospective case-control study to identify factors that might contribute to failure (explantation) of titanium arthroereisis implants. (14) All patients who required removal of a self-locking wedge-type subtalar arthroereisis (n=22) were compared in a 1:2 ratio (n=44) with patients with nonexplanted arthroereisis who were treated during the same period. Subjects were matched for preoperative radiographic measurements, age, sex, presenting diagnosis, and length of follow-up. Multivariate logistic regression showed no significant effect of age, sex, implant size, shape, length of follow-up, implant position, surgeon experience, or concomitant procedures. Patients who required explantation had slightly greater odds of radiographic undercorrection (odds ratio, 1.175) or residual transverse plane-dominant deformities (odds ratio, 1.096). The percentage of explantations in this retrospective analysis was not described.

Summary of Evidence
For individuals who have flatfoot who receive subtalar arthroereisis, the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing subtalar arthroereisis with lateral column calcaneal lengthening. Relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (n=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to subtalar arthroereisis, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have talotarsal joint dislocation who receive subtalar arthroereisis, the evidence consists of one prospective single-arm study of talotarsal stabilization using HyProCure. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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 draw conclusions about treatment efficacy with certitude. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines And Position Statements

National Institute for Health and Care Excellence (NICE)

Guidance from the NICE (2009) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot was inadequate in quality and quantity. (15)

American College of Foot and Ankle Surgeons

In 2004, the American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of pediatric and adult flatfoot (neither is included in the ACFAS library of current clinical practice guidelines). (16, 17)

The ACFAS guidelines on adult flatfoot have stated:
"In the adult, arthroereisis is seldom implemented as an isolated procedure. Because of the long-term compensation and adaptation of the foot and adjunctive structures for flatfoot function, other ancillary procedures are usually used for appropriate stabilization. Long-term results of arthroereisis in the adult flexible flatfoot patient have not been established. Some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly."

The ACFAS guidelines on pediatric flatfoot have stated:
"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."

Piraino et al. (2020) published the following Clinical Consensus Statement on the appropriate clinical management of adult-acquired flatfoot deformity: "Subtalar arthroereisis should not be considered as a single corrective procedure for stage IIB AAFD [adult flatfoot]." (18)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2022 did not identify any ongoing or unpublished trials that would likely influence this medical policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	28899, 0335T, 0510T, 0511T
HCPCS Codes	S2117

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. Reference 18 added.
09/15/2021	Reviewed. No changes.
01/15/2021	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2019	Reviewed. No changes.

07/15/2018	Document updated with literature review. Clarification made to Note by changing the term “pricing” to “coding”. No new references added.
07/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
03/15/2015	Document updated with literature review. Coverage unchanged.
01/01/2014	CPT/HCPCS code(s) updated
03/01/2013	Document updated with literature review. Coverage unchanged.
09/01/2010	Document updated with literature review. Coverage unchanged.
11/01/2008	CPT/HCPCS code(s) updated
09/15/2007	Revised/updated entire document
08/01/2007	Revised/updated entire document
11/15/2005	New medical document