

Medical Policy Manual

Topic: Subtalar Arthroereisis

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Subtalar arthroereisis (also referred to as arthrorisis) involves placing an implant in the sinus tarsi through a small incision. The subtalar implant acts as a spacer to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. It has been performed for some 40 years with a variety of implant designs and compositions, primarily for treatment of flexible flatfoot (pes planus deformity), although its use in other deformities such as club foot have been reported.

Subtalar arthroereisis is most often performed on young children and is designed to correct excessive talar displacement and calcaneal eversion. Operative intervention, particularly for juvenile flexible flatfoot, is considered only after a protracted course of orthotics, shoe modifications, and modifications in activity have failed to relieve associated symptoms.

In young children, insertion of the implant is frequently offered as a stand-alone procedure, while older children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities. Surgical alternatives to arthroereisis include tendon reconstruction or transfer, calcaneal osteotomy and arthrodesis, with the best results reported when a combination of these procedures is performed.

Regulatory Status

There are several arthroereisis implants that have received FDA approval via either the PMA or 510(k) approval processes. The following are examples of FDA approved subtalar implants:

- Arthrex ProStop Plus™ (Arthrex, Naples, FL)
- Arthroereisis Implant Talus of Vilex
- HyProCure® Subtalar Implant System (Graham Medical Technologies)
- Sub-Talar Lok™ (Instrateck™ Inc.)
- MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ)
- MBA_{Resorb} Implant
- Osteomed Talar-Fit™
- Subtalar Peg Implant (Nexa Orthopedics, Inc.)
- SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France)
- Wright Medical Smith Sta-Peg

Note: This policy addresses subtalar *arthroereisis* only; it does not address subtalar *arthrodesis* which is a significantly different procedure and is considered a standard of care.

POLICY/CRITERIA

Subtalar arthroereisis for the treatment of pes planus (flatfoot) or other deformities in adults and children is considered **investigational**.

SCIENTIFIC EVIDENCE

Literature Appraisal

The most clinically relevant outcomes of treatment of symptomatic flexible flatfoot are pain reduction and improved function. Relief of pain is a subjective outcome that is typically associated with a placebo effect. In addition, adjunctive treatments are often performed along with the implantation of a subtalar implant, making it difficult to isolate the contribution of the implant. Therefore, assessment of the net health outcomes requires blinded, randomized, controlled trials (RCT) to control for the placebo effect, to control for potential bias, and to determine whether any treatment effect from subtalar arthroereisis provides a significant advantage over nonsurgical treatment or surgical correction without the subtalar implant.

There are no controlled trials of subtalar arthroereisis compared to alternative treatments. The evidence base consists entirely of single-arm case series that report on success rates following this procedure. Interpretation of the current 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. The evidence base is also limited by the lack of long-term follow-up, which may be particularly important for a procedure performed in children.

The following is a summary of articles that are representative of the currently available published evidence.

Systematic Reviews

In 2011, Metcalfe et al. published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot.^[1] Seventy-six case series or case reports were identified; no controlled trials were found. The influence of adjunctive procedures on outcomes was not addressed in this review. In addition to the findings listed below, the systematic review included a critical analysis of the quality of the included studies, which found the literature to consist primarily of case reports and retrospective reviews. Pooling of data for statistical analysis was generally not possible due to the following factors:

- Methodological heterogeneity in device type, inclusion criteria, surgical technique, adjunctive procedures, and outcome measures.
- Some articles combined results for adults and children.
- Few studies used validated outcome measures.

The authors reported the following findings and conclusions:

- Ten of the studies (756 feet) provided 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 non-validated outcome measures, while one 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 relationship between radiographic and clinical outcomes is uncertain.
- Complications included sinus tarsi pain, device extrusion, and undercorrection. Complication rates ranged from 4.8% to 18.6%, with unplanned removal rates between 7.1% and 19.3% across all device types.

The authors concluded that, while arthroereisis is a feasible minimally invasive procedure and the implant can be readily removed in case of complications, this technique continues to “polarize opinion” as a treatment option for pediatric flatfoot.

Randomized Controlled Trials

There is currently no published evidence from randomized controlled trials on subtalar arthroereisis.

Non-randomized Trials

There are currently no published controlled trials comparing subtalar arthroereisis with nonsurgical treatment or alternative surgical techniques. The current body of published literature consists mainly of small, short- to mid-term case series, retrospective reviews, and individual case reports. Evidence from these studies is unreliable due to design limitations such as non-random allocation of treatment, lack of adequate comparison groups, small study populations, and short-term follow-up.

The following is a summary of findings from studies published after the Metcalfe et al systematic review summarized above.

- In 2012 Graham et al., the inventors of the HyProCure subtalar implant, reported on a retrospective study of talotarsal stabilization in patients who did not have adjunct procedures.^[2] The HyProCure device was implanted in 117 feet in 83 adults. The mean follow-up was 51-month. Seventy-eight patients completed the Maryland Foot Score Questionnaire; the five patients who did not complete

the questionnaire had 7 implants removed for prolonged pain (4 cases), psychogenic reaction (2 cases), and postoperative infection (1 case). There were 16 revision surgeries with HyProCure; 9 involved repositioning of a partially displaced device or a change in size of the device. Of the patients who retained the device, 52% reported complete alleviation of foot pain, 69% had no limitations on their foot functional abilities, and 80% of cases reported complete satisfaction with the appearance of their feet.

- A 2012 retrospective study by Brancheau et al. reported mean 36-month follow-up (range 18 to 48 months) of radiographic outcomes in 35 consecutive patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis (MBA) implant with adjunct procedures.^[3] The mean age of the patients was 14.3 years (range, 5 to 46 years). Significant changes were observed in radiographic measures (talocalcaneal angle, calcaneocuboid angle, first to second intermetatarsal angle, calcaneal inclination angle, and talar declination angle) compared with preoperative measures. The authors noted that radiographic parameters are not always a reliable predictor of patient satisfaction with a surgical outcome. Complications were reported in five feet in four patients (11.4%) and included hematoma, infected incision site, suture abscess, and retrograde lateral implant slippage. Nine implants (15%) required removal after the initial surgery. At a mean of 33 months postoperatively, a subgroup of 24 patients (68.6%) participated in a postoperative interview (in person or by telephone) which included a questionnaire for subjective outcomes. Resolution of the chief presenting complaint was reported by 95.8%, 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. As noted by the authors, limitations in this study include a number of biases common in retrospective reviews that could threaten the validity of conclusions. For example, the survey used had not been validated for any particular age group. The reason for the loss to follow-up for the longer-term subjective measures could not be determined due to the investigators' inability to contact all of the initial patients. Assessment was done by unblinded investigators. No statistical analysis was performed to determine associations between variable and outcomes. For these reasons, the evidence and conclusions related to this study are considered unreliable.
- Cook et al. conducted a retrospective case-control study to identify factors that may contribute to failure (explantation) of titanium arthroereisis implants.^[4] All patients who required removal of a self-locking wedge-type subtalar arthroereisis (n=22) were compared in a 1:2 ratio (n=44) to patients with nonexplanted arthroereisis who were treated during the same time period. Subjects were matched for preoperative radiographic measurements, age, gender, presenting diagnosis, and length of follow-up. Multivariate logistic regression showed no significant effect of age, gender, 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 [OR]: 1.175) or residual transverse plane-dominant deformities (OR: 1.096). The percentage of explantations in this retrospective analysis was not described.

Adverse Effects

The evidence is insufficient to establish whether the benefits of SA outweigh the risks. The following are examples of complications that have been reported in the published literature:

- Implant dislocation/extrusion
- Foreign body reaction
- Pain, locking, or stiffness of the subtalar joint
- Peroneal spastic flatfoot

- Poor tendon balancing with implant placement, resulting in rearfoot pain due to overload of the implanted region.
- Inaccurate sizing, resulting in poor correction if the implant is too small, and painful locking of the rearfoot if the implant is too large

Clinical Practice Guidelines and Position Statements

- There are currently no published evidence-based clinical practice guidelines from U.S. professional associations that recommend subtalar arthroereisis.
- American College of Foot and Ankle Surgeons (ACFAS) consensus statements

Per executive director at the ACFAS via direct e-mail communication with us, in 2012 the ACFAS board voted to deactivate their clinical practice guidelines for adult^[5] and pediatric^[6] flatfoot as no longer meeting their current standards for clinical practice guidelines. While the documents will remain on the ACFAS web site, they are to be considered informational Clinical Consensus Statements.

These published clinical consensus statements included subtalar arthroereisis in a list of surgical options and noted the controversial nature of this surgical technique:

- Adult flatfoot^[5]

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.”

- Pediatric flatfoot^[6]

“[P]roponents of this procedure 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.”

Summary

The available evidence is insufficient to permit conclusions about the long-term benefits and safety of subtalar arthroereisis for the treatment of pes planus (flatfoot) and other deformities. Therefore, this technique is considered investigational in adults and children for any indication.

- There are no randomized controlled trials comparing subtalar arthroereisis (SA) with either nonsurgical treatment or surgery without a subtalar implant. Without these comparisons, it is not possible to determine whether SA results in similar or better health outcomes with respect to pain, activity levels, or footwear limitations.
- A significant limitation in the published literature is the lack of long term outcomes data. It is particularly important to determine the effectiveness and durability of the subtalar arthroereisis implant in growing children, and the difficulty in separating the effect of this procedure from that of other adjunctive treatments.

- The published literature continues to report that SA for the treatment of flexible flatfoot remains controversial within the surgical community due to the lack of long term outcomes data and risks associated with the procedure.

REFERENCES

1. Metcalfe, SA, Bowling, FL, Reeves, ND. Subtalar joint arthroereisis in the management of pediatric flexible flatfoot: a critical review of the literature. *Foot Ankle Int.* 2011 Dec;32(12):1127-39. PMID: 22381197
2. Graham, ME, Jawrani, NT, Chikka, A. Extraosseous talotarsal stabilization using HyProCure(R) in adults: a 5-year retrospective follow-up. *J Foot Ankle Surg.* 2012 Jan-Feb;51(1):23-9. PMID: 22196455
3. Brancheau, SP, Walker, KM, Northcutt, DR. An analysis of outcomes after use of the Maxwell-Brancheau Arthroereisis implant. *J Foot Ankle Surg.* 2012 Jan-Feb;51(1):3-8. PMID: 22196453
4. Cook, EA, Cook, JJ, Basile, P. Identifying risk factors in subtalar arthroereisis explantation: a propensity-matched analysis. *J Foot Ankle Surg.* 2011 Jul-Aug;50(4):395-401. PMID: 21708340
5. Lee, MS, Vanore, JV, Thomas, JL, et al. Diagnosis and treatment of adult flatfoot. *J Foot Ankle Surg.* 2005 Mar-Apr;44(2):78-113. PMID: 15768358
6. Harris, EJ, Vanore, JV, Thomas, JL, et al. Diagnosis and treatment of pediatric flatfoot. *J Foot Ankle Surg.* 2004 Nov-Dec;43(6):341-73. PMID: 15605048

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
Subtalar arthroereisis and subtalar arthrodesis are significantly different procedures for which the description and coding are not interchangeable. The appropriate CPT code for subtalar arthroereisis is 28899 as there is no specific CPT code for this procedure.		
CPT	0335T	Extra-osseous subtalar joint implant for talotarsal stabilization
	28899	Unlisted procedure, foot or toes
HCPCS	S2117	Arthroereisis, subtalar