Medical Policy Manual Surgery, Policy No. 144

Subtalar Arthroereisis

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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

In this procedure to correct flat foot, an implant is placed in the foot to prevent the ankle/foot from leaning inward during weight-bearing.

MEDICAL POLICY CRITERIA

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Subtalar arthroereisis (also referred to as arthroisis) is the surgical implantation of a device for limitation of movement across the subtalar joint. Subtalar arthroereisis or extraosseous talotarsal stabilization (EOTTS) 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. 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.[1] 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)
- TARSA-LINK™ Stand-Alone Wedge Fixation System (Centric Medical)
- 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.

EVIDENCE SUMMARY

The most clinically relevant outcomes of treatment for 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 in order to determine whether any

treatment effect from subtalar arthroereisis provides a significant advantage over nonsurgical treatment or surgical correction without the subtalar implant.

The evidence base consists primarily of single-arm case series that report on success rates following this procedure. Interpretation of the current evidence is limited by the use of adjunctive procedures in addition to subtalar arthroereisis, which create difficulties in determining the extent to which each modality contributed to the study 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 publications that are representative of the currently available published evidence.

SYSTEMATIC REVIEWS

Baryeh (2022) published a systematic review of nine studies on the use of subtalar arthroereisis for the correction of adult acquired flatfoot evaluating both radiologic and clinical outcomes.[2] A total of 190 arthroereisis surgeries were completed across the included studies with improved outcomes demonstrated for both radiologic and clinical outcomes. However, the authors report significant heterogeneity, small sample sizes, and the need for additional high-quality studies to establish the clinical utility of subtalar arthroereisis in the treatment of adult acquired flatfoot.

Metcalfe (2011) published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot.[3] 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 SR 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 methodological heterogeneity in device type, inclusion criteria, surgical technique, adjunctive procedures, and outcome measures, and few studies used validated outcome measures.

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 eight of nine 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. Two studies reported complications, including talar neck fracture[4] and spontaneous subtalar fusion.[5] 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

No RCTs were identified.

NONRANDOMIZED STUDIES

Wen (2017) published a study that compared nonfusion subtalar arthroereisis using a subtalar joint stabilizer (SJS) with Dennyson-Fulford subtalar arthrodesis (D-FSA). The study included 26 children with cerebral palsy and spastic flatfoot.[6] Follow-up occurred in the SJS group (n-12) for up to 48 months and in the D-FSA group for up to 60 months. The authors concluded both procedures have similar outcomes for spastic flatfoot.

Chong (2015) reported a small prospective nonrandomized trial that compared STA with lateral column calcaneal lengthening for the treatment of 24 painful flatfeet in children.[7] Seven children (13 feet) enrolled at the Primary Children's Medical Center were treated with arthroereisis and eight children (11 feet) enrolled at the Shriners Hospital for Children were treated with lateral column lengthening. Children who underwent STA had a small incision with insertion of the implant and were placed in below-knee walking casts for three weeks. Children treated with lateral column lengthening had an opening wedge osteotomy with insertion of a wedge of cadaveric bone and were placed in non-weight-bearing casts for one month and walker type 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 in kinematics. Both groups showed a statistically significant lateralization of the hindfoot and midfoot center of pressure ($p<0.01$). There were no between-group differences in any of the clinical or functional outcomes. On within-group comparison, only the STA 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 STA group had a statistically significant improvement in this small sample. There were two complications in each group, with removal of the hardware in one patient and removal of the implant in two patients. The improvement in pain and foot position was retained following implant removal.

The remaining 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. These studies, published since the Metcalfe et al SR, are summarized below.

Graham (2012) the inventors of the HyProCure subtalar implant, reported on a retrospective study of talotarsal stabilization in patients who did not have adjunct procedures.[8] The HyProCure device was implanted in117 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 seven implants removed for prolonged pain (four cases), psychogenic reaction (two cases), and postoperative infection (one case). There were 16 revision surgeries with HyProCure; nine 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. Brancheau (2012) published a retrospective study that 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.[9] 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 (2011) conducted a retrospective case-control study to identify factors that may contribute to failure (explantation) of titanium arthroereisis implants.[10] 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.

Numerous other non-randomized, non-comparative studies have been identified that suffer significant study design limitations and results from those should be interpreted with caution.[11-13] Additional high-quality studies are needed to demonstrate the long-term effectiveness of subtalar arthroereisis.

SECTION SUMMARY

There are no RCTs or large comparative studies with long term follow-up that compare 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.

TALOTARSAL JOINT DISLOCATION

Bresnahan (2013) reported a prospective study of talotarsal stabilization using HyProCure® in 46 feet of 35 patients diagnosed with recurrent and/or partial talotarsal joint dislocation.[14]

Patients who had the following characteristics were included: deformity characterized by talar displacement medially, plantarly, and/or anteriorly; collapse of the medial longitudinal arch; hyperpronation about the subtalar joint axis; ability to manipulate the foot to correct the deformity; a prolonged period of pronation or delayed resupination and/or flattening of the arch; and anteroposterior/dorsoplantar and lateral weightbearing radiographs revealing talotarsal misalignment. No procedures other than insertion of the HyProCure® device were performed to address the talotarsal joint dislocation. At one year postoperatively, scores on the Maryland Foot Score had improved from a pre-operative score of 69.53 to a postoperative score of 89.27 out of 100 (n=30). Foot pain decreased by 37.0%, foot functional activities improved by 14.4%, and foot appearance improved by 29.5%. Implants were removed from two feet with no unresolved complications.

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

PRACTICE GUIDELINE SUMMARY

There are currently no evidence-based clinical practice guidelines that recommend subtalar arthroereisis.

SUMMARY

There is not enough research to show that subtalar arthroereisis improves health outcomes for adults and children with pes planus (flat foot) or other deformities. No clinical guidelines based on research recommend subtalar arthroereisis for adults or children with flat feet or other deformities. Therefore, subtalar arthroereisis is considered investigational.

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CODES

Codes	Number	Description
CPT	0335T	Insertion of sinus tarsi implant
	0510T	Removal of sinus tarsi implant
	0511T	Removal and reinsertion of sinus tarsi implant
	28899	Unlisted procedure, foot or toes
HCPCS	S2117	Arthroereisis, subtalar

Date of Origin: *January 2006*