Medical Policy

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Title: Subtalar Arthroereisis

Professional
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DESCRIPTION

Arthroereisis (also referred to as arthroisis) is the limitation of excessive movement across a joint. Subtalar arthroereisis is performed by placing an implant in the sinus tars (a canal located between the talus and the calcaneus) and is designed to correct excessive talar displacement and calcaneal eversion.

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 in nature, or it may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, and inflammatory disorders, among others. 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. Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Arthroereisis with a variety of implant designs has also been investigated.

Subtalar arthroereisis (STA) has been performed for over 50 years, with a variety of implants designs and compositions. Currently, the Maxwell-Brancheau Arthroereisis (MBA) implant is favored due to the simple and reversible implantation procedure, although other devices such as the STA peg and Kalix device are reported in the medical literature. The MBA 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 MBA 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 received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) pathway. For example, the SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France) received FDA marketing clearance in 2010 (K093820) and the Arthrex ProStop Plus™ (Arthrex, Naples, FL) received marketing clearance in 2008 (K071456). The MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ) received 510(k) marketing clearance in 1996 (K960692) because it was substantially equivalent to products on the market prior to device regulation. According to the FDA summary, the primary indication for the Subtalar MBA device is "as a spacer for stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela." (1) The MBAResorb Implant received 510(k) marketing clearance in 2005 (K051611). This implant employs the same basic mechanical features as the predicate MBA implant but is composed of a material (poly l-lactic acid) that is resorbed by the body. Predicate devices include the Osteomed Talar-Fit™ (K031155), Nexa Orthopedics Subtalar Peg (K032902 and K033046), Arthroereisis Implant Talus of Vilex (TOV, K041289), Instrateck (K080280), and Wright Medical Smith Sta-Peg (K792670).

POLICY

Subtalar arthroereisis is considered **experimental / investigational**.

RATIONALE

Periodic literature searches of the MEDLINE database on subtalar arthroereisis (STA) have identified minimal published studies, primarily consisting of single institution case series and individual case reports. The most recent literature update, using the MEDLINE database, was performed for the period of August 2011 through June 2012. Following is a summary of the key literature to date.

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.

In 2011, Metcalfe et al. published a systematic review of the literature on subtalar arthroereisis for pediatric flexible flatfoot. (2) Seventy-six case series or case reports (no controlled trials) were identified. 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 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 relationship between radiographic and clinical outcomes is uncertain. The procedure was associated with a number of complications including 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 influence of adjunctive procedures on outcomes was not addressed in this review.

One case series that was not confounded by adjunctive procedures and that had a relatively long follow-up was published by Graham et al. in 2012. This study reported mean 51-month follow-up of talotarsal stabilization in 117 feet using the HyProCure device. (3) Patients who received adjunctive procedures affecting the talotarsal joint were excluded from the analysis. Adult patients who met the inclusion/exclusion criteria were invited to participate in the study. Eighty-three patients gave consent to participate, and 78 completed the Maryland Foot Score Questionnaire; 5 patients who had 7 implants (6%) removed did not complete the questionnaire. 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. 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 generally did not exclude the use of other adjunctive treatments. For example, in 1998 Vedantam and colleagues reported on a series of 78 children (140 feet) with neuromuscular disease who underwent STA with an STA-peg. (4) The stem of this implant is placed into the calcaneous with the collar abutting the inferior surface of the lateral aspect of the talus, thus limiting motion. All but 5 of the children had additional procedures to balance the foot. Satisfactory results were reported in 96.4% of patients, although the contribution of the STA-peg cannot be isolated. In 2004, Nelson and colleagues reported on 37 patients (67 feet) who underwent Maxwell-Brancheau Arthroereisis (MBA) implant with 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. Another series from 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, since

results were not compared with controls receiving reconstructive surgery without STA, the contribution of the implants to these outcomes is unclear. In addition, the authors reported an overall complication rate of 46%, with surgical removal of 39% of the implants due to sinus tarsi pain. The authors also commented that postoperative sinus tarsi pain was unpredictable.

Cicchinelli et al. reported on radiographic outcomes in a retrospective analysis of 28 feet in 20 pediatric patients treated with STA combined with gastrocnemius recession or with STA combined with gastrocnemius recession and medial column reconstruction. (7) Lucaccini et al. 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 STA performed in one stage. (8) In a 2010 study, Scharer and colleagues conducted a retrospective radiographic evaluation of 39 patients (68 feet) who had received the MBA implant for the treatment of painful pediatric flatfoot deformities. (9) The average age of the patients 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 either a larger or smaller implant. These case series do not allow comparison with nonsurgical interventions or with other surgical interventions.

An example of a case series with longer follow-up is a 2012 retrospective study by Brancheau et al., which reported mean 36-month follow-up (range 18 to 48 months) in 35 patients (60 feet) after use of the Maxwell-Brancheau Arthroereisis (MBA) implant with adjunct procedures. (10) 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). Seventeen percent of patients reported that 9 implants (15%) were removed after the initial surgery. Of the 24 patients (68.6%) 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.

Complications are frequently reported in the literature. Scher and colleagues reported 2 cases of extensive implant reaction in 2 children 2 years after a STA-peg procedure. (11) 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 flexible flatfoot in children. A radiographic study on a bioabsorbable STA found poor outcomes in 3 of 6 patients who met the inclusion criteria and consented to additional imaging. (12) 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 prior to implantation. They concluded that the current width and length of commercially available implants may need to be modified and that more research and long-term clinical study are needed.

Cook et al. conducted a retrospective case-control study to identify factors that may contribute to failure (explantation) of titanium arthroereisis implants. (13) 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 arthroereises 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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009

In response to requests, input was received through 1 physician specialty society (3 reviews) and 5 academic medical centers while this policy was under review in 2009. The input of reviewers was mixed regarding the medical necessity of arthroereisis.

2012

In response to requests, input was received through 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Input was mixed, with a majority of reviewers considering this procedure to be investigational.

Summary

The evidence in the published medical literature on subalar athroereisis is inadequate to permit scientific conclusions. The main limitation is the lack of controlled studies comparing use of the implants with other surgical procedures, alone or in combination. Other 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. Therefore, subtalar arthroereisis is considered investigational.

Practice Guidelines and Position Statements

2009 Guidance from the United Kingdom's National Institute for Clinical Excellence (NICE) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity. (14) Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit, or research.

The American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of adult and pediatric flatfoot in 2004 and 2005 (these are not included in the ACFAS library of current clinical practice guidelines). (15, 16)

The ACFAS guideline on adult flatfoot states: "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 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."

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

S2117 Arthroereisis, subtalar

- There is no specific CPT code for this procedure. It is possible that providers may be using the following codes to describe subtalar arthroereisis:

28725 Arthrodesis, subtalar
28735 Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)
28740 Arthrodesis, midtarsal or tarsometatarsal, single joint
28899 Unlisted procedure, foot or toes
29907 Arthroscopy, subtalar joint, surgical; with subtalar arthrode

DIAGNOSES

Experimental / investigational for all diagnoses related to this policy.

REVISIONS

01-27-2009	Updated Description section and Coding section.
	Added Rationale section.
	First published on www.bcbsks.com.
02-10-2010	Updated Rationale section with 2009 Update.
10-26-2010	Description Section updated.
	Rationale Section updated.
	References Section updated.

12-27-2012	Description Section updated.
	Rationale Section updated.
	In Coding section ▪ Added the Diagnoses sub-section and phrase "Experimental / investigational for all diagnoses related to this policy." which is reflected in BCBSKS experimental / investigational policies, but was inadvertently not included on this policy.
	References Section updated.

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