Aetna Better Health®
2000 Market Street, Suite 850
Philadelphia, PA 19103

AETNA BETTER HEALTH®

Clinical Policy Bulletin:
Subtalar Implant for Foot Deformity

Revised April 2014

Number: 0669

Policy

Aetna considers subtalar implants (e.g., the Maxwell-Brancheau arthroereisis (MBA) implant and the HyProCure Sinus Tarsi implant) experimental and investigational for the treatment of subtalar instability, talipes equinovarus deformity (club foot), foot drop (dangle foot), and flatfoot deformity including congenital and adult-onset (acquired) flatfoot deformity (also known as posterior tibial tendon dysfunction) or any other conditions because their clinical value has not been established.

Aetna considers the following subtalar implants experimental and investigational because their effectiveness has not been established:

- Arthrex Prostop and Arthrex Prostop Plus Subtalar Arthroereisis Implant
- Bioarch Subtalar Arthroereisis Implant
- bioBLOCK Resorbable Subtalar Implant
- BioPro Horizon Subtalar Implant
- Futura Angled Subtalar Implant
- Futura Conical Subtalar Implant
- Kalix II
- Lundeen Subtalar Implant
- MetaSurg BioArch Subtalar Implant System
- OsteoMed Talar-Fit Subtalar Implant System
- Smith Subtalar Arthroereisis Implant
- Sub-Talar Lok Arthroereisis Subtalar Implant System
- Twist Subtalar Implant

Background

Flatfoot (hyperpronation and flattening-out of the longitudinal arch) (also known as pes planus or pes planovalgus) is a common deformity among children and adults. Another cause of flatfoot can be attributed to posterior tibial tendon dysfunction. Conservative treatments to relieve pain from the foot and leg associated with flatfoot include orthotics, stretching exercises, and medication (e.g., non-steroidal anti-inflammatory drugs). Corticosteroid injections continue to be controversial. These methods may fail to provide relief and do not provide any correction at the point of contact. Various surgical techniques of subtalar joint arthroereisis have been used in the treatment of patients who have failed conservative approaches. Some surgeons use bone blocks and bond grafts placed into the sinus tarsi to limit excessive subtalar joint pronation. Others advocate the use of endoprosthetic devices. Arthroereisis is the limitation of exogenous joint motion without complete arthrodesis. This has been achieved by using a variety of endoprosthetic devices such as the subtalar arthroereisis peg, the Silastic silicone sphere, and the Subtalar Maxwell-Brancheau arthroereisis (MBA) implant (KMI - Kinetikos Medical Incorporated, San Diego, CA).

The Subtalar MBA implant was cleared by the U.S. Food and Drug Administration (FDA) via a 510(k) premarket notification in 1996. It is an "internal orthotic" designed for correction of pediatric pes valgus and adult posterior tibial dysfunction deformity. There are 5 different MBA implant sizes: 6, 8, 9, 10, and 12 mm in diameter. The implant is a soft-threaded titanium device that is inserted into the sinus tars. It aims to restore the arch by blocking the anterior and inferior displacement of the talus and by preventing the foot from pronating; thus allowing normal subtalar joint motion. Tissue grows normally around the implant and aids in holding it in place. In adults, ancillary procedures may be performed simultaneously (e.g., an Achilles tendon lengthening if an equines deformity is present). The patient can ambulate the day after surgery in a Cam Walker for approximately 3 weeks. Thereafter, regular shoes can be worn with an ankle brace for an additional 2 to 3 weeks.

Husain and Fallat (2002) performed biomechanical analysis of MBA implants in fresh-frozen cadaver limbs to quantitate the effects on subtalar joint motion restriction and radiographic angles. This study did not contain any clinical data on the value of MBA implants.

Well-designed studies are needed to ascertain the effectiveness and durability of the Subtalar MBA implant for the treatment of pathologic flatfoot.

Needleman (2006) ascertained the functional outcomes as well as radiographical results of adult patients who had an operation for flexible flatfeet without any hindfoot osteotomies or fusions. A total of 28 feet in 23 patients with problems caused by their flexible flatfoot deformities had reconstructive foot and ankle surgery that included a subtalar arthroereisis with the MBA sinus tarsi implant. The American Orthopedic Foot and Ankle Society (AOFAS) Hind-foot Scale and a patient assessment questionnaire were obtained from all patients before surgery and at final follow-up. Pre-operative and post-operative standing radiographs were analyzed to determine radiographical correction of the deformities. The average follow-up was 44 months. The MBA implant was surgically removed in 11 of 28
feet (39 %) because of sinus tarsi pain. The average pre-operative AOFAS score was 52 and had improved to 87 (p < 0.00001) at final follow-up. The average response to 4 of 5 questions in the patient assessment had significantly improved (p < 0.05). On a 10-point scale, average patient satisfaction was 8.3 points; 78 % said that they would have the surgery again. Correction after surgery was significant (p < 0.0001) in each of the 3 radiographical parameters evaluated for ‘correction with MBA’ and “final correction”. With the numbers available, no significant differences could be detected after the MBA was removed. Complications included sinus tarsi pain in 46 % (13) of the 28 feet in this study; after implant removal, 73 % (8) of 11 feet had less discomfort than before surgery with AOFAS scores 80 or better. The author concluded that reconstructive foot and ankle surgery that included a subtalar arthroereisis with the MBA sinus tarsi implant resulted in favorable clinical outcomes and patient satisfaction in 78 % (18) of 23 patients. In spite of the high incidence of temporary sinus tarsi pain until the implant was removed, this operative approach compares favorably with other operations for flexible flatfoot deformities in adults. The major drawbacks of this study were its small sample size as well as the multiple etiologies of the flexible flatfoot deformity (13 feet had congenital etiologies and 15 feet had acquired etiologies). Other pitfalls of this study included the 42 % occurrence of sinus tarsi discomfort and the associated 8 post-operative months of pain until the implant was removed.

In a review on acquired adult flatfoot deformity (AAFD), Pinney and Lin (2006) described the key elements of AAFD and outlined therapeutic options based on the peer-reviewed literature. The authors stated that the limited research on subtalar arthroereisis (the use of a sinus tarsi plug or implant to restrict eversion of the subtalar joint) in adult patients with AAFD means that there is insufficient evidence to make a recommendation for or against this treatment option.

The Interventional Procedures Advisory Committee of the National Institute for Clinical Excellence (NICE, 2008) examined sinus tarsi implant insertion for mobile flatfoot. Provisional recommendations from the Committee stated “current evidence on the safety and efficacy of sinus tarsi implant for mobile flatfoot is inadequate in quality and quantity”. Furthermore, a review of the published literature on this procedure that was commissioned by NICE (2008) identified 8 case series and 4 case reports (643 feet) of sinus tarsi implant insertion for mobile flatfoot; no prospective comparative data were found. The published literature focused mainly on the pediatric population. Only 1 case series (n = 23) was reported in adults. The provisional review found that the procedures described in the studies varied significantly, particularly in relation to the design, size and instrumentation/insertion of the implant(s). The Committee recommended that this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Formal guidance on this procedure (NICE, 2009) concluded: “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.”

In a retrospective study, Scharer et al (2010) evaluated the outcome of pediatric patients who have undergone MBA subtalar implants for the treatment of painful pediatric flatfoot deformities. A total of 39 patients (68 feet) were evaluated clinically and radiographically. The mean age of the patients was 12 years (range
of 6 to 16 years). The mean period of follow-up was 24 months (range of 6 to 61 months). Statistical evaluation was performed on all radiographical measurements. Additional surgical procedures (gastrocnemius recession, Achilles tendon lengthening, Kidner posterior tibial tendon advancement) were performed in 22 of 68 feet. There were 10 (15%) complications, which consisted of 10 re-operations in 10 feet. Implants were exchanged in 9 feet because of implant migration, under-correction, and over-correction. There was 1 re-operation (in 1 foot) for implant removal because of persistent sinus tarsi pain. Radiographical evaluation demonstrated an improvement of all parameters determined. The parameters that were evaluated include talo-navicular joint coverage, as well as lateral and anterior-posterior talo-calcaneal angles. There were significant changes noted in pre- and post-operative measurements (p < 0.001). The authors concluded that the MBA implant is effective for the correction of painful, flexible flatfoot deformity in children in short-term follow-up. However, this is a multi-planar deformity, and additional procedures may be needed in addition to the MBA.

Yu et al (2011) reviewed the application progress of subtalar arthroereisis for the correction of pediatric flatfoot in children and analyzed the problems at present as well as to predict the trend of development in the field. Domestic and abroad literature concerning the methods of subtalar arthroereisis applied in pediatric flatfoot in recent years was reviewed extensively and thoroughly analyzed. Subtalar arthroereisis has proved to yield good results for correction of the flatfoot in children. In addition to the advantages of subtalar arthroereisis for pediatric flatfoot treatment (simple procedure, mature technology, and less complications), it allows further surgery if needed. The authors concluded that subtalar arthroereisis is a simple and effective way to treat flatfoot in children, however, its biomechanics mechanism and managements to complication need to be explored further.

Metcalfe et al (2011) noted that pediatric flexible flatfoot is a common deformity for which a small, but significant number undergo corrective surgery. Arthroereisis is a technique for treating flexible flatfoot by means of inserting a prosthesis into the sinus tarsi. The procedure divides opinion in respect of both its effectiveness and safety. A database search up until 2010 was used to find articles regarding arthroereisis in pediatric patients. These researchers summarized the findings of this study. A total of 76 studies were identified; 8 of the 9 radiographical parameters reported show significant improvement following arthroereisis reflecting both increased static arch height and joint congruency. Calcaneal inclination angle demonstrated the least change with only small increases following arthroereisis. Arthroereisis remains associated with a number of complications including sinus tarsi pain, device extrusion, and under-correction. Complication rates range between 4.8% and 18.6% with unplanned removal rates between 7.1% and 19.3% across all device types. The authors concluded that current evidence is limited to consecutive case series or ad hoc case reports. Limited evidence exists to suggest that devices may have a more complex mode of action than simple motion blocking or axis altering effects. The interplay between osseous alignment and dynamic stability within the foot may contribute to the effectiveness of this procedure. They stated that although literature suggests patient satisfaction rates of between 79% to 100%, qualitative outcome data based on disease specific, validated outcome tools may improve current evidence and permit comparison of future study data.

In a retrospective study, Graham et al (2012a) determined the long-term functional outcomes and device tolerance achieved in adult patients who chose to undergo
an extra-osseous talotarsal stabilization (EOTTS) procedure HyProCure for the treatment of flexible talotarsal joint deformity. A total of 83 adult patients participated in this study. Post-operative subjective assessment of device performance was evaluated using Maryland Foot Scores, which were collected at a mean follow-up period of 51 months. The mean post-operative Maryland Foot Score was 88 out of 100; post-operatively, 52 % of cases reported complete alleviation of foot pain, 69 % of cases had no limitations on their foot functional abilities, and 80 % of cases reported complete satisfaction with the appearance of their feet. The implant was removed in 7 out of 117 cases (removal rate: 6 %) due to prolonged pain of the anterior talofibular ligament (4 cases), psychogenic reaction (2 cases), and post-operative infection (1 case). The authors concluded that the long-term positive subjective outcomes and excellent patient satisfaction obtained in this study may imply that EOTTS was effective in stabilizing the talotarsal joint complex and eliminating excessive abnormal pronation, thus reducing pain and improving quality of life of the patients; it represents a possible treatment option for partial talotarsal dislocation in cases with flexible and reducible deformity. This study had several major drawbacks: (i) 16 subjects underwent revision surgeries, (ii) the effectiveness of the HyProCure device as a stand-alone procedure is unclear since 32 % of the cases (35 of 110 feet in whom the implants were not removed) were performed with adjunctive procedures to achieve the desired amount of correction, and (iii) these researchers failed to quantify the improvement in terms of pre-operative subjective participant satisfaction scores.

Graham et al (2012b) determined radiographic correction achieved in adult patients treated with an EOTTS procedure. Patients diagnosed with flexible/reducible talotarsal joint dislocation (partial) underwent surgical correction with the HyProCure EOTTS device. Pre-operative and post-operative weight-bearing radiographs taken in the antero-posterior (AP) and lateral views for a total 95 feet (in 70 patients) were analyzed to determine standardized radiographic angles, and to quantify the correction obtained after the EOTTS procedure. Post-operative radiographs were taken at an average follow-up of 17 days from the surgery date. The mean pre-operative and post-operative talar 2nd metatarsal angles (measured from the AP radiographs) were 24.8° ± 1.0° and 5.8° ± 0.9°, respectively, that is, mean decrease by 19°. The mean pre-operative and post-operative talar declination angles (measured from the lateral radiographs) were 25.1° ± 0.7° and 19.4° ± 0.5°, respectively, that is, mean decrease by 5.7°. The mean pre-operative and post-operative calcaneal inclination angles (measured from the lateral radiographs) were 21° ± 0.7° and 21.8° ± 0.7°, respectively, that is, mean increase by 0.8°. Post-operatively, the talar 2nd metatarsal and talar declination angles were reduced to average values reported in the literature for normal feet. The authors concluded that the findings of this study showed the effectiveness of a minimally invasive EOTTS procedure in restoring the normal angular relationships between hind-foot and fore-foot osseous structures on weight-bearing, in both the transverse and sagittal planes. They noted that this indicated that stabilization of the talotarsal joint complex and elimination of hyperpronation, which may lead to reduced pain, improved foot functional abilities, and patient satisfaction. The drawbacks of this study included (i) its retrospective nature, and (ii) the lack of pre-operative lateral radiographs in the talotarsal joint neutral position, which resulted in an inability to determine whether the HyProCure
device was completely successful in re-aligning the talonavicular joint to its maximally neutral position.

In a prospective, multi-center, case-series study, Bresnahan et al (2013) evaluated the subjective outcomes in patients after EOTTS using the HyProCure stent as a stand-alone procedure for the treatment of recurrent and/or partial talotarsal joint dislocation (RTTD) in a population of pediatric and adult patients. Recurrent and/or partial talotarsal joint dislocation has been cited as a possible etiology for a number of foot ailments and might contribute to the development of pathologic features localized more proximally in the weight-bearing musculoskeletal chain. Correction of RTTD might, therefore, lead to the reduction of pathologic features associated with this deformity. A total of 46 feet in 35 patients were included in the present study. Subjective evaluation used the Maryland Foot Score assessment, which was obtained pre-operatively and 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year post-operatively. The mean overall scores improved from a pre-operative value of 69.53 ± 19.56 to a post-operative value of 89.17 ± 14.41 at the 1-year follow-up. Foot pain decreased by 36.97 %, foot functional activities improved by 14.39 %, and foot appearance improved by 29.49 %. The greatest magnitude of improvement occurred 4 weeks post-operatively, with gradual improvement continuing through to the 1-year follow-up. Implants were removed from 2 patients (2 feet, 4.35 %). No unresolved complications were observed. The authors concluded that the positive subjective outcomes resulting from the EOTTS procedure suggested that the intervention employing the HyProCure device alleviated pain and improved foot function and appearance in patients with RTTD. The drawbacks of this study included (i) the broad nature of the inclusion and exclusion criteria, including a lack of measurement of certain variables (e.g., the planar dominance of the recurrent talotarsal deformity, the presence of certain secondary conditions, as well as the relative activity level, all of which could have affected the subjective outcomes), and (ii) there was a significant number of subjects lost to follow-up and incomplete data at the 1-year post-operative assessment, as 46 feet in 35 pre-operative subjects decreased to 30 feet in 21 subjects.

CPT Codes / HCPCS Codes / ICD-9 Codes

There is no specific CPT code for subtalar implants:

CPT codes not covered for indications listed in the CPB:

0335T

Other CPT codes related to the CPB:

28735

29907

HCPCS codes not covered for indications listed in the CPB:

S2117 Arthroereisis, subtalar
ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

268.1  Rickets, late effect
718.87 Other joint derangement not elsewhere classified involving ankle and foot [subtalar instability]
734   Flat foot
736.71 Acquired equinovarus deformity [clubfoot, acquired]
736.79 Other acquired deformities of ankle and foot [foot drop]
754.51 Talipes equinovarus [congenital]
754.61 Congenital pes planus
754.69 Other valgus deformities of feet
754.70 Talipes, unspecified [clubfoot, congenital]

The above policy is based on the following references:

Copyright Aetna Inc. All rights reserved. Clinical Policy Bulletins are developed by Aetna to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Clinical Policy Bulletin contains only a partial, general description of plan or program benefits and does not constitute a contract. Aetna does not provide health care services and, therefore, cannot guarantee any results or outcomes. Participating providers are independent contractors in private practice and are neither employees nor agents of Aetna or its affiliates. Treating providers are solely responsible for medical advice and treatment of members. This Clinical Policy Bulletin may be updated and therefore is subject to change.

CPT only copyright 2008 American Medical Association. All Rights Reserved.