CHAPTER **4**

EXTRAARTICULAR ARTHROEREISIS IMPLANT IN THE PEDIATRIC FLEXIBLE FLATFOOT: A Comprehensive View of the Evidence

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INTRODUCTION

Flexible flatfoot or pes valgoplanus is a condition in which the medial longitudinal arch has normal architecture during non-weight bearing and there is a flattening of the arch during stance or weight bearing.[1,2] It is characterized by calcaneal eversion, talar adduction with plantar flexion, medial arch collapse, and varying degrees of dorsolateral forefoot subluxation.[3] This may otherwise be termed "excessive pronation."[4] It is a complex deformity involving hindfoot, midfoot and forefoot changes.[5]

Infants are usually born with a flexible flatfoot and do not develop a normal arch until towards the end of the second decade of life, typically around the age of 7-10 years.[2,6] The flexible flatfeet persist in 1 of 9 children, and remain constant throughout their lives.[7] This is the time when children are making significant weight gains through growth spurts and are becoming more athletically active. As result, it is often the time when some of the first symptoms may appear as a result of the persistent flexible flatfoot.

EXAMINATION

Even though the majority of children with flexible flatfoot will eventually undergo spontaneous correction or become asymptomatic, some will become symptomatic and pathologic and require treatment.[8] Presenting symptoms may include one or more of the following: dull, aching, throbbing pain or cramping in the arches; generalized fatigue of the foot, ankle or leg; leg pains such as shin splints; low back, knee, or heel pain; avoidance of walking long distances, running or participating in athletics. The child's foot may be progressing in pathologic deformity or be observed to have excessive shoe wear.[1,2]

Examination consists of evaluation of the appearance of the feet both weight bearing and non-weight bearing; joint ranges of motion, especially in the hindfoot and midfoot; areas of tenderness; forefoot varus/supinatus; available ankle joint motion with the Silverskjold test; relaxed calcaneal stance position; Helbing's sign; "too-many-toes-sign;" Hubscher maneuver or Jack's test; heel raise test for functional integrity of the posterior tibial muscle; and gait analysis. Attention must be paid also to any comorbid conditons that might be evident such as neurologic disorder or obesity.

Weight bearing anteroposterior and lateral radiographs in the angle and base of gait provide useful parameters from which to measure the deformities. Taking the same films again with the affected foot in the neutral position can reveal residual sagittal and transverse plane deformities once the rearfoot has been corrected for excess pronation. This can provide useful information if surgery is a potential consideration.

TREATMENT CONSIDERATIONS

For symptomatic pediatric flatfeet, nonsurgical treatment includes activity modifications, stretching, supportive footwear with medial arch supports, orthotics, mild analgesics or nonsteroidal anti-inflammatory drugs (NSAIDs), and/or modifying comorbid conditions. Although surgery is rarely indicated for children with flexible flatfeet,[9-11] persistent symptoms that fail conservative care, uncontrollable progression of pathologic deformity, or a strong family history of painful and debilitating flatfoot in adult years are indications for the option of surgical intervention.

One of the most important concepts in selecting surgical procedures is that of understanding the planal dominance of the deformities that make up that particular flexible flatfoot.[12-14] Planal dominance refers to the foot being divided into 3 planes: frontal, sagittal and transverse. Flexible flatfoot is made up of deformities to varying degrees in each of these planes and surgical correction should be directed to correcting the deformity in the most dominant plane with consideration for the next most dominant plane after the initial correction and so on. This is because correction of a single plane of the deformity may not bring the foot into a stable alignment. Rather, there may remain a residual or even accentuated deformity in another plane that needs to be corrected.

Various algorithms can be utilized to select the surgical procedures[1,14] but they generally fall into one of 4 categories: soft tissue, osteoteotomies, arthroereises, or fusions. The purpose of this article is to analyze the literature for evidence to support or refute the use of the subtalar arthroeresis implant technique as a primary or combination procedure for the correction of flexible flatfoot in the pediatric patient. Trying to evaluate it as an isolated procedure is very difficult since very few flexible flatfeet are simple deformities that can be corrected with just one procedure. Even pioneer flatfoot surgeons recognized the need for ancillary procedures such as Achilles lengthening. Thus, the arthroereisis procedure is often combined with other flatfoot procedures depending on the presenting pathology.

When considering surgical correction of any flexible flatfoot deformity, but especially in a pediatric patient where there is potential for further growth and adaptation, the goal should be to achieve the best correction towards normal realignment with greatest amount of joint preservation. Although soft tissue reconstruction is rarely successful as an isolated procedure for correction of the flexible flatfoot, a variety of osteotomies have been advocated for joint-sparing correction.[1,2,10,13-15] But even those surgeries often require ancillary procedures in order to result in full correction. Being more invasive, they also have a much greater potential for increased morbidity and complications than the less disruptive arthroereisis procedure.

SUBTALAR ARTHROEREISIS HISTORY AND BIOMECHANICS

By itself, the term arthroereisis refers to the limitation of joint motion without complete arthrodesis. The motion of the subtalar joint can be restricted with an osteotomy to lift the floor of the sinus tarsi, bone wedges in the sinus tarsi, fixation across the subtalar joint with an extraarticular staple, insertion of a bone allograft into the sinus tarsi or utilizing a blocking screw in the sinus tarsi. The most common method today of restricting excess pronation of the subtalar joint in an attempt to hold it in a corrected position is with the use of an arthroereisis implant placed in the sinus tarsi. Not only does it block excess pronation but it preserves supination of the subtalar joint.

LeLievre in 1970[16,17] used the term arthroereisis when he described "lateral arthroereisis" as a process of decreasing motion of the hindfoot without completely eliminating it. To accomplish this in both children and adults, LeLievre placed an accessory bone graft in the sinus tarsi and, if necessary, supported it with a staple. He reported that pain on ambulation was abolished in all the patients studied, with excellent results in 73 of the 80 cases during the 11-year period.

In contrast to the motion-sparing arthroereisis concept, Grice in 1952[18] utilized a bone autograft in the sinus tarsi to create an "extraarticular arthodesis" and thus reduce hindfoot valgus. Haraldsson[19,20] modified Grice procedure by placing bone allograft wedges in the sinus tarsi and terming it a talocalcaneal "arthrohisis" that restricted subtalar motion while avoiding arthrodesis. However, the development of degenerative arthritis in the subtalar and midtarsal joints, as well as the inability of the hindfoot to adapt to uneven surfaces and the late recurrence of deformity, made the extraarticular arthrodesis procedure less attractive.[2]

Other authors have utilized the subtalar arthroereisis with staple fixation, especially in children with neuromuscular disorders, with concerns being bone invasion and the restrictive effect on growth as well as the decision as whether or not to remove the staple. Crawford et al[21] performed this procedure, sometimes with an Achilles lengthening, on 31 feet in 20 children ages 2-10 years with an average follow-up of 4.1 years and reported good or excellent results in 84% of the patients. However, Sanchez et al[22] used the same procedure in an attempt to duplicate Crawford's results and observed nearly double the number of fair and poor results. His group concluded the staple subtalar arthroereisis to be an unpredictable procedure and would not recommend further use.[17]

Well before LeLievre came up with the idea of "arthroereisis," Chambers in 1946[23] elevated the floor of the sinus tarsi with an osteotomy supported by a tibial bone autograph graft in front of the posterior facet of the subtalar joint. By filling the sinus tarsi with the elevated bone, he felt that this would prevent eversion while still allowing for inversion. At the same operation he performed a TAL as well. In 1999 Miller[24] implemented Chambers' technique in the feet of 82 children with flexible flatfeet between the ages of 3 and 14 years and reported 95% good or excellent results after an average follow-up of 6.5 years. In addition, Miller also lengthened the Achilles tendon in 70 of the 82 feet.

Subotnick in 1974 with a follow-up in 1977[25,26] introduced a subtalar arthroereisis with a free-floating sinus tarsi implant from a hand-carved block of silicone elastomer (Silastic, Dow Corning, Midland, MI) instead of bone in selected children. Since then, a variety of extraarticular subtalar joint implants for blocking in the sinus tarsi have been designed and implemented.[2] (Table 1) Geometrically, they may be block, sphere, peg cap, screw, free cylinder or expanding cylinder. They may be free-floating or fastened within the sinus tarsi. Materials

Table 1

HISTORICAL CHRONOLOGY OF SUBTALAR ARTHROEREISIS SINUS TARSI IMPLANTS

YEAR	SURGEON	IMPLANT NAME	MATERIAL
1946	Chambers	Autogenous wedging	Bone
1962	Haraldsson	Wedges	Bone
1970	LeLievre	Wedges	Bone
1974	Subotnick	Custom-carved block	Silastic
1976	Smith	STA-peg	Polyethylene
1976	Valenti	Valenti threaded cylinder	Polyethylene
1977	Vilodot	Viladot umbrella	Silastic
1978	Samuelson	Samuelson 2-component	PE + SS
1979	Lanham	Stem from Swanson gt. toe	Silastic
1982	Addante	Addante sphere	Silastic
1983	Sgarlato	Sgarlato mushroom	Silastic
1984	Pisani	Pisani capped screw	Silastic + SS
1985	Lundeen	STA-peg modified	Polyethylene
1985	Giannini	Giannini FF expanding implant	Teflon + SS
1999	Maxwell-Brancheau	MBA implant	Titanium
2001	Giannini	Giannini FF expanding implant	PLLA
2003	Viladot	Kalix	PE + Titanium

PE, ultra high molecular weight polyethylene; SS, stainless steel; PLLA, polt-L-lactic acid; MBA, Maxwell-Brancheau arthroereisis.

include Silastic, polyethylene, titanium, hybrid (metal and polyethylene), and absorbable poly-L-lactic acid. In the last five years, several different implants have been designed that are conical in design (Figure 1) so as to more easily fit into the conical anatomic shape of the sinus tarsi and perhaps be better tolerated. (Table 2) They are made of inert metals and function as spacers or self-locking wedges in the same manner as the Giannini or MBA arthroereisis implants.

Vogler[27] classified sinus tarsi implants into 3 categories based on their biomechanic functions: 1) the self-locking wedge (e.g., MBA implant); 2) the axis altering device (e.g., STA-peg implant); and, 3) the impact-blocking device (Sgarlato mushroom implant; Figure 2). Whatever the design, a subtalar arthroereisis implant blocks or restricts motion between the talus and calcaneus and beyond while preserving the joint itself. By restricting valgus and orienting the calcaneus more vertically beneath the talus and ankle joint, the subtalar joint axis is altered. With the hindfoot alignment corrected, midfoot and forefoot deformities can be reduced or corrected as well. Distally, the implants appear to correct more transverse plane deformity than frontal plane deformity such as forefoot varus.

Hussain and Fallat[28] demonstrated through biomechanic cadaveric analysis, that the MBA implant restricted postoperative valgus subtalar motion; the larger the implant, the greater the degree of decreased motion. In the 27 patients treated by Zaret and Myerson[16] for flexible flatfoot with the MBA implant alone, 16 had normal motion following surgery, 9 had a loss of 25% to 50% of motion and 2 patients lost 75% to 100% of motion.

By loading 25 normal cadaveric specimens implanted with the STA-peg implant Christensen et al[29] used statistically validated measurements to show improvement in the relationships of the 4 bones making up the subtalar and midtarsal joints. The results showed that the calcaneus and cuboid inverted, the talus dorsiflexed and externally rotated, and the navicular inverted, thus confirming the supinatory effects of the subtalar arthroereisis. They concluded that the subtalar joint arthroereisis did not alter the normal closed kinetic chain mechanics and acknowledged that similar testing should be done on flat feet to confirm their results. Watanabe et al[6,30] tested normal stance phase dynamics on 9 cadaveric feet comparing motions in normal feet, flat feet, and feet implanted with the MBA subtalar arthroereisis. They confirmed that the subtalar arthroereisis implant does not negatively affect the biomechanics of the subtalar joint while limiting excessive hindfoot motion.

Table 2

ARTHROEREISIS SUBTALAR SINUS TARSI IMPLANTS CURRENTLY AVAILABLE

NAME	MANUFACTURER
PEG DESIGN – AXIS-ALTERING IMPLANTS	
STA-peg	Wright Medical
Lundeen Subtalar Implant LSI	Sgarlato Labs
PEG DESIGN – IMPACT-BLOCKING IMPLANTS	
Angled Subtalar Implant ASI	Tornier, Inc.
Domed Subtalar Implant DSI	Nexa Orthopedics
BARREL DESIGN – SELF-LOCKING IMPLANTS	
MBA	Kinetikos Medical Inc./ Integra LifeSciences Corp
Kalix	Integra LifeSciences Corp.
Horizon	BioPro Implants
Subtalar Spacer STS	OrthoPro, LLC
Giannini Endo-orthotic	Spain
Resorbable bioBlock	Kinetikos Medical Inc./ Integra LifeSciences Corp
Giannini bioabsorbable	Spain
CONICAL DESIGN – SELF-LOCKING IMPLANTS	
Conical Subtalar Implant CSI	Tornier, Inc./Nexa Orthopedics
Talar-Fit	Osteomed
BIOARCH	Wright Medical
ProStop	Arthrex, Inc.
HyProCure	Gramedica Foot Cure Solutions
Sub-Talar Lok	Instratek, Inc.
TOV (Talus of Vilex) Implant	Vilex, Inc.

CLINICAL STUDIES OF ARTHROEREISIS IN PEDIATRIC PATIENTS

There have been numerous studies documenting the results of subtalar arthroereisis implants for the correction of flexible flatfoot in pediatric patients. Smith and Millar[31] placed 53 STA-peg implants made of ultra high molecular weight polyethylene in 27 children. With a minimum follow-up of 3 years, in 1983 they reported 96.2% satisfactory results. They noted complications in 2 patients (3.8%): reactive synovitis in 1 and calcaneal fracture with peroneal spasm after a fall in 1. Also 1983, Lundeen[32] reviewed the results of 96 Smith STA-peg implants placed in 49 pediatric patients ages 3-19 years (average 8 years) with an average follow-up of 46 months. He reported that 78% of the patients had good postoperative results with "good" defined as those in which the pes planovalgus deformity was reduced and associated symptoms resolved.

From a subjective questionnaire sent to patients in a study in 1983 by Smith and Rappaport[33] on the results of 68 Silastic block arthroereisis implants in children with an average follow-up of 2 years (range 4 months to 4 years), 94% of the patients reported a 50% or better improvement in their flexible flat feet.

Addante et al in 1992[34] published the results a long-term follow-up study of an arthroereisis implant procedure about which he presented initially in 1982.[35] His group implanted a Silastic sphere implant available in 5 sizes into the sinus tarsi of 25 feet in 15 patients and reported on the responses of 10 of the patients who underwent 16 implantations for treatment of painful flexible flatfoot deformity. Eight of the patients were children ages 6-11 years. Ninety percent of the patients had resolution of their pain symptoms to lead active daily lifestyles including sports activities over an average follow-up of 54.5 months (range 2-10 years) and responded that they would undergo the procedure again. There were no complications.

Tompkins et al[36] in 1993 evaluated the results of 41 STA-peg implants as the sole procedure performed to correct flexible flatfoot in 23 pediatric patients with an average age of 8.9 years (range 5-16 years) at an average follow-up of 32.6 months (range 12-78 months). They observed 95% satisfactory or better results (58.4% optimum, 36.6% satisfactory) using the same evaluation system as Smith and Millar.[31] In the 2 patients (5%) with

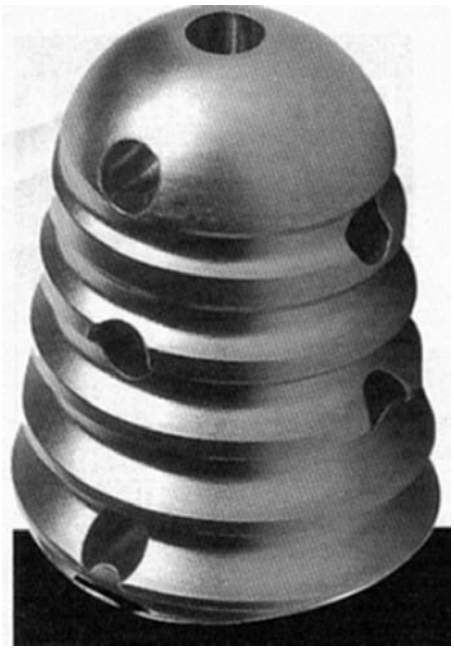

Figure 1. The Conical Subtalar Implant (CSI) was the first subtalar arthroereisis implant designed (by Futura Biomedical, Vista, CA) to fit more anatomically into the sinus tarsi.

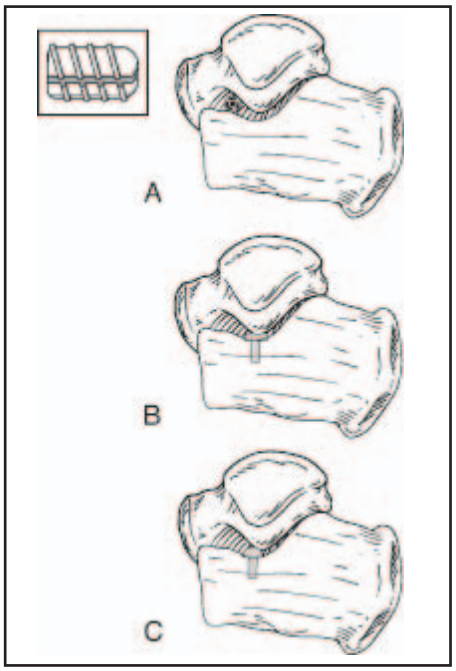

Figure 2. Biomechanical Classification of Subtalar Arthroereisis Implants. A. Self-Locking Wedges. The MBA implant shown here, as well as other barrel and conical designed spacer devices, function by blocking excessive motion between the talus and the calcaneus, thereby preventing contact of the lateral process of the talus with the floor of the sinus tarsi. B. Axis-Altering Devices. The STA-peg implant and its variations changes the axis of the subtalar joint by serving as an extension of the posterior calcaneal facet and redirecting the posterior facet of the talus. C. Direct-Impact Devices. These impact-blocking implants such as the Sgarlato "mushroom" implant (designed by Futura Biomedical, Vista, CA) and the Domed Subtalar Implant (DSI) from Nexa Orthopedics as well as the various screw implants serve to restricting the lateral process of the talus from advancing forward past the posterior facet of the calcaneus. This differs from the self-locking wedge in that motion is limited by contacting only the talus instead of blocking approximation of two bones by contact on either side of the implant.

unsatisfactory (symptomatic) results, one had a painful lack of correction while the other developed painful subtalar arthritis.

In 1998, Vedantum et al[37] reported on the results of 140 STA-peg arthroereisis procedures in 78 ambulatory children with neuromuscular disorders at a mean follow-up of 54 months. Using the presence of pain and the correction of the deformity as the primary criteria of satisfaction, they noted satisfactory outcomes in 96.4% of the feet. Of the 3.5% (5 feet) with unsatisfactory results, 4 were overcorrected and one had persistent pain; all involving one each of the 5 bilateral feet receiving implants.

Grady and Dinnon in 2000[38] evaluated the results of implanting a STA-peg arthroereisis implant alone in the feet of 46 children between the ages of 6 and 13 years. Clinically, they measured a reduction in the resting calcaneal stance position angle from 11.5 degrees to 1.5 degrees with a subjective average pain reduction from 6.4 to 0.1 on a scale of 1-10, 10 being the worst pain.

In 2001, Forg et al[39] presented their study of 21 pediatric patients with an average age of 9.7 years (range 4-16 years) who received 40 disk and peg modified STA-peg arthroereisis implants (Flake-Austin technique, Figure 3). Their results at a follow-up period averaging 36 months (range 12-90 months) demonstrated very successful outcomes with no patient's condition worsening. The study found that 71% of the patients were at least 90% improved, while 14% were at least 70% improved in symptoms. The authors also observed that the most significant changes to the forefoot were more in the transverse plane than in the sagittal plane. All patients in their study described a substantial decrease in preoperative symptoms after their surgery, except for a slight increase in the incidence of night cramps, which were thought to be due to the increased activity level when their severe symptoms decreased.

Giannini presented in 1985[40,41] the use of a new arthroereisis spacer implant he designed composed of a metal screw within a hollow Teflon cylinder with 4 expandable fins that expand as the implant is advanced into the sinus tarsi (Figure 4). He stated that 94% of the first 50 pediatric patients between ages 8-12 years that received

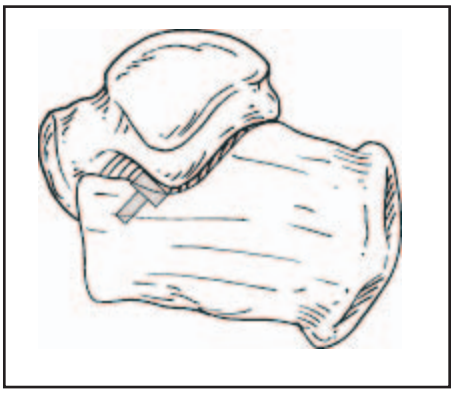

Figure 3. Flake-Austin Technique for STA-peg implant. The STA-peg device is placed on an angle so as to block the forward motion of the talus, thus converting its function to a direct-impact implant.

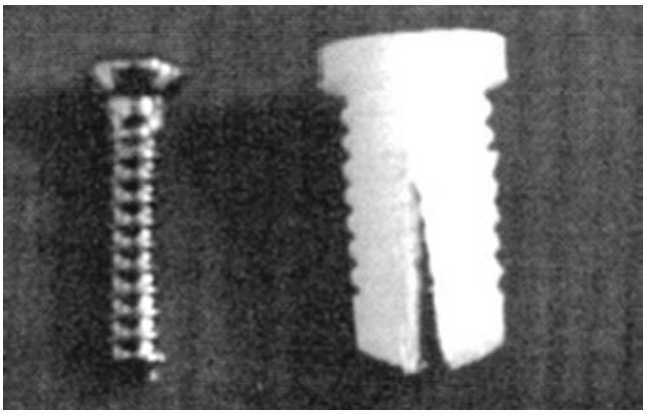

Figure 4. Giannini Non-bioresorbable implant. This is a two-part self-locking implant made of polyethylene with an internal stainless steel screw that expands the fins as it is turned.

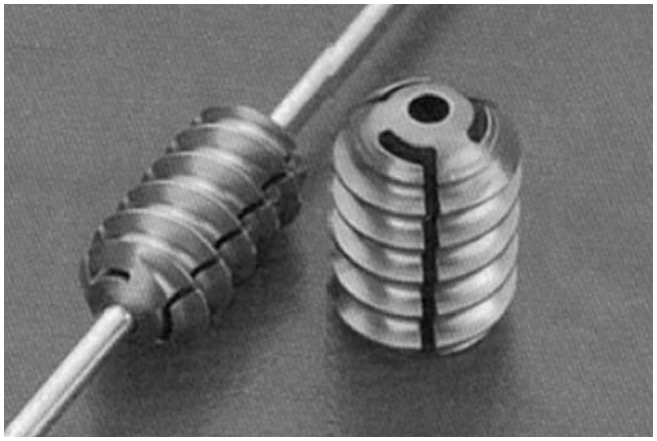

Figure 5. Maxwell-Brancheau Arthroereisis (MBA) Implant. This was the first arthroereisis implant fabricated (by Kinetikos Medical, Inc, Carlsbad, CA) completely of metal (titanium). It is cannulated and threaded with unique slots incorporated into the design for tissue ingrowth.

this implant had good results.[4] The implant was removed at 1-year postoperatively. He then modified the design into an absorbable implant composed of poly-L-lactic acid (PLLA). The device resembled a 2-piece dry-wall fastener that has fins that expand as the central screw is advanced. Giannini placed the implant in both feet of 21 children (42 feet) and, after following them for 4 years, observed in his 2001 paper[42] that of the 81% of the children experiencing painful feet before surgery, only 5% had pain at follow-up.

A more recent study of the Giannini arthroereisis implant by Gutierrez and Lara in 2005[43] looked at the "endo-orthotic" device placed in 65 feet of 37 pediatric patients with an average age of 9.4 years (range 5-14 years) and an average follow-up of 26.5 months (range 13-51 months). Selecting from 4 sizes, they were inserted bilaterally in 30 patients and in 1 foot in 9 patients. All patients had painful flexible flatfeet and met 9 other criteria to be eligible for the surgery. Postoperatively, pain was reported in only 4 (6.2%) of the 65 feet and a sensation of tiredness or fatigue in 3 (4.6%), while 19 patients (51.4%) who had not participated in sports prior to surgery took up rather vigorous athletics after surgery.

Brancheau et al[44] presented a paper in 1996 on the use of the barrel-shaped Valenti arthroereisis implant made of ultra high molecular weight polyethylene. A total of 18 patients with an average age of 8.8 years (range 4-12 years) at the time of surgery had 34 implants placed and were followed over an average of 32.6 months (range 5-120 months). All 18 patients reported painful symptoms preoperatively as a result of flexible flatfoot. Although 2 patients (5.9%) had occasional pain postoperatively, it resolved in both of them using conservative treatments, and the overall observation was a complete resolution of painful symptoms in all patients in the study The patients all reported an increase in activity level with decreased postural symptoms and a decrease in arch pain. There were no complications. The authors also observed that equinus contracture requiring gastrocnemius recession for lengthening was more evident in the older children (11.4 years versus 7.1 years), concluding that it was a secondary adaptation of their flatfoot and not the primary deforming force.

In 1997, Maxwell et al[45] delivered a paper on the early prospective results of the threaded and slotted barrel-designed Maxwell-Brancheau arthroereisis (MBA) implant made of titanium alloy (Figure 5) in 22 flexible flat feet and 5 feet with a tarsal coalition where the coalition was resected and the implant inserted. This study involved 17 pediatric patients with an average age of 10.9 years (range 6-16 years) and an average follow-up of 6.9 months (range 3-18 months). Although they reported only on the clinical improvement in the realignment of the feet, they did observe 1 complication in a patient who had undergone bilateral reconstruction.

Zaret and Myerson[17] in 2003 published a study of the MBA subtalar sinus tarsi implant in which they critically reviewed the device as well as the results from a mixed population study consisting of 12 implants in adults and 31 implants in 23 children (age 8-18 years). Due to recalcitrant sinus tarsitis, only 2 children had to have their implant removed. Interestingly, their corrected foot structure did not reverse, an observation also made by Giannini[4] after removal of his arthroereisis implants approximately 1 year after placement without degradation of foot function.

In 1992, Viladot[46] reported on the results of inserting his Silastic wine-glass or umbrella-shaped arthroereisis implant into 234 feet of children 5-15 years for the correction of painless flexible flatfoot. At a follow-up of 1 to15 years, he reported excellent results in all 234 feet using clinical, radiographic, and pedobarographic parameters with little or no discomfort and a return to preoperative levels of activity including sports. One implant had to be removed but the foot did not lose any of the corrected position. Carranza-Bencano et al in 1997[47] used the Viladot implant in 77 flatfeet in 43 children aged 6-15 years and followed them for 6-14 years. In 24 cases (31%) Achilles lengthening was also performed. They observed that 88% were asymptomatic (good or excellent) with 3% showing undercorrection (fair) and 9% (7 feet) poor. Two implants had to be removed due to infection but did not result in loss of the correction achieved by surgery.

In spite of the results of these two studies as well as 8 other studies in foreign journals,[47] Black et al[48] had almost completely contradictory findings in their limited study presented in 2000. They placed 22 implants of the Viladot design into the feet of 15 children ages 5-14 years with painless flexible flatfeet and followed them for an average of 35 months (range 11-54 months). Although there were no complications from the surgery itself, virtually all of the patients had loss of correction and none were completely pain-free with 73% reporting that their feet were significantly painful. The authors did not lengthen the Achilles tendon in any of their patients. Their study has not been duplicated.

More recently, there have been several papers published, each reviewing fairly large series that involve the percutaneous placement of a screw either in the roof (talus) or floor (calcaneus) of the sinus tarsi, oriented so the head acts as an athroereisis stop to block motion between the talus and calcaneus. In 1997, Magnan et al[49] obtained 83% good results in 475 patients in which they used this "calcaneo-stop" method with an average follow-up of 20 months (range 12-112 months). De Pellegrin[50] in 2005 utilized the procedure in 226 flexible flatfeet in 152 children with an average age of 10.6 years (range 6-13 years) and reported 95.4% good results with 4.6% complications. At an average of 2.9 years since implantation, 55 screws had been removed. In 2007, Roth et al[51] performed this screw arthroereisis procedure in 94 feet of 48 children between the ages of 8 and 14 years and followed them for an average of 60 months (range 38-112 months). The screws were removed from all feet at approximately 30 months, sooner for the younger patients. Eighty-six children (91.49%) had good and excellent results and eight (9%) had poor results, mostly (7%) due to incorrect screw positioning. They reported complications in 11 feet (12%) which included 9 of their technique.[52,53]

Nelson et al in 2002[4] presented the results of an interesting study that looked not only at the changes in angular radiographic relationships of the osseous structures of flexible flatfeet after surgical correction with the MBA arthroereisis implant but also utilized the Child Health Assessment Questionnaire (C-HAQ) to determine the effect of the procedure on the overall health of the children. The C-HAQ evaluates the quality of life in children 5 years and older by measuring 15 unique physical function and psychosocial health concepts plus interpersonal relationships with parents. The results are then compared to a validated child's normal values within the same age group and to children with juvenile rheumatoid arthritis. Nelson's group studied MBA implant results in 67 feet of 37 patients, 34 of whom were pediatric patients with an average age of 11.9 years (range 6-17 years) at the time of surgery. The mean time follow-up review was 18.4 months at which 27 of the 34 pediatric patients completed the C-HAQ. The results were remarkable in that the children functioned as well as the population norms in their same age group as soon as 4 months after the surgery.

COMPLICATIONS OF THE ARTHROEREISIS IMPLANTS IN CHILDREN

Reports of complications of arthroereisis implants to correct the pediatric flatfoot have been summarized in review articles[27,54-56] and presented in clinical series or case reports. Almost all clinical series report complications well under 10%. The most common complication is pain, usually at the sinus tarsi site: local irritation termed "sinus tarsitis," "sinus tarsalgia," or "lateral impingement pain"[57] due to local irritation, or reactive synovitis from the implant material.[54] These problems usually respond to conservative care such as rest, temporary and slightly inverted casting, orthotic devices, heel lifts, physical

Table 3

COMPLICATIONS OF THE SUBTALAR ARTHROEREISIS IMPLANT PROCEDURE

INAPPROPRIATE APPLICATION
- Unstable midtarsal joint
- Advanced arthrosis/arthritis
- Rigid flatfoot (if bar not removed)
- Uncorrected ankle equinus

SURGEON MISJUDGEMENT
- Overcorrection
- Undrecorrection
- Extrusion
- Subluxation

ADAPTATION/IRRITATION
- Sinus tarsitis
- Peroneal spasm
- Soft tissue entrapment

NERVE ENTRAPMENT
- Loosening

BIOMATERIAL FAILURE
- Breakage
- Excessive wear

REACTIVE SYNOVITIS

LOCAL EROSION

therapy, and steroid injections.[57] On relatively rare occasions following the arthroereisis implant in children, the implant must be removed due to complications; it may be replaced at the same operation with an implant of different size or type or position, usually with good results of less or complete relief of pain. If the implant (various designs) is removed, it has been observed that the position of the foot remains corrected in the children.[4,17,51,58,59] Postoperative trauma to the surgical site is frequently reported as the cause for pain and reoperation.[31,32,39,58]

Miller divided complications into 4 categories as outlined in Table 3.[60] They include inappropriate application, surgeon error, adaptation/irritation, and biomaterial failure. The STA-peg, with more than 25 years of use, has had reports of limited incidences of loosening, synovitis, arthritis, wear fragments, foreign body reaction, implant fracture, and one report of degenerative arthritis in the subtalar joint.[36] Bilateral talar intraosseous ganglion cysts were observed in an athletically-active 15-year-old patient.[59] Kuwada and Dockery[58] presented 3 case reports of complications of the STA-peg in children due to traumatic incidents. The first was sinus tarsi pain and peroneal spasm from dentritic synovitis after a skiing injury. The second was a nondisplaced fracture of the calcaneus from a bicycling injury. The third involved residual sinus tasi pain following an eversion ankle injury. Exploration at surgery revealed a spur on the anterolateral edge of the talus, erosion of the cartilage on the anterior leading edge of the talus, and dentritic synovitis.

Smith and Millar[31] reported 2 complications (3.8%) in their series on the STA-peg implant, both from subsesquent trauma. One developed synovitis following an ankle sprain and the other a local calcaneal fracture. Lundeen's series[32] on the STA-peg had 19% fair results attributed to metatarsus adductus (n = 4) and midtarsal breach instability (n = 10). He had 3 poor results, 2 as a result of trauma where the patients fell out of trees and 1 where the implant loosened and had to be reimplanted. He also observed that 2 patients showed gradual flattening of the lateral process of the talus and "occasional spur formation at the point of contact of the lateral talar process with the polyethylene peg." In their 1984 review of 20 patients with the STA-peg implant, Smith and Wagreich[61] noted no abnormal radiographic signs at 25.9 months mean follow-up. Oloff et al[62] found that 6 of 23 patients implanted with the STA-peg arthroereisis had residual symptoms. All 6 underwent computed tomography (CT) scans. Three studies were read as normal and the patients symptoms spontaneously resolved. The scans of the other 3 patients revealed improper medial positioning of the implant, implant extrusion laterally, and dentritic matter. It has been found that for these arthroereisis implants, the best investigation study beyond radiographs is the CT scan and guidelines for reading them have been published.[63]

The 5% complication incidence reported by Tompkins et al[36] consisted of 2 patients, one with painful lack of correction and the other, 14-years-old, developed subtalar arthritis thought to be due in part to the patient's weight and activity level. They observed that over 50% of the 41 feet in their study demonstrated mild postoperative radiographic changes in the lateral process of the talus and/or the floor of the calcaneus. However, all of these 21 feet had either an optimum or satisfactory result and all patients were completely satisfied with their result. Forg et al[39] reported that 3 patients with 4 implants (10%) had postoperative pain: 1 after a sports injury which was resolved after a second surgery; 1 whose sinus tarsi pain decreased to an acceptable level with injection therapy; and, 1 whose pain persisted even after removal of her implants, but left her better off than prior to the original surgery.

In Giannini's series on his bioresorbable implant,[42]

there were 2 patients with complications (4.8%) with a follow-up of 4 years. Small implant fragments migrated under the skin in 2 feet causing local irritation. In the study of his Teflon implant,[40] he routinely removed the implant at 1 year. Gutierrez and Lara[43] described complications in 10.7% of the patients with pain being the most common (6%). There were no foreign body reactions or infections but if pain persisted over 6 months the implant was removed, a procedure that was necessary in 7.5% of the feet.

In 1997, Verheyden et al[64] presented a study on their use of the subtalar arthroereisis Teflon spacer implant that was designed by Giannini et al.[40] They reported a high incidence of postsurgical foot pain plus a high rate of implant dislocation. This was in contrast to the good results obtained by Giannini[40,42] and subsequently by Gutierrez and Lara in 2005.[43] In his review paper on the arthroereisis implant, Needleman[2] presented a compelling analysis that pointed out improper technique and application of the implant by Verheyden et al who evacuated the fat pad from the sinus tarsi and cut the deep interosseus ligament. These soft tissue structures were preserved by Giannini et al thus preventing bone and joint irritation leaving tissue to secure local fixation of the implant within the sinus tarsi. Attention to technique compatible with the design of the implant was noted as an important consideration for successful placement of the device.

Maxwell et al[45] in their clinical series on 27 pediatric feet had only 1 complication in a patient with bilateral MBA implants (3.7%). One implant apparently displaced medially causing pain and had to be removed. The contralateral foot healed without complication. Out of 31 MBA implants in pediatric patients, Zaret and Myerson[17] due to recalcitrant sinus tarsitis, had only 2 explantations, a complication incidence of 6.5%. In the study of Nelson et al[4] involving 34 pediatric MBA implants, 2 patients (5%) required removal of the implant and 2 patients (5%) needed a readjustment of the implant.

DISCUSSION

Flexible flatfoot in children has been shown to have a pathologic incidence of 2.7%[65] to 4%.[5,43,66-69] In reviewing the natural history of the feet of 377 preschool children, Lin et al[70] identified a decrease in the incidence of flexible flatfoot, including severity, with age and increased body height and weight: 57% of children at 2 to 3 years had moderate (43%) or severe (14%) flatfeet; 40% at age 3 to 4 years had moderate (31%) or severe (9%) flatfeet; 28% at age 4 to 5 years had moderate (24%) to severe (4%) flatfeet; and, 21% at age 5 to 6 years had moderate (19%) to severe (2%) flatfeet. This was supported by Garcia-Rodriguez et al[65] who found the highest incidence of flexible flatfeet in their youngest age group (4 to 5 years). Lin's group concluded, "The clinical significance of flexible flatfoot in preschoolers can be of great concern for their parents and should never be underestimated. Flexible flatfoot must be regarded not only as a problem of static alignment of the ankle and foot complex, but also as a dynamic functional abnormality of the lower extremity." Therefore, the first consideration when evaluating the pediatric flexible flatfoot is to differentiate between its physiologic and pathologic forms.

The diagnosis of flexible flatfoot has been well-defined with both physical findings and weight bearing radiographic measurements. The indications for surgical intervention in children with flexible flatfoot have been identified with the precautions that it should seldom be necessary. Sometimes the deformity can be corrected with a single procedure, but more frequently multiple procedures are required. Depending on the structural planal dominance as well as the age and associated deformities, the extraarticular subtalar arthroereisis implant procedure can be utilized alone or in combination with other procedures.

Needleman[2] pointed out that the results in the clinical papers of Verdantum et al[37] and Giannini et al[42] of subtalar athroereisis implants in children compare favorably with Mosca's series,[15] involving the Evan's anterior osteotomy, subsequently claimed to be treatment of choice for flexible flatfoot.[9,71] To these supportive studies can be added the subsequent studies cited and summarized in this paper regarding the Valenti arthroereisis implant,[44] the Giannini implant,[43] and the MBA implant (Table 4).[4,17,45] The studies of the use of the screw as the implant of choice as an arthroereisis stop with their long-term follow-up serve to reinforce the efficacy of the subtalar arthroereisis procedure to correct flexible flatfoot and maintain correction after the implant has been removed, even though it is a bone-invasive operation.[49-53] They also obviate the questioning of the placement of a relatively inert implant into the foot of a child when the beneficial results with limited complications have been well-documented.

Some authors have advocated for patient-matched prospective studies[9] and long-term studies.[72,73] Others have cautioned that the arthroereisis implant is being over-utilized, although they failed to present any statistics to support their observation.[13] Studies of the implantation as an isolated procedure are difficult to do because it is seldom done alone in children. Trying to perform clinical studies using matched patients or a control cohort are also challenging because for each patient implanted, one patient is denied this surgical treatment. Probably the best

Table 4

COMPARISON OF TREATMENT OF PEDIATRIC FLEXIBLE FLATFOOT: Subtalar Arthroereisis vs Other Studies

LEAD AUTHOR (DATE OF PUBLICATION)	GUTIERREZ (43) (2005)	GIANNINI (42) (2001)	VEDANTUM (37) (1998)
Country	Spain	Italy	USA
Procedure	Subtalar arthroereisis	Subtalar arthroereisis	Subtalar arthroereisis
Implants	Giannini flatfoot implant	Giannini flatfoot implant	STA-peg
Material	SS screw inside Teflon	PLLA – bioresorbable	Polyethylene
Feet	69	42	140
Patients	39	21	78
Age (av – range)	9.4 (5-14)		
Diagnosis	Flexible flatfoot (FF)	100% flexible FF	100% neurologic FF
Preop Evaluation	100% symptomatic	81% discomfort	
Postop Evaluation	95.8% pain-free	5% discomfort	96.4% satisfied
F/U (mean-months)	26.5 +/- 12.7	48	54
% Implants Removed	7.5%	0%	3.6%
Achilles Lengthening	38 (59%)		

LEAD AUTHOR (DATE OF PUBLICATION)	MAXWELL (45) (1997)	BRANCHEAU (44) (1996)	MOSCA (15) (1995)
Country	USA	USA	USA
Procedure	Subtalar arthroereisis	Subtalar arthroereisis	Evan's calcaneal osteoty
Implants	MBA implant	Valenti threaded	Steinman pin 8/27
Material	Titanium	Polyethylene	SS
Feet	27	34	31
Patients	17	18	20
Age (av – range)	10.9 (6-16)	8.8 (4-12)	10.5 (4-16)
Diagnosis	22 FFF; 5 coalition	100% flexible FF	93% neurologic FF
Preop Evaluation	100% symptomatic	100% symptomatic	93% callus & 59% pain
Postop Evaluation	96.3% relief	100% asymptomatic	93% satisfied
F/U (mean-months)	6.9	32.6	32
% Implants Removed	3.7%	0%	30%
Achilles Lengthening	19 (70%)	10 (29)	19 (61%)

Adapted with permission from Needleman RL: Current topic review: subtalar arthroereisis for the correction of flexible flatfoot. Foot Ankle Intl 26:336-346, 2005.

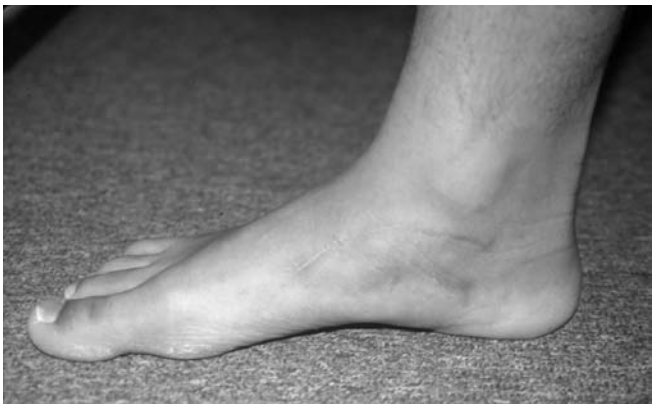

Figure 6A. Clinical view of right foot eleven years after STA-peg arthroereisis, medial arch reconstruction and Achilles lengthening procedures when patient was 5 years old.

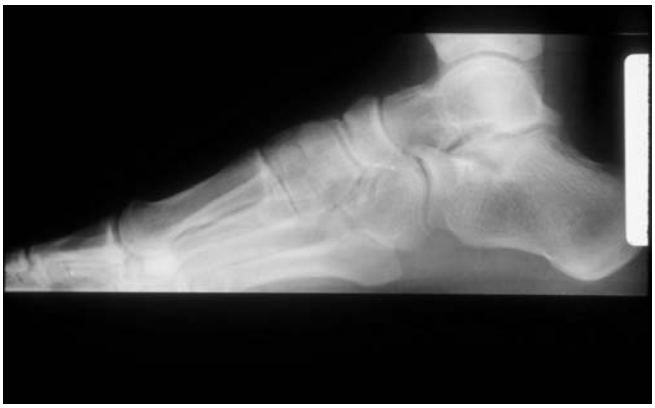

Figure 6B. Radiographic view.

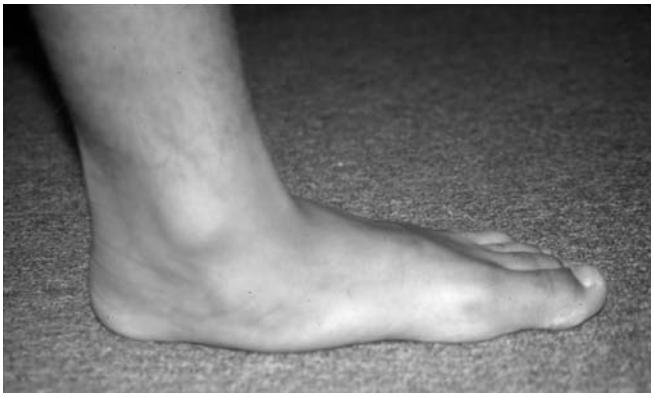

Figure 6C. Clinical appearance of uncorrected left foot in same patient at 16 years of age.

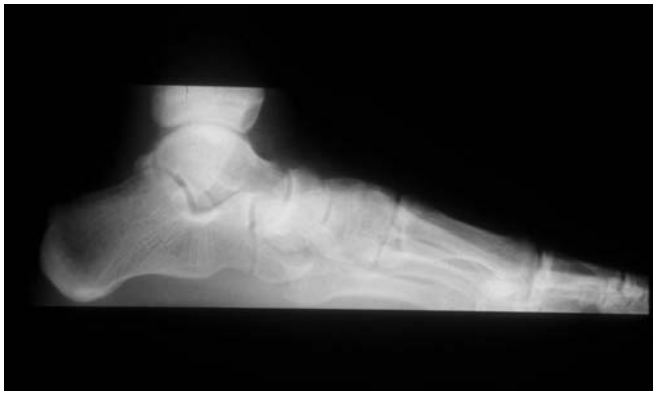

Figure 6D. Radiographic view.

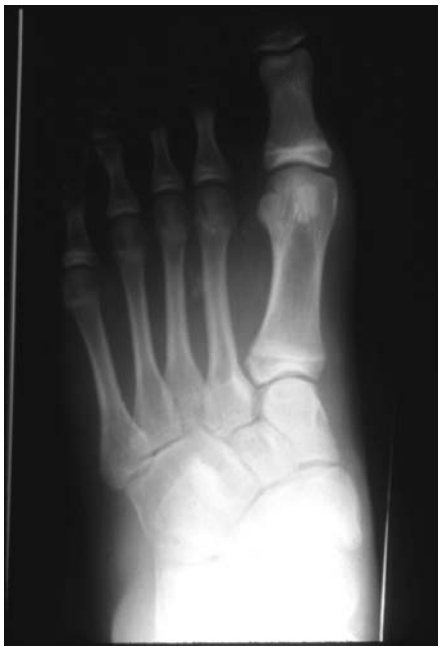

Figure 6E. AP radiograph of patient JE, left untreated; right foot aligned after 11 years.

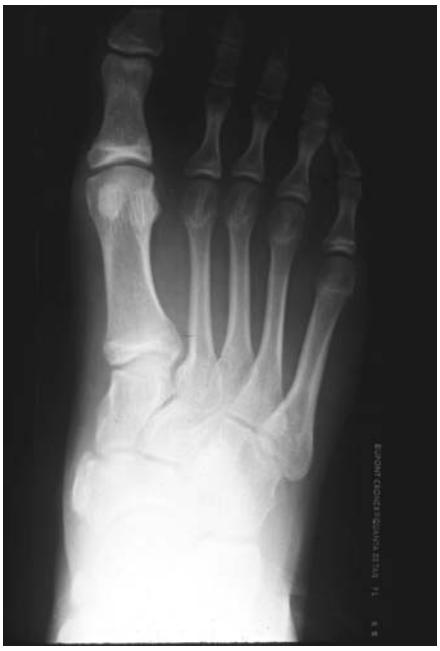

Figure 6F. AP radiograph of patient JE.

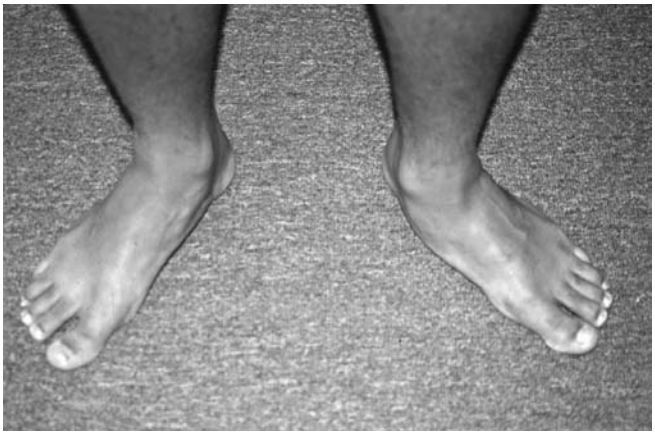

Figure 6G. Anterior clinical view of feet of patient JE. Left untreated flexible flatfoot; right remains corrected eleven years postoperatively.

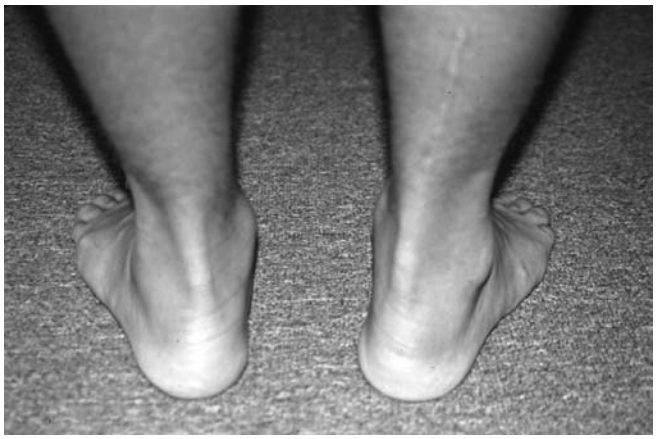

Figure 6H. Posterior clinical views of feet of patient JE. Left untreated flexible flatfoot; right remains corrected eleven years postoperatively.

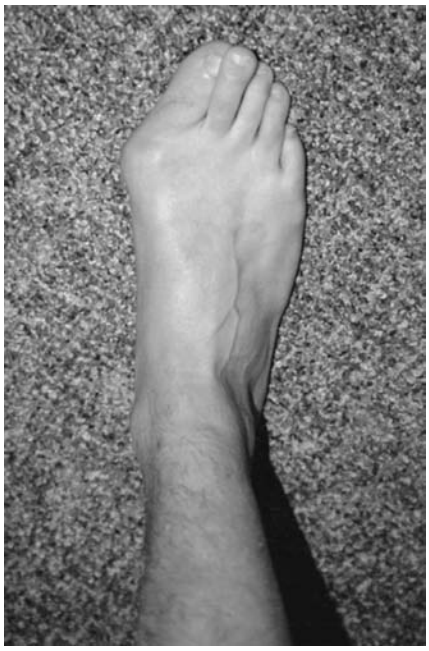

Figure 7A. Right foot: Preoperative AP clinical.

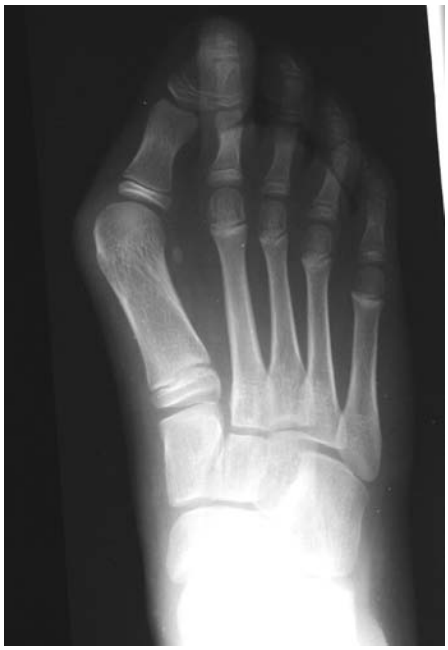

Figure 7B. Preoperative AP x-ray.

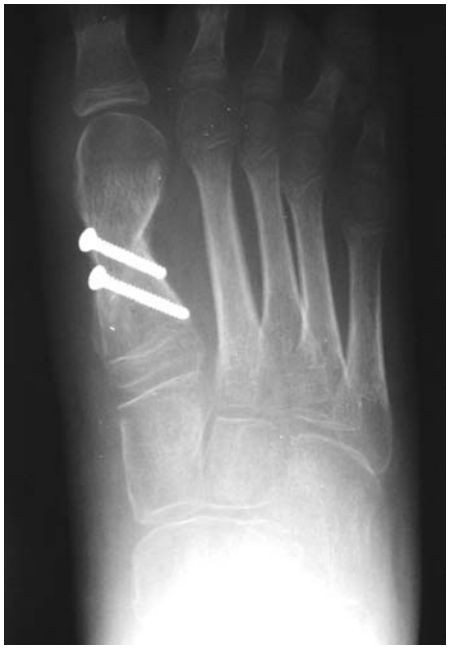

Figure 7C. Postoperative AP x-ray.

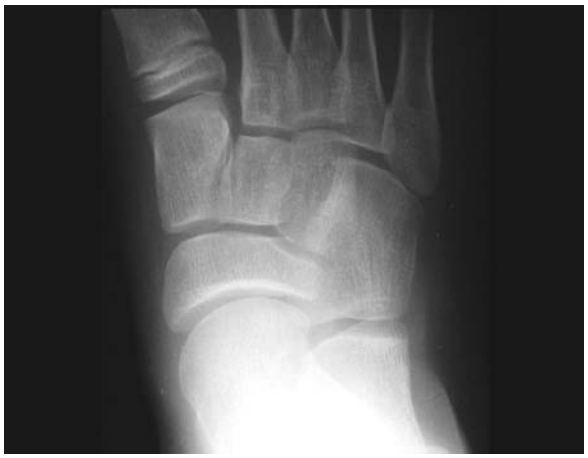

Figure 7D. Preoperative AP midfoot x-ray.

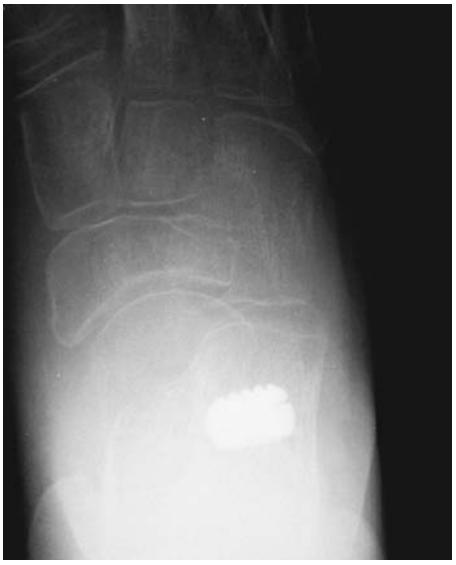

Figure 7E. Postoperative AP midfoot x-ray.

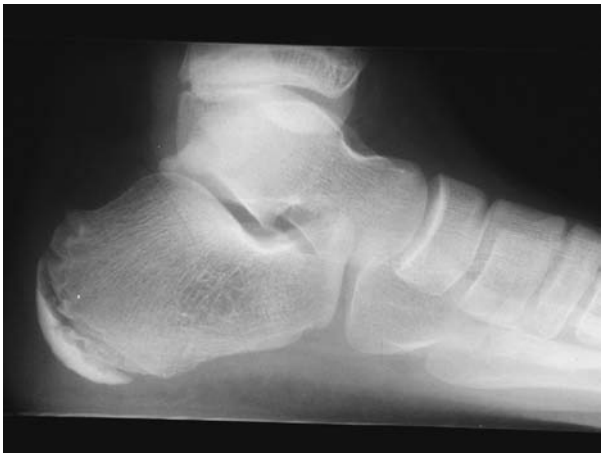

Figure 7F. Preoperative lateral rearfoot x-ray.

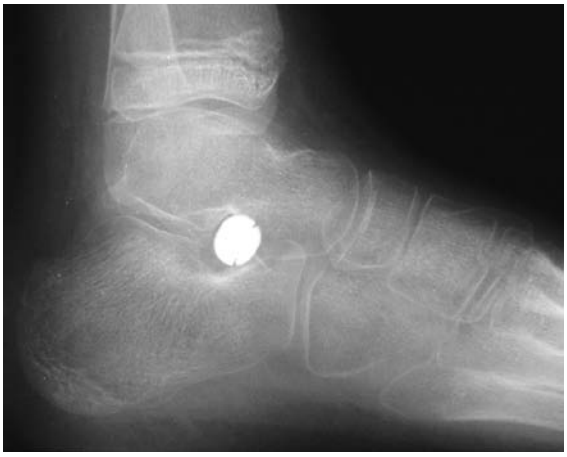

Figure 7G. Postoperative lateral rearfoot x-ray.

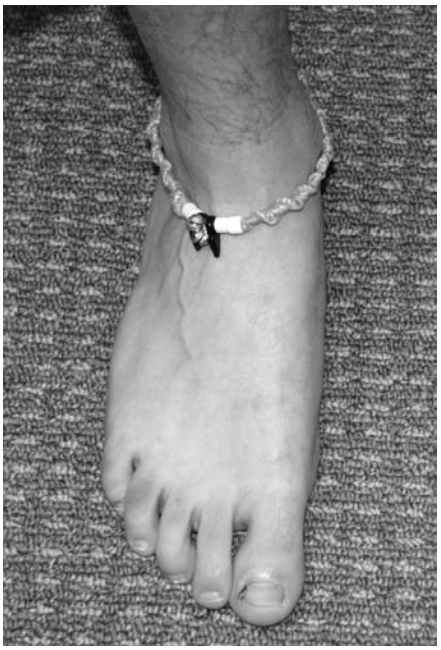

Figure 8A. Anterior view of right foot clinical photograph at six years after MBA arthroereisis implant and hallux valgus repair.

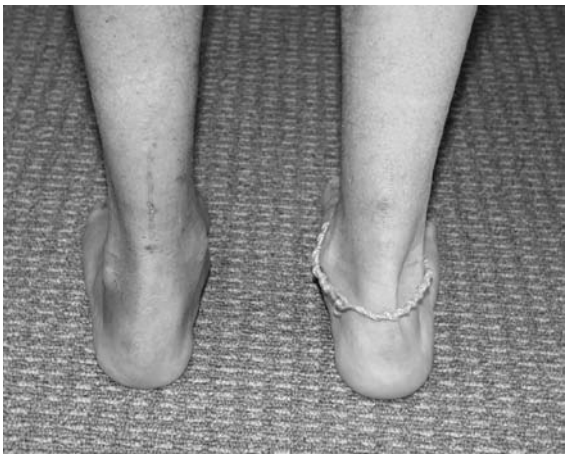

Figure 8B. Posterior view of both feet comparing corrected right with uncorrected left at six years.

example of a utilizing a control is by performing the arthroereisis implant correction on one flexible flatfoot and comparing it with nonoperated contralateral flexible flatfoot in the same pediatric patient, then reevaluating both feet over time. Although this would border on unethical for a prospective study, the 2 cases presented below demonstrate the beneficial results of the subtalar arthroereisis implant procedure under these circumstances.

Case 1

JE was a 5-year-old boy when he was presented by his mother for treatment of intractably painful flexible flatfeet. He was physically large for his age and had failed conservative treatment. Since his right foot was more painful it was selected for the first foot to be surgically corrected. The procedures utilized were gastrocnemius recession, a STA-peg arthroereisis implant, and a medial arch soft tissue reconstruction using a combination of a modified Young's tendosuspension and a modified Kidner procedure. Due to a change in his Medicaid insurance coverage, the left foot was never surgically corrected. However, eleven years later, at the age of 16, he returned to the office with his mother as he was having considerable increased pain in his left foot after starting football on the freshman squad. He was evaluated, and the contrast between the feet was dramatic. The surgically corrected foot, pain-free, had developed normally and was maintained in its realignment while the nonoperated foot had progressed into an adult acquired flexible flatfoot, never morphing into a normal foot by natural history (Figure 6). This case clearly demonstrates the long-term success of the arthroereisis implant and the negative results of lack of correction in the same patient. Interestingly, the mother requested the same procedures to correct JE's left foot. It was pointed out that unfortunately, due to the fact that the left foot had acquired many adaptive changes, the arthroereisis procedure would no longer be an indicated surgical approach to achieve correction for his foot.

Case 2

A combination of bilateral painful pediatric flexible flatfoot and juvenile hallux valgus deformity were the complaints that brought 12-year- old BR to the clinic. His parents were frustrated because his ongoing complaints were not responding to orthotic therapy and multiple shoe changes and they were being told that "he would grow out of it." He subsequently underwent a corrective surgery on the more symptomatic right foot to repair the hallux valgus deformity with an osteotomy at the base of the first metatarsal and to correct the flexible flatfoot with the placement of an MBA arthroereisis implant. An Achilles lengthening was not necessary (Figure 7). Due to a temporary loss of the family's health insurance, the left foot did not undergo surgical correction. Nevertheless, six years later, the left foot pain intensified and the patient was brought back to the clinic with a request for corrective surgery since updated orthotics were unsuccessful and activities were being curtailed. Again, the previously corrected right foot, realigned via the joint-sparing arthroereisis implant procedure, had been allowed to grow naturally into a functionally normal foot, in spite of BR's mild tibial varum (Figure 8). The left foot had not developed into a normal foot on its own, but had adaptive changes evident in addition to the persistent characteristics of a flexible flatfoot. He had not "outgrown" the symptoms or the deformities.

In each of the 3 reviews in the American orthopedic literature of the treatment of flatfoot,[9,71,73] as noted by Needleman,[2] the authors stated that they had seen complications from the arthroereisis implant but had never done the procedure. Other authors have stated that the indications for the arthroereisis "remain controversial in the surgical community"[1,13] or "not clearly defined."[15] Harris et al cited[1] 11 references, 9 of which clearly defined their indications for the procedure while 1 paper was a case report on an unusual application for a convex pes valgus deformity. They clearly demonstrated a lack of experience with the arthroereisis procedure, allotting it only 4 sentences in their sentinel Clinical Practice Guidelines: Diagnosis and Treatment of Pediatric Flatfoot. Soomekh

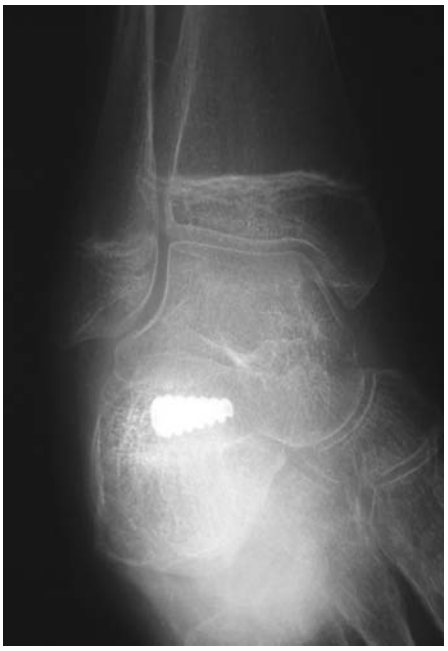

Figure 9. Example of implanted conical self-locking arthroereisis subtalar device.

and Baravarian[13] cited virtually the same unfounded references as Harris et al but felt that the arthroereisis procedure had a clinically-supported place in the surgical management of the pediatric flatfoot. They concluded that the arthroereisis procedure was excellent in select pediatric cases with minimal midfoot transverse plane deformity and mild to moderate hindfoot valgus, with the precaution that it may accentuate any forefoot varus deformity present.

CONCLUSION

As already noted, the primary goal for correction of any foot deformity should be to achieve the best correction while preserving as much of the joints and their function as possible.[13] This is especially critical in children so as to encourage normal joint motion and not impede or disturb growth. Such a philosophy favors the joint preserving arthroereisis procedures and osteotomies over arthrodesis for the pediatric flatfoot, especially with regard to the subtalar, talonavicular and calcaneocuboid joints. The arthroereisis procedure truly meets these criteria in that, with the least amount of invasion and risk of morbidity, it restores and maintains the physiologic alignment between the talus and calcaneus while allowing the bones of the foot to remodel to normal functional anatomy during the subsequent period of growth,[3,27,31,38] Thus, at skeletal maturity, the result is a more biomechanically stable foot secondary to the adaptive soft tissue and osseous changes.[36,43] Compared with procedures that involve osteotomy or arthrodesis, with arthroereisis there is less morbidity to the patient and there is no risk of nonunion plus less immobilization is usually necessary and the procedure is technically easier to perform.[17]

With these compelling reasons, then, the extraarticular subtalar arthroereisis implant has been advocated as an "internal orthosis,"[74] "internal orthotic device,"[75] or an "endorthotic"[40,41] for the surgical correction of excessive pronation, hyperpronation, or lateral peritalar subluxation, terms used to describe pathologic flexible flatfoot. Some authors believe that it should be used only temporarily in children and adolescents,[40,41,50,74] to be explanted usually after 1 year or more. Whether to subsequently remove the arthroereisis implant from pediatric patients is a question that has yet to be answered because long-term studies of these implants into adulthood are lacking. Nevertheless, after over 30 years of use there is only 1 report in the literature of significant complications in an adult who had subtalar arthroereis implants placed when they were children or adolescents.[76]

The arthroereisis implants have also been used successfully to correct rigid flatfeet in selected children with tarsal coalitions.[17,45,77] The technique involves resection of the tarsal coalition, thereby converting it to a flexible flatfoot, followed by placement of the implant into the sinus tarsi to help realign the talus with the calcaneus and reduce or eliminate the preoperative pain. It has also been successfully implemented to help correct a pediatric vertical talus deformity.[78]

Clearly, this review paper demonstrates favorable long-term outcomes of the subtalar arthroereisis implant procedure in pediatric patients for flexible flatfoot and selected cases of rigid flatfoot, satisfying the reservations of Peters and Sammarco[72] and Murphy[73] as well as Roye and Raimondo,[9] and Mosca.[15,71] Complications are relatively few, often due to trauma unrelated to the surgery, usually easily resolved and rarely debilitating. Judging by the literature, refinement in the design of the implant over the years has lead to a decrease in reported complications. The conical subtalar arthroereisis implants, other than being more anatomically designed, function the same as the barrel-shaped self-locking devices (Figure 9).

By measuring radiographic parameters of foot structure and alignment preoperatively and post-operatively, numerous studies have shown conclusively that the arthroereisis implant operation in children correctively re-aligns the flexible flatfoot to improve function.[4,26,32-34,36,39,43-47,51,61] It also appears that the literature review reveals better clinical results for the subtalar arthroereisis implant when treating the painful, rather than the painless, pes planus deformities in children and adolescents.[17]

Besides the STA-peg implant's proven success in multiple studies, the arthroereisis sinus tarsi spacer implants such as the Giannini design[40-43] and the MBA implant,[17,44,45] have demonstrated good long-term outcomes including relief of symptoms,[2] with low complication rates, while improving the overall health of the children after correction of their flexible flatfeet.[4] It has also been clearly shown that even though the subtalar arthroereisis implant reduces motion in the hindfoot, it does not negatively affect the biomechanics of the subtalar joint, even in the flatfoot.[16,29] Not only does the arthroereisis implant restrict excessive pronation but it allows adequate motion for normal foot function thus permitting growth and adaption of the hindfoot and midfoot joints in more functionally correct realignment without invading any of the joints. Even more beneficially in children, the postsurgical re-aligned foot retains its correction after removal of the arthroereisis device, including calcaneo-stop screws. The conical subtalar arthroereisis implants, other than being more anatomically designed, function the same as the barrel-shaped self-locking devices.

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