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Subtalar Arthroereisis Implant Removal in Adults: A Prospective Study of 100 Patients

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ABSTRACT

Subtalar joint arthroereisis (STA) can be used in the management of adult acquired flatfoot deformity (AAFD), including posterior tibial tendon dysfunction. The procedure is quick and normally causes little morbidity; however, the implant used for STA often needs to be removed because of sinus tarsi pain. The present study evaluated the rate and risk factors for removal of the implant used for STA in adults treated for AAFD/posterior tibial tendon dysfunction, including patient age, implant size, and the use of endoscopic gastrocnemius recession. Patients undergoing STA for adult acquired flatfoot were prospectively studied from 1996 to 2012. The inclusion criteria were an arthroereisis procedure for AAFD/posterior tibial tendon dysfunction, age >18 years, and a follow-up period of ≥2 years. The exclusion criteria were hindfoot arthritis, age <18 years, and a follow-up period of <2 years. A total of 100 patients (average age 53 years) underwent 104 STA procedures. The mean follow-up period was 6.5 (range 2 to 17) years. The overall incidence of implant removal was 22.1%. Patient age was not a risk factor for implant removal ($p = .09$). However, implant size was a factor for removal, with 11-mm implants removed significantly more frequently ($p = .02$). Endoscopic gastrocnemius recession did not exert any influence on the rate of implant removal ($p = .19$). After STA for AAFD, 22% of the implants were removed. No significant difference was found in the incidence of removal according to patient age or endoscopic gastrocnemius recession. However, a significant difference was found for implant size, with 11-mm implants explanted most frequently.

Subtalar joint arthroereisis (STA) has been used for the treatment of flatfoot deformities in pediatric patients with good results (1,2). It has also recently gained support for the treatment of adult acquired flatfoot deformity (AAFD) and posterior tibial tendon dysfunction (PTTD) (3–8). More than 4,000,000 people complain of pain related to flat feet each year in the United States (9), with a 5% incidence of symptomatic flexible flatfoot in children and adults (10). Patients will usually report generalized fatigue of the foot, ankle, and leg or debilitating pain that interferes with walking and daily activities. If symptoms do not improve after 3 to 6 months of appropriate nonoperative treatment or if the severity of the deformity is worsening, surgery should be recommended (11). Although AAFD is a common deformity affecting the adult population, the indications for surgical treatment and appropriate procedures are still debated.

Because the etiology of flexible flatfoot is multifactorial and deformities can occur in any of the 3 cardinal planes, rarely is STA the only surgical procedure performed in adults. Many different surgical techniques have been described for the treatment of the flexible flatfoot, including primary repair and advancement of the posterior tibial tendon, flexor digitorum longus tendon transfers, calcaneal osteotomies, single or multiple joint arthrodesis, spring ligament repair (12), gastrocnemius muscle recession, and Achilles tendon lengthening (11). Often, several of these procedures will be performed at the same surgical setting. According to the 2005 clinical practice guidelines for adult flatfoot (13), arthroereisis is indicated as an adjunctive procedure. Many different implant materials are now available, including high-molecular-weight polyethylene endorthesis, titanium alloy, and bioresorbable materials. The use of these can also differ by surgical

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technique, placement of the motion blocking mechanism, and implant shape. Vogler (14) classified sinus tarsi endorthesis into 3 groups according to their biomechanical properties.

STA is considered to be technically nondemanding and quick; however, it is not free of complications (6,15–18). Sinus tarsi pain has been the most common complication reported in published studies (5,18–21). Dislocation of the implant is another indication for removal (5,6,16,19–22). The rate of subtalar arthroereisis removal can be high, and the rate of patients requiring reoperation has ranged from 5% to 40% (5,23,24). The etiology of sinus tarsi pain is multifactorial and not completely understood. Some investigators believe that the large size of the implant is an important cause of pain (19); however, others did not find any statistically significant difference between those patients undergoing implant removal and those who did not (22). The shape of the endorthesis (5), Achilles tendon tension and continued equinus (23), overcorrection (25), and poor correction (22) of the deformities have also been considered as possible sources of pain.

The purposes of our study were to evaluate the following:

1. The incidence of STA implant removal in adult patients treated for AAFD/PTTD
2. Whether patient age is a risk factor for implant removal
3. Whether the implant size increases the incidence of removal
4. Whether endoscopic gastrocnemius recession (EGR) increases or decreases the risk of implant removal

Patients and Methods

All patients were treated surgically for symptomatic flexible flatfoot, and STJ arthroereisis was performed as an adjunctive procedure when indicated. The inclusion criteria for the study were performance of the arthroereisis procedure for flexible flat foot deformity or PTTD, age >18 years, and a follow-up examination at ≥2 years by an examiner not involved in the index procedure. The procedure was performed to assist in the repair of a dysfunctional posterior tibial tendon and to help reduce flatfoot deformity, as described by many investigators (8,13,19,20,22–30). The main radiographic indication was talar head uncoverage on the weightbearing anteroposterior radiograph (23). The exclusion criteria were age <18 years and a follow-up period of <2 years. Two patients were lost to follow-up and were thus excluded from the present study, and 47 patients were excluded because they were <18 years old, leaving 100 patients for the present study. The institutional review board approved the study. The patients were prospectively enrolled starting in 1996 through April 2012. All patients were followed up annually for as long as possible. If they had reported pain at, or dislocation of, the implant, they were candidates for implant removal. Both the primary surgery and implant removal were performed by the senior author (A.S.).

We used Student's *t* test to determine any statistically significant differences between patient age and the incidence of endorthesis removal. We also evaluated which implant size was most frequently removed. We used Fisher's exact test to evaluate whether the size of the implant increased the incidence of removal. We also used Fisher's exact test to find any statistically significant difference between EGR and implant removal. We used the Microsoft Excel™ program for Windows XP software (Microsoft Inc., Everett, WA) for all analyses. A p value of $\leq .05$ was considered statistically significant.

Results

A total of 100 adults (34 males and 66 females; 104 procedures) met the inclusion criteria. No patient withdrew from the study. The mean patient age was 53.3 ± 14.7 (range 19 to 82) years. The mean duration of follow-up was 6.5 ± 3.17 (range 2 to 17) years. Many patients underwent adjunctive procedures such as calcaneal osteotomy and posterior tibial tendon advancement: 29/104 feet (27.9%). No revisions or adjunctive procedures of deformity were performed at implant removal, other than calcaneal osteotomy hardware removal (2 [2%] patients). EGR was the most common adjunctive procedure, performed in 62 (62%) patients. The size and number of implants were as follows: 7.0 mm for 7 (6.73%) implants, 8.0 mm for 29 (27.9%), 9.0 mm for 29 (27.9%), 10.0 mm for 14 (13.46%), 11.0 mm for 15 (14.42%), and 12.0 mm for 10 (9.62%) implants (Table 1). The cohort had a total of 23 (22.1%) implants removed at a mean of 12.9 ± 8.6 months after the index procedure. The most commonly used implant (placed in 58 [55.8%] procedures) was the Prostop™ (Arthrex, Inc., Naples, FL). The cohort with the Prostop™ had 12 (20.7%) implants removed. Of the remaining 46 implants, 11 (23.9%) required removal. This was not a statistically significant difference ($p = .81$). Of the 46 implants, 21 (45.7%) were Arthrex Bio-tenodesis implants (Arthrex, Inc.), 12 (26.1%) were MBA™ (Integra LifeSciences, Plainsboro, NJ), 4 (8.69%) were Prostop Plus™ (Arthrex, Inc.), 5 (10.87%) were Kalix® (Integra LifeSciences), 2 (4.35%) were Bionix interference implants (now Bioretec, Tampere, Finland), and 1 (2.17%) was an CSI™ implant (Nexa Orthopedics, San Diego, CA).

The mean patient age for those who required implant removal was 51.8 ± 14.1 (range 19 to 77) years and for those not requiring implant removal was 54.1 ± 14.29 (range 19 to 82) years. No statistically significant differences in age were found between the 2 groups ($p = .091$). The implant size most frequently removed was 11 mm (7 removals in 15 procedures; 46%; Table 1). This was a statistically significant difference compared with the rest of the cohort ($p = .02$), relative to the incidence of removal. The next most frequently removed implant size was the 12-mm implant (3 of 10 procedures; 30%). In practice, 10 implants of the 2 largest sizes were removed; however, 10 implants of the 2 smallest sizes, 7 and 8 mm, were also removed. The implants removed less often were those sized 9 and 10 mm, with a 7% incidence of removal for each. In 4 (4.7%) cases, implant dislocation dictated removal of the implant, with the rest removed because of pain (17.4%). Finally, we did not find any statistically significant difference between the use of EGR and implant removal ($p = .19$; Table 2).

Discussion

AAFD is a multifactorial condition, and multiple deformities will be present in all 3-dimensional planes. It is therefore not surprising that many different surgical treatments have been described. According to the staging of the deformity, these can include soft tissue procedures (tendon repair or tendon transfer, Achilles or gastrocnemius lengthening), osteotomies (calcaneal medial slide osteotomy, lateral column lengthening, and Cotton opening wedge osteotomy), and arthrodesis (single or multiple). The medial calcaneal heel slide, associated with tendon repair or transfer, has been shown to correct deformity and provide satisfactory results in patients with stage IIA PTTD (26,27). The Achilles tendon or the gastrocnemius–soleus complex can be contracted in every stage of AAFD (26). The relationship between flexible flatfoot and a contracted Achilles muscle–tendon complex is well-established, because the limited ankle dorsiflexion caused by a tight Achilles tendon will result in collapse of the medial arch (31). Therefore, Achilles tendon lengthening or gastrocnemius recession is frequently performed in conjunction with reconstructive flatfoot surgery (32). The effectiveness of performing posterior lengthening in conjunction with other procedures has not been prospectively studied. Gastrocnemius recession has been reported to cause less

Table 1
Implant sizes and incidence of implant removal (N = 104 implants in 100 patients)

Size (mm)	Total Implanted	Total Removed (n)
7	7 (6.73)	2 (28)
8	29 (27.9)	8 (27)
9	29 (27.9)	2 (7)
10	14 (13.46)	1 (7)
11	15 (14.42)	7 (46) ($p = .02^*$)
12	10 (9.62)	3 (30)
Total	104	23 (22.1)

Data in parentheses are percentages.
* Only size 11 was statistically significant.