Mid-term Results of Subtalar Arthroereisis with Talar-Fit Implant in Pediatric Flexible Flatfoot and Identifying the Effects of Adjunctive Procedures and Risk Factors for Sinus Tarsi Pain

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Objectives: To (i) report the mid-term outcomes of subtalar arthroereisis using Talar-Fit implant for the treatment of flexible flatfoot patients; (ii) compare clinical and radiographic outcomes between arthroereisis with and without adjunctive operative procedures to investigate the effects of adjuncts on the outcomes; and (iii) analyze the risk factors associated with sinus tarsi pain, which is the most common postoperative complication of arthroereisis.

Methods: Thirty-one flexible flatfoot children and adolescents (46 feet) treated with subtalar arthroereisis using Talar-Fit implant from June 2014 to May 2019 were retrospectively analyzed. The feet were divided into four treatment groups: (i) arthroereisis alone, (ii) arthroereisis with gastrocnemius recession, (iii) arthroereisis with Kidner procedure, and (iv) arthroereisis with gastrocnemius recession and Kidner procedure. Clinical function was evaluated based on the American Orthopaedic Foot and Ankle Society (AOFAS) ankle and hindfoot score. The following angles were measured for radiographic evaluation: talar-first metatarsal angle, calcaneal pitch angle, and talar declination angle on the lateral view; and talar-first metatarsal angle, talocalcaneal angle, and anteroposterior talonavicular coverage angle on the anteroposterior (AP) view. The paired Student’s t-test was used to compare the pre- and postoperative angular measurements and AOFAS scores. The Wilcoxon rank-sum test was undertaken to determine the outcome differences among four treatment groups. Multivariate logistic regression analysis was used to analyze risk factors for sinus tarsi pain. P value <0.05 is considered statistically significant.

Results: The mean follow-up of the feet was 32.8 months (range, 10–71 months). The mean AOFAS score significantly improved from 55.5 ± 14.5 preoperatively to 86.3 ± 9.9 (P < 0.001). Comparison of radiographic outcomes showed that the lateral talar-first metatarsal angle decreased by a mean of 19.1° ± 11.9° (P < 0.001), the calcaneal pitch angle increased by a mean of 5.4° ± 3.4° (P < 0.001), the talar declination angle decreased by a mean of 14.8° ± 9.9° (P < 0.001), the AP talar-first metatarsal angle decreased by a mean of 15.6° ± 10.3° (P < 0.001), the AP talocalcaneal angle decreased by a mean of 5.4° ± 3.4° (P < 0.001), and the AP talonavicular coverage angle decreased by a mean of 20.4° ± 9.0° (P < 0.001). There were no statistically significant differences with regard to AOFAS score and all angle measurements on both the AP and lateral views among the four treatment groups. There was one dislocation case caused by a fall 6 weeks after surgery, which was treated nonoperatively. The incidence of sinus tarsi pain was 13% and logistic regression analysis indicated that patients with a longer distance from the tail end of the implant to the lateral calcaneal wall had 38.8% greater odds of developing sinus tarsi pain.

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Conclusions: The mid-term clinical and radiographic results were satisfactory in patients who underwent the subtalar arthroereisis procedure using Talar-Fit implant, alone or in combination with other adjuncts, for the treatment of flexible flatfoot.

Key words: Flexible flatfoot; Risk factor; Subtalar arthroereisis; Surgery

Introduction

Flexible flatfoot (FFF) is a common disease with a reported incidence of 5% in children and adults. The main characteristics of FFF are collapse of the medial longitudinal arch, hindfoot valgus, and forefoot abduction caused by excessive eversion of the subtalar joint, and most patients are asymptomatic. Other characteristics are usually observed, such as contracture of the Achilles tendon or the gastrocnemius aponeurosis, spasm of the peroneus, and medial column instability. Although the treatment of FFF is still controversial, surgery is appropriate for patients with significant pain along the medial side of the foot, easy fatigue, gait changes, and compromised ankle dorsiflexion.

The surgical procedures can be categorized as tendon lengthening and transfers, osteotomies, subtalar arthroereisis (STA), and arthrodesis of one or more joints. Isolated soft tissue procedures routinely lead to unsatisfactory outcomes and are combined with other procedures in most cases. Osteotomies include medial displacement calcaneal osteotomy (MDCO) and lateral column lengthening (LCL), and both types are capable of correcting valgus deformity of the hindfoot. However, they do not actually address the deformity of the subtalar joint complex, and patients are faced with the risk of nonunion or malunion and a longer recovery time. Arthrodesis should be avoided if at all possible because of the risk of nonunion or malunion and a longer recovery time.

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Sinus tarsi pain is the most common postoperative complication of STA with a reported incidence of approximately 10% to 40%, and many patients require implant removal or replacement to address this issue. The etiology of postoperative sinus tarsus pain is multifactorial and not fully known. Cook et al. performed a propensity-matched case–control study to identify risk factors in subtalar arthroereisis explantation and found that patients who required implant removal had greater odds of radiographic undercorrection. Their results suggested that higher postoperative anteroposterior (AP) talar-first metatarsal angles and calcaneocuboid abduction angles were associated with greater odds of undergoing implant removal, and that smaller postoperative AP Kite angles were associated with a 16.7% reduction in odds for removal. Patient age, gender, implant size, shape, position, and adjunctive procedures were found to be insignificant factors. Saxena et al. performed a prospective study to determine the risk factors for removal of the implant caused by sinus tarsi pain in adults treated for adult acquired flatfoot deformity or posterior tibial tendon dysfunction. Contrary to the results of Cook et al., they found that implant size was a risk factor for explanation, with 11-mm implants removed most frequently, while gastrocnemius recession and patient age were not. Although other variables such as overcorrection, soft tissue irritation, and impingement between the screw and the posterior subtalar articlular surface have also been suspected as possible sources of pain, the actual risk factors are not yet clear.

Therefore, the purposes of this study are to: (i) report the mid-term outcomes of STA using Talar-Fit implant for the treatment of pediatric FFF patients; (ii) compare clinical and radiographic outcomes between arthroereisis with and without adjunctive operative procedures to investigate the effects of adjuncts on the outcomes; and (iii) analyze the risk factors associated with sinus tarsi pain, which is the most common postoperative complication of arthroereisis.

Patients and Methods

Inclusion and Exclusion Criteria

Inclusion criteria included: (i) patients diagnosed as FFF and aged between 9 and 20 years at the time of operation;
STA in Treating Pediatric FFF

If the accessory scaphoid was present in preoperative X-rays and there was a significant tenderness at the location of the accessory scaphoid during physical examination, we would perform dissection of the accessory scaphoid and reconstruction of the end point of the posterior tibialis tendon (Kidner procedure). If the tenderness was negligible, the accessory scaphoid would not be removed and the Kidner procedure would be omitted. In addition, Cotton osteotomy was performed in cases of significant medial column instability.

Subtalar Arthroereisis
The tarsal sinus was approached through a 1- to 2-cm slightly curved incision. The subcutaneous tissue and the deep fascia were bluntly dissected to expose the tarsal sinus. Then the Talar-Fit guide pin was inserted in an anterolateral-distal to posteromedial-proximal orientation, passing through the tarsal canal. A small incision was made to allow passage of the guide pin through the medial aspect of the foot. The trial implants were inserted with the subtalar joint inverted. The appropriate size would allow a good screw purchase and the calcaneal subtalar joint complex to evert to approximately 2° to 4° with the tail end of the implant 1 to 1.5 cm beyond the lateral calcaneal wall. It should be noted that although the Talar-Fit instructions recommended the location of the implant within the sinus portion of the tarsal sinus and the leading edge not exceeding the talar bisection line, we chose the location within the canals portion to increase stability (Fig. 3). Finally, the appropriate permanent implant was inserted. The implant position was checked again with fluoroscopy, and ROM of the subtalar joint was examined to be physically normal. Incision was closed in layers, and a compression dressing was applied.

Postoperative Management
All patients received short leg cast immobilization for 6 weeks after operation to maintain the neutral position of the ankle joint and avoid weight-bearing. The cast was removed after 6 weeks and weight-bearing was allowed gradually after its removal.

Clinical Evaluation
American Orthopaedic Foot and Ankle Society (AOFAS) Ankle and Hindfoot Score
The AOFAS ankle and hindfoot score was used to evaluate postoperative recovery of ankle and hindfoot function for FFF patients. It mainly includes three aspects: pain, function, and alignment. The score standard had a maximum of 100 points. A mark of 90–100 was considered as excellent, 75–89 as good, 50–74 as fair, and <50 as poor. Postoperative complications were recorded including pain, dislocation, and revision.

(ii) underwent STA in our hospital between June 2014 to May 2019; (iii) a successful follow-up to enable comparison between preoperative and postoperative measurements; (iv) clinical and radiographic outcomes were accessible; and (v) a retrospective study. Exclusion criteria were: (i) patients lost to follow-up; (ii) rigid flatfoot; (iii) neurological flatfoot; and (iv) patients with previous surgery for the treatment of FFF.

Prosthesis
The titanium alloy Talar-Fit (Osteomed, Addison, TX, USA) implant was employed in all patients (Fig. 1). It adopts a conical shape to adapt to the anatomical features of the sinus tarsi. Deep and blunt threads are claimed to promote soft tissue ingrowth and reduce irritation. It is categorized as type IB self-locking wedge device according to Graham's classification.

Surgical Techniques

Adjunctive Procedures
The patients were placed in a supine position and general anesthesia or continual epidural anesthesia was used. First, we assessed whether the patients were accompanied by Achilles tendon contracture or gastrocnemius contracture before surgery through the Silfverskiold test. If the ankle joint could be dorsiflexed more than 10° with the subtalar joint locked in inverted position and the knee flexed, but less than 10° with the knee extended, then gastrocnemius contracture was indicated and a gastrocnemius recession was performed. A 4- to 5-cm longitudinal posteromedial incision was made approximately midway between the knee and the ankle, the sural nerve and the long saphenous vein were protected, and the musculotendinous junction of the gastrocnemius was identified. After careful dissection, the gastrocnemius aponeurosis was cut as far distally as possible and the plantaris tendon was divided. Finally, we rechecked the Silfverskiold test to ensure the amount of ankle dorsiflexion was more than 10° with the subtalar joint inverted and the knee extended (Fig. 2). If the ankle joint was dorsiflexed less than 10° with the subtalar joint locked in inverted position and the knee both extended and flexed preoperatively, it indicated Achilles tendon contracture; then, a triple-hemisection percutaneous Achilles tendon lengthening would be performed (Hoke technique).

Postoperative Management
All patients received short leg cast immobilization for 6 weeks after operation to maintain the neutral position of the ankle joint and avoid weight-bearing. The cast was removed after 6 weeks and weight-bearing was allowed gradually after its removal.

Clinical Evaluation
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Fig. 1 The Talar-Fit implants (size 12, 11, 10, 9, and 8 mm).
Radiographic Measurement
For radiographic evaluation, the following angles were measured on both pre- and postoperative weight-bearing radiographs to perform quantitative comparisons23, 24.

The Lateral Talar-First Metatarsal (Meary’s) Angle
The lateral Meary’s angle was measured as the angle formed between the longitudinal axis of the talus and the axis of the first metatarsal (negative values were noted if the axis of the first metatarsal was oriented in dorsiflexion) (Fig. 4).

The Calcaneal Pitch Angle
The calcaneal pitch angle was defined as the angle formed by a line parallel to the ground and a line connecting the two most inferior points on the calcaneus on the lateral view25 (Fig. 4).

The Talar Declination Angle
The angle formed between the longitudinal axis of the talus and a line parallel to the ground on the lateral view (Fig. 4).

The AP Talar-First Metatarsal (Meary’s) Angle
Similar to the lateral Meary’s angle, the AP Meary’s angle was traced between the long axis of the talus and the axis of the first metatarsal on the AP view (Fig. 5).

Fig. 2 An illustration of pre- and postoperative Silfverskiold tests. (A) Preoperative test showed that the amount of ankle dorsiflexion was less than 10° with the subtalar joint locked in inverted position and the knee extended. (B) The ankle joint could be dorsiflexed more than 10° with the subtalar joint locked in inverted position and the knee flexed, indicating gastrocnemius contracture. (C) After gastrocnemius recession, Silfverskiold test was rechecked and the amount of ankle dorsiflexion was more than 10° with the subtalar joint inverted and the knee extended.

Fig. 3 Typical intraoperative X-ray films after the permanent implant was inserted, showing that this device was inserted in an anterior-lateral to posterior-medial orientation. (A) Anteroposterior view showing that the leading edge slightly exceeded the talar bisection line; and (B) lateral view.

Fig. 4 Lateral view of preoperative radiograph, illustrating measured angles. CPA, calcaneal pitch angle; LMA, lateral Meary’s angle; TDA, talar declination angle.
The AP Talocalcaneal Angle
The AP talocalcaneal angle was measured as the angle between the axis of the talus and the axis of the calcaneus on the AP view (Fig. 5).

The AP Talonavicular Coverage Angle
The angle formed between the lines connecting the endpoints of the talar and navicular articular surfaces (Fig. 5).

In addition, the implant depth, position, and orientation were measured on the AP X-rays. The implant depth was defined as the perpendicular distance from the leading edge of the implant to the longitudinal talar bisection line (negative values were noted if the leading edge did not exceed the talar bisection), the implant position as the perpendicular distance from the tail end of the device to the lateral calcaneal wall, and the implant orientation as the angle formed between the longitudinal axis of the implant and the talar bisection12 (Fig. 6).

Statistical Analysis
The results of AOFAS score and radiographic angles were presented as mean and standard deviation (SD). SPSS 23.0, (IBM, Armonk, NY, USA) was used for data analysis. The paired Student’s t-test was used to compare the pre- and postoperative angular measurements and AOFAS scores. The Wilcoxon rank-sum test was undertaken to determine the outcome differences among four treatment groups: STA alone, STA with gastrocnemius recession, STA with Kidner procedure, and STA with gastrocnemius recession and Kidner procedure. Multivariate logistic regression analysis was used to analyze risk factors for sinus tarsi pain. Regression candidates included age at the time of initial surgery, gender, implant size, follow-up duration, pre- and postoperative angular measurements, and implant depth, position, and orientation. P value <0.05 is considered statistically significant.

Results
Follow-up and General Results
A total of 31 patients (46 feet) were included in this study. Of the 31 patients, 26 (83.9%) were male and five (16.1%) were female, with a mean age at the time of surgery of 12.8 years (range, 11–20 years). The right foot was involved in 22 (47.8%) of the feet and the left foot was involved in 24 (52.2%). The mean follow-up of the feet was 32.8 months (range, 10–71 months).

The mean operation time was 46.1 min (range, 30–72 min), and mean blood loss was 17.0 mL (range, 5–30 mL). Intraoperatively, increased ROM of the subtalar joint was confirmed in all feet. STA was performed alone in 10 feet (21.7%). The surgical techniques most often associated with
to the baseline characteristics except for follow-up period (*P* = 0.046) (Table 1).

To determine the effects of adjunctive procedures on the outcomes, the feet were divided into four groups: STA alone (*n* = 10), STA with gastrocnemius recession (*n* = 12), STA with Kidner procedure (*n* = 13), and STA with gastrocnemius recession and Kidner procedure (*n* = 6). There were no significant differences among the four groups with regard to the baseline characteristics except for follow-up period (*P* = 0.046) (Table 1).

### Radiographic and Clinical Outcomes

Comparison of radiographic outcomes showed that the lateral talonavicular coverage angle decreased by a mean of 7.2° ± 8.3° (*P* = 0.001), and the talonavicular coverage angle decreased by a mean of 20.4° ± 9.0° (*P* < 0.001) (Table 2, Fig. 8). The mean AOFAS score significantly improved from 55.5 ± 14.5 (range, 24–74) preoperatively to 86.3 ± 9.9 (range, 60–97) at the final follow-up (*P* < 0.001).

### Subgroup Analysis

Table 3 showed the clinical and radiographic correction obtained in the four treatment groups, namely, STA alone (group 1), STA with gastrocnemius recession (group 2), STA with Kidner procedure (group 3), and STA with gastrocnemius recession and Kidner procedure (group 4), for the AOFAS score and different angles measured. There were no statistically significant differences with regard to AOFAS score, lateral Meary’s angle, calcaneal pitch angle, talar declination angle, AP talocalcaneal and AP talonavicular coverage among the four groups (*P* > 0.05). Although the overall difference for AP Meary’s angle was significant (*P* = 0.046), all adjusted *P*-values were greater than 0.05 after pairwise comparisons across groups (Table 3).

### Complications

Six feet (13%) complained of the presence of pain in the sinus tarsi, requiring implant removal in one foot. There was one dislocation case, which was caused by a fall six weeks after surgery and then confirmed by X-ray. She

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**TABLE 1** Comparison of baseline characteristics among four treatment subgroups (mean ± SD)

| Characteristics               | †Group 1         | ‡Group 2         | §Group 3         | ¶Group 4         | P-value |
|-------------------------------|------------------|------------------|------------------|------------------|---------|
| Age at the time of surgery (years) | 12.1 ± 0.6       | 13.8 ± 3.2       | 12.3 ± 1.0       | 12.9 ± 0.7       | 0.240   |
| Follow-up period (months)     | 23.7 ± 12.0      | 27.4 ± 15.6      | 43.8 ± 23.0      | 19.9 ± 20.7      | 0.046*  |
| Height (cm)                   | 168.4 ± 9.1      | 168.6 ± 7.1      | 166.0 ± 12.1     | 166.0 ± 9.7      | 0.853   |
| Weight (kg)                   | 99.3 ± 13.3      | 53.6 ± 11.2      | 55.0 ± 8.7       | 53.5 ± 6.8       | 0.975   |
| AOFAS score                   | 53.6 ± 19.2      | 59.8 ± 8.7       | 53.4 ± 14.8      | 61.9 ± 8.5       | 0.863   |
| Preoperative lateral view (°) |                  |                  |                  |                  |         |
| Meary’s                       | −17.5 ± 11.9     | −24.3 ± 11.0     | −13.0 ± 11.3     | −21.1 ± 9.1      | 0.171   |
| Calcaneal pitch               | 15.8 ± 3.5       | 17.4 ± 4.1       | 15.8 ± 6.5       | 12.7 ± 5.1       | 0.353   |
| Talar declination             | 36.9 ± 9.3       | 40.5 ± 8.5       | 31.1 ± 9.5       | 36.4 ± 8.2       | 0.252   |
| Preoperative AP view (°)      |                  |                  |                  |                  |         |
| Meary’s                       | 15.1 ± 8.1       | 21.4 ± 7.4       | 18.4 ± 9.6       | 27.1 ± 9.9       | 0.114   |
| Talocalcaneal                 | 24.5 ± 5.4       | 28.0 ± 7.6       | 21.8 ± 4.6       | 25.7 ± 7.7       | 0.240   |
| Talonavicular coverage        | 15.1 ± 6.5       | 21.5 ± 5.1       | 17.4 ± 9.3       | 24.6 ± 10.2      | 0.074   |

AOFAS, American Orthopaedic Foot and Ankle Society; AP, anteroposterior.; † Significant.; † Group 1, STA alone; ‡ Group 2, STA with gastrocnemius recession.; § Group 3, STA with Kidner procedure.; ¶ Group 4, STA with gastrocnemius recession and Kidner procedure.
underwent nonoperative treatment and took two more weeks to start weight-bearing. At the final follow-up, she had no symptoms and had resumed all daily activities although the implant could be palpable in the sinus tarsi area (Fig. 9).

Multivariate Logistic Regression
Age, implant size, follow-up duration, angular measurements, and implant depth, position, and orientation were analyzed as continuous covariates. Logistic regression analysis showed that implant position was the only risk factor associated with sinus tarsi pain with an odds ratio of 1.388 ($P = 0.025$, 95% CI: 1.042–1.849). In other words, patients with a longer distance from the tail end of the implant to the lateral calcaneal wall had 38.8% greater odds of developing sinus tarsi pain.

Discussion
The treatment of FFF with STA is still controversial. In this study, we reported the mid-term results of STA.

| TABLE 2 Radiographic comparison between preoperative and last follow-up values in feet treated with subtalar arthroereisis (mean ± SD) |
|---|---|---|---|---|
| Angles | Preoperative | Last follow-up | $P$-value | Change |
| --- | --- | --- | --- | --- |
| **Lateral view (°)** | | | | |
| Talar-first metatarsal (Meary's) | $-24.4 \pm 10.4$ | $-5.3 \pm 5.5$ | 0.000 | 19.1 ± 11.9 |
| Calcaneal pitch | $13.5 \pm 5.4$ | $18.9 \pm 5.3$ | 0.000 | 5.4 ± 3.4 |
| Talar declination | $40.2 \pm 8.5$ | $25.4 \pm 4.4$ | 0.000 | 14.8 ± 9.9 |
| **Anteroposterior view (°)** | | | | |
| Talar-first metatarsal (Meary's) | $22.1 \pm 9.1$ | $6.6 \pm 7.4$ | 0.000 | 15.6 ± 10.3 |
| Talocalcaneal | $25.9 \pm 9.2$ | $18.2 \pm 6.8$ | 0.001 | 7.2 ± 8.3 |
| Talonavicular coverage | $23.3 \pm 7.9$ | $3.3 \pm 7.3$ | 0.000 | 20.4 ± 9.0 |

Fig. 8 Gross photos and X-ray films of the left foot before and 1 year after surgery in a typical patient (male, 12 years old at the time of surgery). (A, B) Comparison of gross photos of hindfoot before and 1 year after surgery showing that the hindfoot valgus deformity was corrected; (C, D) comparison of gross photos of the medial aspect of the foot before and 1 year after surgery showing appearance of the medial longitudinal arch; (E) lateral weight-bearing X-ray before surgery showing lateral Meary’s angle was $-23.2°$ and talar declination angle was $41.9°$; (F) lateral weight-bearing X-ray 1 year after surgery showing lateral Meary’s angle decreased to $-6.3°$ and talar declination angle decreased to $28.2°$; (G) AP X-ray before surgery showing AP talonavicular coverage angle was $21.8°$; and (H) AP X-ray 1 year after surgery showing AP talonavicular coverage angle decreased to $6.6°$. AP, anteroposterior.
using Talar-Fit implant for the treatment of FFF, investigated the effects of adjunctive procedures on the outcomes, and analyzed the risk factors associated with postoperative pain in the sinus tarsi area.

### Role of STA in the Treatment of FFF and Comparison Between STA and Other Procedures

Compared with traditional osteotomies such as MDCO and LCL, STA has many advantages: the procedure is easy and

| Outcomes                        | †Group 1 | ‡Group 2 | §Group 3 | ¶Group 4 | P-value |
|---------------------------------|----------|----------|----------|----------|---------|
| AOFAS score                     | 87.4 ± 9.6| 90.8 ± 4.6| 81.0 ± 15.9| 88 ± 4.1| 0.772   |
| Lateral view angles (°)         |          |          |          |          |         |
| Meary’s                         | −5.2 ± 4.8| −1.9 ± 4.4| −6.2 ± 6.3| −1.7 ± 2.4| 0.585   |
| Calcaneal pitch                 | 17.6 ± 2.8| 20.8 ± 1.8| 18.2 ± 8.7| 20.3 ± 4.4| 0.640   |
| Talar declination               | 25.4 ± 4.7| 23.1 ± 3.9| 27.0 ± 4.0| 20.3 ± 2.2| 0.252   |
| AP view angles (°)              |          |          |          |          |         |
| Meary’s                         | −2.7 ± 1.7| 11.3 ± 4.8| 7.3 ± 6.6| −2.0 ± 9.1| 0.046*  |
| Talocalcaneal                   | 10.1 ± 5.9| 22.6 ± 6.3| 16.3 ± 4.3| 9.3 ± 5.4| 0.054   |
| Talonavicular coverage          | −6.3 ± 2.2| 8.4 ± 7.2| 2.6 ± 5.1| −1.2 ± 4.9| 0.071   |

AOFAS, American Orthopaedic Foot and Ankle Society; AP, anteroposterior.; *Although the overall difference was significant, all adjusted P-values were greater than 0.05 after pairwise comparisons across groups.; †Group 1, STA alone; ‡Group 2, STA with gastrocnemius recession; §Group 3, STA with Kidner procedure; ¶Group 4, STA with gastrocnemius recession and Kidner procedure.

**Fig. 9** X-ray films of the dislocation case (female, 11 years old at the time of surgery, right foot). (A, B) Preoperative lateral and anteroposterior weight-bearing X-rays showed the flatfoot deformity; (C) Dislocation was caused by a fall 6 weeks after surgery and confirmed by X-ray; (D, E) Nonoperative treatment was administrated; lateral and anteroposterior weight-bearing X-rays 6 months after surgery showed that the flatfoot deformity was corrected although the implant was in dislocated position (the tail end of the implant lateral to the lateral calcaneal wall (Arrow)); (F) Eighteen months after surgery, lateral weight-bearing X-ray showed that the correction was maintained; (G) Anteroposterior X-ray 18 months after surgery showed that the device was dislocated more laterally; the implant could be palpable in the sinus tarsi area.
less invasive; and there is no problem of nonunion or mal-
union since no osteotomy is performed, so it requires less
time to recover. In addition, unlike MD.CO which can only
correct the flatfoot deformity on the coronal plane (hindfoot
valgus) and LCL on the transverse plane (forefoot abduc-
tion), STA provides a three-dimensional correction by
preventing the talus from slipping forward, inward, and
downward during pronation7. Finally, it does not affect the
bone development and does not interfere with potential
osteotomies that may be needed in the future.

Fernández et al. argued that STA was an alternative
to MD.CO for the correction of valgus hindfoot in FFF
patients but was not suitable for forefoot abduction defor-
mity7. There are few controlled studies comparing these
procedures and the level of evidence is low. Chong et al.
performed a prospective study comparing STA with LCL
for the treatment of pediatric FFF26. At 1-year follow-up,
they did not find statistically significant differences between
the two groups with regard to clinical, radiographic, and
kinematic outcomes. However, the groups were not ran-
domized and the LCL group had a greater preoperative
radiographic deformity. In summary, randomized con-
trolled trials (RCTs) need to be done in many specific areas
to determine the role of STA in the treatment of FFF and
which procedure is superior.

Graham et al. reported the 5-year functional out-
comes of 83 adult FFF patients treated with the self-locking
wedge implant and found that the mean postoperative
Maryland Foot Score was 88 out of 100 and 80% of the
patients were satisfied with the appearance of their feet27.
The mean talar second metatarsal angle decreased by 19°,
the mean talar declination angle decreased by 5.7°, and the
mean calcaneal pitch angle increased by 0.8°. De Pellegrin
et al. conducted a retrospective study of 485 FFF children
treated with the calcaneo-stop implant. The average follow-
up was 4.5 years and 93.7% of cases reported satisfactory
clinical and radiographic outcomes without complications.
The mean talar declination angle decreased by 18° and the
mean calcaneal pitch angle increased by 3°. These results
were comparable to those of our study.

**Effects of Adjunctive Procedures on the Outcomes**

STA is often performed in combination with other proce-
dures in order to achieve full correction. Research regard-
ing the effects of adjunctive procedures is lacking. Cicchinelli
et al. undertook a retrospective evaluation of pediatric pes
valgus patients who had undergone STA as a sole interven-
tion, or in combination with other adjuncts, and suggested
that gastrocnemius recession displayed a positive effect on
the correction of transverse plane deformity when used as
an adjunct to STA, and medial column arthrodesis had a
negative impact as an adjunct to STA and gastrocnemius
recession11. However, our findings did not find the effects
of gastrocnemius recession on both clinical and
radiographic outcomes and medial column arthrodesis was
not taken into account because it was performed on only
two feet (4.3%). Further studies are needed due to the small
sample size of both studies.

**Risk Factors Associated with Sinus Tarsi Pain**

Sinus tarsi pain is the most common complication with a
considerably high rate (10%–40%)7. The pathogenesis of
sinus tarsal pain is not completely understood. Over-
correction, undercorrection, impingement between the screw
and the posterior subtalar articular surface, and soft tissue
irritation have been considered as possible causes9–11. Saxena
et al. performed a prospective study to determine the risk
factors for removal of the implant caused by sinus tarsi pain
in adults treated for adult acquired flatfoot deformity or pos-
terior tibial tendon dysfunction and found that implant size
was a factor for removal, with 11-mm implants explanted
most frequently, while gastrocnemius recession and patient
age were not13. Our finding suggested that implant position
was also a risk factor and patients with a longer distance
from the tail end of the implant to the lateral calcaneal wall
had 38.8% greater odds of developing sinus tarsi pain. There-
fore, we recommend that when both a smaller size with a
longer distance from the tail end of the implant to the lateral
calcaneal wall and a bigger size with a shorter distance could
achieve the satisfactory correction, choosing the bigger one
could reduce the incidence of postoperative sinus tarsi pain.

**Limitations of the Study**

We acknowledge that this study has limitations, and its
results should be understood with these limitations in mind.
First, it was retrospective and may be biased, such as selec-
tion bias and information bias. Second, the evaluation of
STA could have been compared with patients treated with
nonoperative methods and our study lacked a control group.
In addition, although the overall sample size was not small,
we only had a small number of feet in each treatment group,
which may affect the reliability of our results. Future pro-
spective, randomized controlled studies are needed to con-
firm our results. Finally, aside from the factors in our logistic
regression model, there may be other significative factors
such as the shape and material type of the implant; thus, our
results may have changed if these factors were considered.

**Conclusion**

In conclusion, the present study indicated that the mid-term
clinical and radiographic results were satisfactory in patients
who underwent the subtalar arthroereisis procedure using
Talar-Fit implant, alone or in combination with other
adjuncts, for the treatment of flexible flatfoot. Implant posi-
tion was associated with postoperative sinus tarsi pain. Fur-
ther research is needed to provide the long-term outcomes,
and RCTs need to be done in many specific areas around
flexible flatfoot.
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