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Original article

Midterm assessment of subtalar arthroereisis for correction of flexible flatfeet in children

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ABSTRACT

Background: The role of subtalar arthroereisis (STA) for treating flexible flatfoot (FFF) in children is controversial. We hypothesized that (1) STA provided significant radiographic correction of low longitudinal arch and forefoot abduction in paediatric FFF and that (2) mid-term clinical outcomes were satisfactory and comparable to a normal population.

Methods: A retrospective comparative study was performed of paediatric patients with symptomatic FFF who underwent STA between 2012 and 2015. Multiple measurements on preoperative and latest follow-up radiographs were recorded by two observers and compared to assess for correction of the FFF. Intra- and inter-observer reliability was also assessed. Ankle and hindfoot range of motion (ROM), AOFAS hindfoot score and VAS-FA score were compared with controls without foot symptoms or deformity. From 70 consecutive feet, 62 (31 patients) treated at 10.5 years of age were identified and compared to 48 controls (24 patients). Mean follow-up was 62 months.

Results: Intra- and inter-observer reliability was excellent for all angles (range, 0.81–0.97). Radiographic measurements demonstrated significant improvement after surgery ($p < 0.001$) but significance was not reached in talonavicular coverage angle ($p = 0.49$) and calcaneo-fifth metatarsal angle ($p = 0.53$) on dorsoplantar view. At latest follow-up, patients had less hindfoot inversion than controls (15.1° vs. 19.3°, $p = 0.03$), lower AOFAS scores (94.1 vs. 99.6 points, $p = 0.01$), due to pain ($p = 0.01$) and alignment ($p = 0.006$) subscores. Using the VAS-FA score, patients were found to demonstrate higher pain at rest (*p range*, 0.02–0.03) and during activity ($p = 0.009$), and felt limited when standing on one leg (*p* range, 0.01–0.03) and running ($p = 0.04$). No loss of correction was found after removal of the implant.

Conclusion: This study showed that STA corrected the low longitudinal arch in symptomatic paediatric FFF, but did not correct forefoot abduction in relation to the hindfoot. Mid-term assessment revealed STA provided satisfactory ankle and hindfoot ROM, pain and function levels, but limitations are witnessed compared to unaffected individuals. This aspect should be considered when counselling patients and their parents or caregivers to allow for realistic expectations.

Level of Evidence: III, retrospective comparative study.

1. Introduction

Flexible flatfoot (FFF) is a three-dimensional deformity involving hindfoot pronation, forefoot supination and calcaneal valgus associated with internal rotation of the talotibiofibular unit (TTFU) over the underlying calcaneopedal unit (CPU, consisting of the calcaneus and all midfoot and forefoot bones) [1,2]. Forefoot abduction may be present both as rotation of the whole CPU in relation to the TTFU or as abduction of the forefoot relative to the hindfoot (as a inner "break" of the CPU) [2]. Among different surgical options, subtalar arthroereisis (STA) has been largely discussed but still remains a controversial procedure [3,4]. In spite of the different shapes and materials used for multiple implants proposed so far, their common aim is to "limit" the movement of the subtalar joint therefore reducing pronation and correcting the flexible flatfoot through mechanisms that may be mechanical, proprioceptive or a combination of them both [4,5]. Two reviews published in 2011

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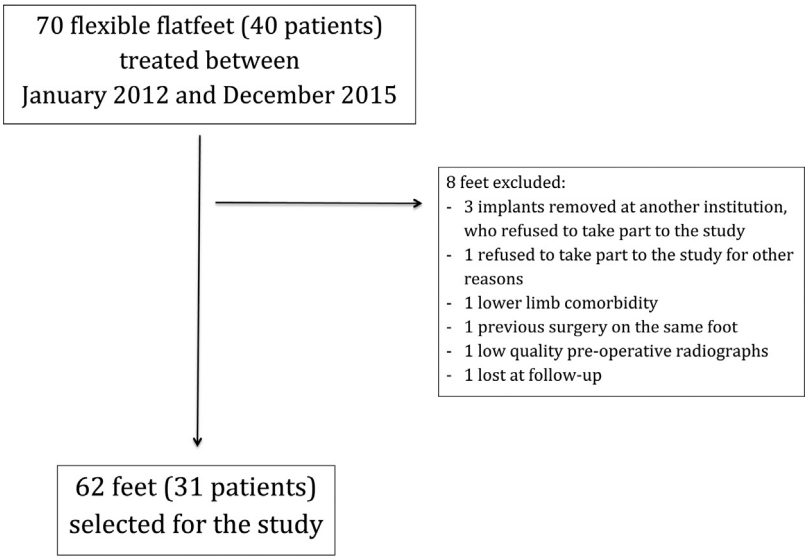

Fig. 1. Flow chart showing selection of patients.

and 2017 found that evidence provided in favour of STA is poor and based mainly on cohort studies and expert opinions [3,4]. A more recent systematic review comparing lateral column lengthening (LCL) with STA concluded that LCL achieved better radiographic correction and clinical scores, similar re-operation rates but more complications [6].

In this study, we hypothesized that:

- STA provided significant radiographic correction of low longitudinal arch and forefoot abduction in paediatric FFF and that;
- mid-term clinical outcomes were satisfactory and comparable to a normal population.

2. Methods

2.1. Study design

A retrospective review was carried out of patients diagnosed with FFF and treated with STA at a single institution by the senior author (FS) between January 2012 and December 2015. The study was compliant with the Health Insurance Portability and Accountability Act and the Declaration of Helsinki. It was led according to STROBE guidelines. Informed consent was signed by all participants.

2.2. Participants

Inclusion criteria were: age between 8 and 15 years at time of surgery; symptomatic foot/feet (activity related pain and/or tiredness); clinical signs of FFF (collapse of the medial longitudinal arch associated with hindfoot valgus and forefoot abduction); correctable deformity (confirmed by passive assessment of hindfoot inversion and eversion with patient sitting and correction of valgus hindfoot with a single-heel raise test); failure to improve with non-operative treatment consisting of minimum 6 months of corrective insoles and physical therapy; surgical correction of flatfoot by means of STA with expanding non-resorbable Giannini implant (Stryker Italia, Formello, Italy) [7].

Patients were excluded in case of: inadequate radiographs; hereditary degenerative condition, neurological and/or rigid deformity; additional procedures other than STA performed during surgery; history of prior lower-limb surgery or comorbidity.

A total of 26 feet were required to have a power of 95% using a two-sided alpha set to 0.05 to show a difference greater than 10° in the lateral talo-metatarsal angle between pre and postoperative radiographs [8]. Seventy feet (40 patients) were initially identified and after strict application of the inclusion/exclusion criteria, this left 62 feet (31 patients) to be enrolled in this study (of which 14 who had the implant removed) who were followed up to 62 ± 15 months (Fig. 1). Forty-eight feet from 24 healthy volunteers comparable by age at follow-up, sex, side and body mass index (BMI) were recruited (Table 1).

2.3. Surgical technique

Patient was positioned supine with a support under the buttock to allow internal rotation of the lower limb. Sinus tarsi was approached with an oblique 2 cm incision anterior and distal to the tip of the fibula. Blunt scissors were used to identify the axis of the canalis tarsi, then a trial 6 mm implant was inserted into it, and this was exchanged sequentially for those of 8 and 10 mm diameters until hindfoot correction was achieved (tested in a simulated weight-bearing position with a flat surface pushed under the foot, and with the ankle neutrally aligned). The suitably sized definitive screw was then implanted under image intensifier to check the screw position, as previously described (Fig. 2) [8]. This implant is composed of a central steel screw and peripheral threaded Teflon™ with four expanding fins. Screwing the steel screw leads to opening of the fins thereby expanding the girth of the implant leading to 'self-stabilisation'. No cast immobilisation was applied and weight-bearing was allowed after 2 days with sporting activity allowed after 3 months. Routine removal of screw was not planned but was performed for persistent pain at the sinus tarsi.

2.4. Outcome assessment

2.4.1. Radiographic outcome

Standardised weight-bearing dorsoplantar and lateral radiographs of the feet taken pre-operatively and at latest follow-up were assessed (Figs. 3 and 4). For patients requiring removal of the implant, radiographs from before and after surgery were retrieved. The variables investigated, gathered from literature [9,10], were talonavicular coverage angle (TNCA), talocalcaneal divergence angle (TCDADP) and calcaneo-fifth metatarsal angle (CFMA)

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Table 1
Patients' demographics.

	Subtalar arthroereisis	Controls	*p*-value
Feet (Patients)	62 (31)	48 (24)	1
Age at surgery, yr	10.5 ± 1.6 (8–15)	–	–
Age at follow-up[a], yr	15.1 ± 1.8 (11–20)	15.8 ± 1.9 (12–19)	0.744*
Male, *n*(%)	45 (72)	36 (78)	0.330**
Right side, *n*(%)	31 (50)	24 (50)	1
Bone Mass Index[a], kg/m^2	23.4 ± 4.1 (15–35)	23.3 ± 3.5 (17–27)	0.750*

[a] Mean ± standard deviation, range in brackets.
* Unpaired *t*-Student test.
** Chi^2 test.

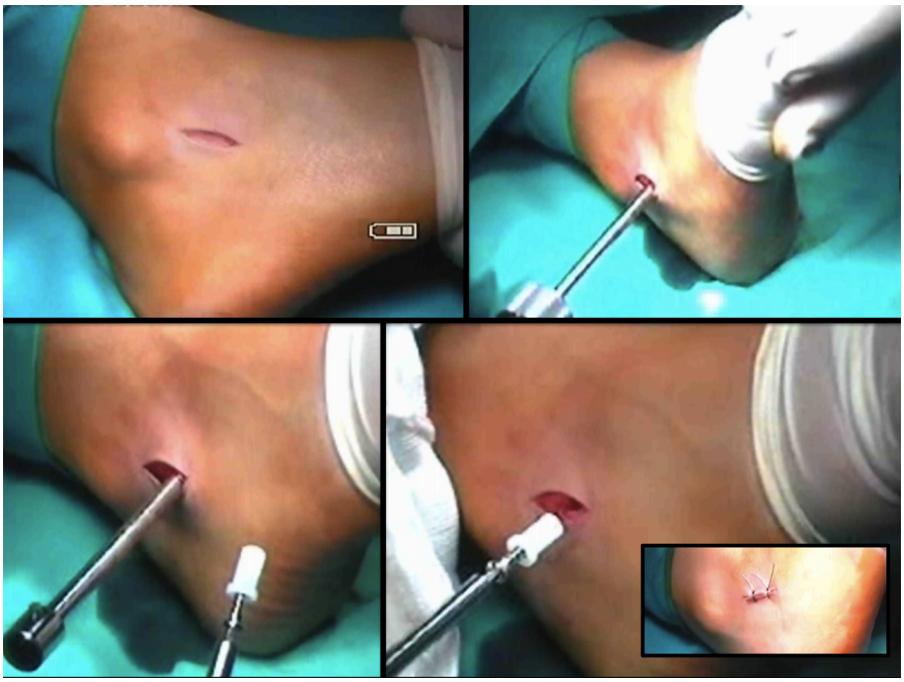

Fig. 2. Illustration of some parts of the surgical procedure: incision (upper left), testing of stability with the probe (upper right), preparation (lower left) and implant of the screw (lower right), and suture (small inset).

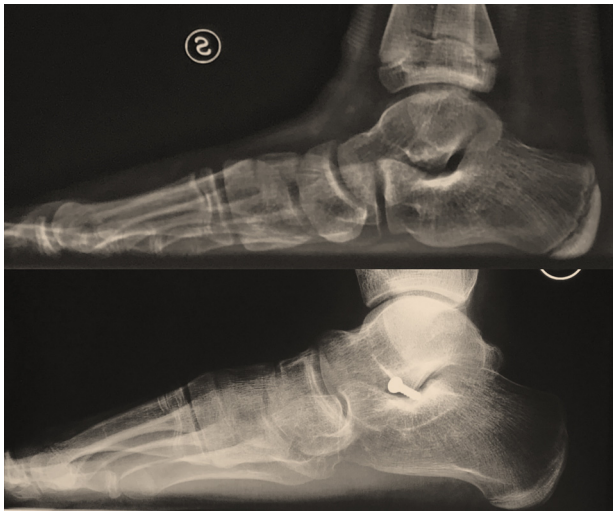

Fig. 3. Example of preoperative and 48-month follow-up lateral radiographs.

on dorsoplantar view; Dijan-Annonier angle (DAA), talo–first metatarsal angle (TFMA), calcaneal pitch (CPA) and talocalcaneal divergence angle (TCDALL) on lateral view. These were recorded by two orthopaedic residents and repeated after two weeks.

2.4.2. Clinical outcome

Clinical evaluation was performed using passive range of motion (ROM) of the ankle and hindfoot, AOFAS hindfoot score and VAS-FA score at latest follow-up. In patients who underwent implant removal, the clinical status was documented as "pain-free", "improved but still in pain" and "not improved" after surgery.

2.5. Statistical analysis

Descriptive statistics were collected as mean, standard deviation (SD) and range. After Shapiro–Wilk test (to identify normal distribution), a two-tailed Student's *t* test (parametric data) or the Wilcoxon rank-sum test (nonparametric data) was undertaken to compare clinical and radiographic variables. Categoric variables were assessed using chi-squared test. Intraobserver and interobserver reliability for radiographic measurements was assessed through Pearson/Spearman's test (depending on the normality of distribution) and Intra Class Coefficient, respectively. *p*-value was set at 0.05.

3. Results

3.1.1. Radiographic outcome

Excellent inter and intra-observer reliability was confirmed for all angles (range, 0.81–0.97).

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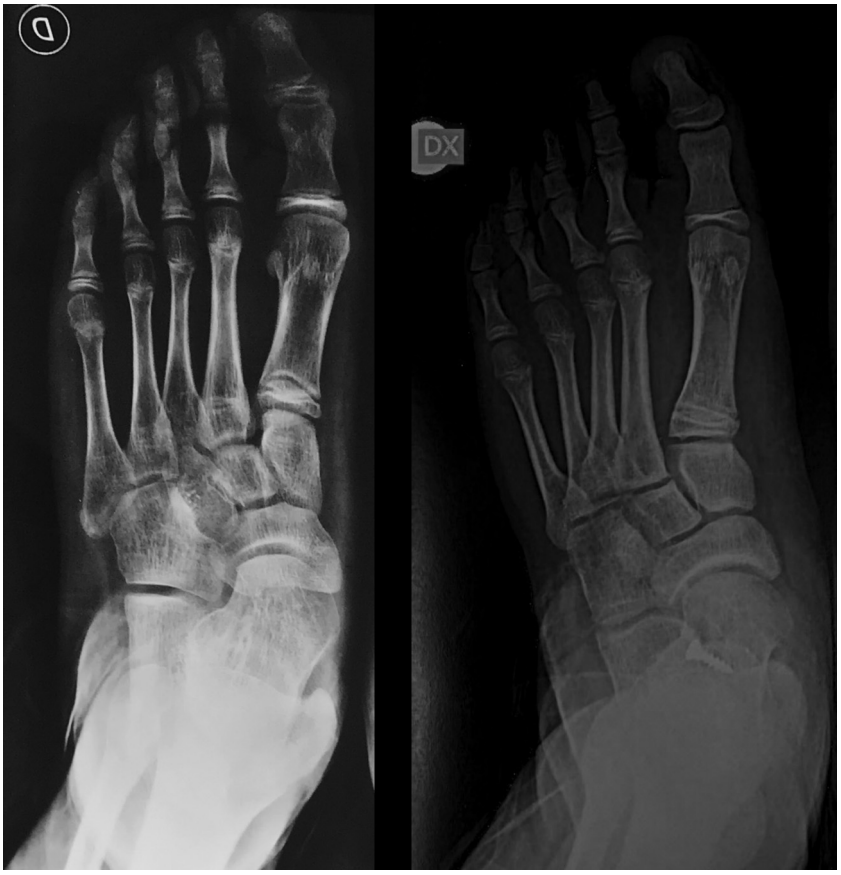

Fig. 4. Example of preoperative and 48-month follow-up dorsoplantar radiographs.

Table 2
Radiographic comparison between preoperative and last follow-up values in feet treated with subtalar arthroereisis (*n* 62).

	Preoperative	Postoperative	
	Mean ± SD (range)	Mean ± SD (range)	*p*-value
Lateral view (degrees)			
Talo–First Metatarsal Angle (Méary)	18.4 ± 6.0 (9–34)	9.9 ± 3.1 (0–15)	< 0.001*
Dijan-Annonier Angle	144 ± 7.7 (125–156)	135.1 ± 6.1 (121–143)	< 0.001*
Talo–Calcaneus Divergence Angle	40.2 ± 5.1 (31–50)	33.2 ± 3.5 (28–37)	0.004**
Calcaneal Pitch	12 ± 3.1 (7–18)	16.8 ± 4.6 (9–27)	< 0.001*
Dorsoplantar view (degrees)			
Talo–Navicular Coverage Angle	19.2 ± 7.2 (5–36)	12.3 ± 8.2 (4–31)	0.499**
Talo–Calcaneus Divergence Angle	29.3 ± 4.1 (17–39)	21.3 ± 3.4 (15–31)	0.04*
Calcaneo-Fifth Metatarsal Angle	17.3 ± 4.2 (5–31)	14.3 ± 5.3 (0–25)	0.534**

* Student *t* test.
** Wilcoxon rank-sum.

The medial longitudinal arch was significantly heightened after STA ($p < 0.001$ for all angles measured on sagittal plane) but no appreciable improvement in foot abduction relatively to the hindfoot was detected ($p = 0.49$ for TNCA, and $p = 0.53$ for CFMA) (Table 2).

Comparison of radiographic angles between pre and post removal of the implant (mean time of 7.2 months, range 6 to 12) demonstrated no significant loss of correction (p values > 0.05 for all angles) (Table 3).

3.1.2. Clinical outcome

At latest follow-up, STA patients had lower AOFAS scores than controls ($p = 0.01$), due to pain ($p = 0.01$) and alignment ($p = 0.006$) subscores (Table 4). As expected, STA patients showed less hindfoot inversion than controls ($p = 0.03$). The VAS-FA score identified that STA patients complained of higher pain at rest (p range in related items, 0.02–0.03) and during activity ($p = 0.009$), and felt limited when standing on one leg (p range, 0.01–0.03) and running ($p = 0.04$) (Table 4). Clinical status after implant removal is depicted in Table 3.

4. Discussion

In this study, we showed that a non-resorbable expanding subtalar endo-orthesis as standalone procedure is effective to radiographically correct the low longitudinal arch in paediatric FFF, but without significant correction of forefoot abduction in relation to the hindfoot. We also found that patients report a satisfactory foot and ankle function at a mean of 5 years (documented through AOFAS and VAS-FA scores) although some limitations may persist at

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Table 3
Outcome of feet who underwent implant removal (*n* 14).

Implant removal			
Time between index procedure and implant removal, *months*		7.2 ± 1.6 (6–12)	
Follow-up after implant removal, *months*		42.6 ± 11.2 (29–67)	
Clinical outcome	*n*(%)		
Pain-free	10 (72%)		
Improved	2 (14%)		
Not improved	2 (14%)		
Radiographic outcome	Before removal Mean ± SD (range)	After removal Mean ± SD (range)	*p*-value
Lateral view (degrees)			
Talo–First Metatarsal Angle (Méary)	5.1 ± 3.1 (0–9)	7.7 ± 3.3 (4–15)	0.422*
Dijan-Annonier Angle	131.2 ± 5 (122–135)	134.4 ± 5.8 (124–143)	0.291*
Talo–Calcaneus Divergence Angle	32.1 ± 3.8 (28–37)	32.3 ± 3.1 (29–35)	0.657**
Calcaneal Pitch	15.2 ± 4.1 (12–26)	15.9 ± 4.6 (9–27)	0.711*
Dorsoplantar view (degrees)			
Talo–Navicular Coverage Angle	10.7 ± 7.4 (4–20)	11.3 ± 7.7 (4–27)	0.344**
Talo–Calcaneus Divergence Angle	20.1 ± 3.2 (15–26)	21.1 ± 2.7 (15–30)	0.340*
Calcaneo-Fifth Metatarsal Angle	13.2 ± 4.9 (2–22)	13.9 ± 4.9 (3–25)	0.677**

Table 4
Clinical outcome. Among VAS-FA items, one question (problems while driving a car) was not applicable because of age of patients, being therefore removed.

	STA (N 62)	Controls (N 48)	*p*-value
	Mean ± SD (range)		
ROM (degrees)			
Ankle dorsiflexion	12.6 ± 3.9 (5–20)	14.2 ± 4.8 (10–30)	0.1
Ankle plantarflexion	37.2 ± 9 (20–60)	42.7 ± 6.2 (30–54)	0.07
Hindfoot inversion	15.1 ± 5 (6–30)	19.3 ± 4.1 (10–27)	**0.03**
Hindfoot eversion	10.8 ± 3.9 (5–20)	11.5 ± 3.1 (8–20)	0.08
AOFAS (points)			
Total	94.1 ± 9.3 (58–100)	99.6 ± 2 (90–100)	**0.01**
Pain	36.7 ± 5.3 (20–40)	39.6 ± 2 (30–40)	**0.01**
Function	49.1 ± 3.3 (33–50)	50 ± 0 (50–50)	0.3
Alignment	8.3 ± 2 (5–10)	10 ± 0 (10–10)	**0.006**
VAS-FA (points)			
How much do foot problems affect your gait?	9.8 ± 0.8 (7–10)	10 ± 0 (10–10)	0.3
How often do you have foot pain in physical rest?	9.1 ± 1.9 (3–10)	9.9 ± 0.2 (9–10)	**0.02**
How intense is this foot pain during physical rest?	9.4 ± 1.2 (6–10)	10 ± 0 (10–10)	**0.03**
How often do you have foot pain during physical activity?	8.6 ± 2.3 (1–10)	10 ± 0 (10–10)	**0.009**
How strong is this foot pain during physical activity?	8.7 ± 2.1 (3–10)	10 ± 0 (10–10)	**0.009**
Do you have the impression that one leg is weaker than the other?	9.1 ± 1.8 (2–10)	9.8 ± 0.8 (6–10)	0.1
Do you have callous at the foot/feet?	9.8 ± 0.3 (8–10)	9.6 ± 1.1 (5–10)	0.2
Do you have a limitation of ankle or foot range of motion	8.7 ± 2.7 (2–10)	9.8 ± 0.8 (7–10)	**0.05**
Do you have problems when climbing stairs?	9.6 ± 1.1 (7–10)	10 ± 0 (10–10)	0.12
How much do foot problems affect your occupation?	9.6 ± 1.8 (1–10)	9.9 ± 0.2 (9–10)	0.31
How long can you stand without foot problems?	8.4 ± 2.3 (3–10)	9.7 ± 0.8 (7–10)	**0.01**
How much do foot problems affect your ability to stand on one leg?	8.8 ± 2.6 (1–10)	9.8 ± 0.8 (6–10)	**0.03**
How long can you walk without foot problems?	9.1 ± 2.6 (5–10)	9.7 ± 0.9 (6–10)	0.21
Do foot problems stop you from running?	8.9 ± 2.6 (1–10)	9.9 ± 0.4 (8–10)	**0.04**
How much do foot problems affect your daily activities?	9.9 ± 0.2 (9–10)	9.8 ± 0.8 (6–10)	0.5
How much do foot problems restrict travelling?	9.8 ± 0.7 (6–10)	9.9 ± 0.2 (9–10)	0.25
Do you have problems finding good footwear?	9.1 ± 1 (7–10)	10 ± 0 (10–10)	0.19
How much do foot problems restrict walking on uneven ground?	9.3 ± 1.5 (5–10)	9.8 ± 0.7 (7–10)	0.1
How much is your sensation in your foot/feet reduced?	10 ± 0 (10–10)	10 ± 0 (10–10)	1

Significant differences are outlined in bold.

rest, during physical activity or during single-leg stance compared to healthy controls.

When dealing with pes planovalgus (defined as an "untwisting" of the CPU whereby the calcaneus moves into valgus to compensate the forefoot supination) [1,2], it's challenging to distinguish how much of the foot shape is related to a deformity and how much to physiology. This is due to at least 2 reasons. Firstly, the existence of multiple morphotypes of CPU, varying from a more vertical (high arch) to horizontal (flatfoot) calcaneus in the normal population [2]. Secondly, the continuous adaptation of the CPU to lower limb rotation, with arch flattening or heightening to counteract the internal or external rotation of the leg, respectively [1]. This certainly increases the difficulty in determining what is physiological and what is pathological in terms of foot shape and, consequently, in interpreting radiographic measurements.

In our series, subtalar endo-orthesis heightened the medial longitudinal arch in flexible FFF which is in accordance with the results of other groups [7,8,11–13]. Bearing in mind the concept of CPU [1,2], our results suggest STA leads to a re-positioning of CPU under the TTFU (assessed though the TCDADP) but no significant correction of the forefoot abduction relatively to the hindfoot (CFMA). Even if we are unable to provide a clear reason for this, one possible explanation is that Achilles lengthening was not performed in our series. Although after STA an intraoperative

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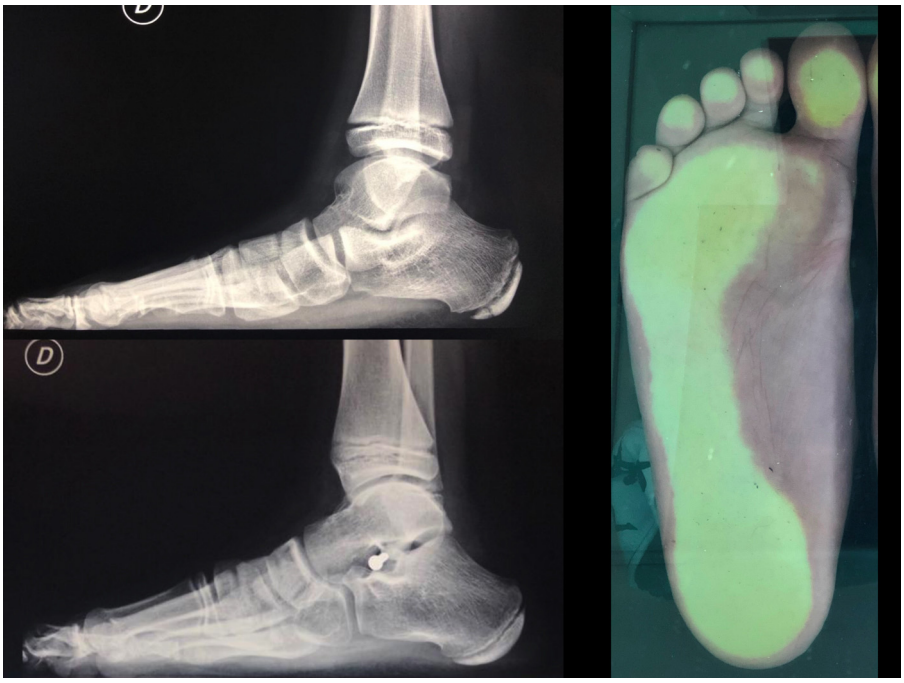

Fig. 5. Preoperative and 3-month postoperative lateral radiograph showing restoration of longitudinal arch but antalgic forefoot supination with elevation of the first ray confirmed on podoscopic examination. This led to removal of implant.

passive dorsiflexion of at least five degrees was always achieved in the cohort assessed, we cannot rule out that the posterior muscolotendinous chain kept pulling the forefoot in an off-axis direction maintaining some abduction.

Indeed, abduction correction after STA remains debated within literature as well. On a side, some studies do report substantial improvements in talonavicular coverage [11–13] and dorsoplantar talocalcaneal angle [8,11]. Interestingly, Chong et al. and Indino et al. achieved abduction correction without Achilles procedures but both documenting the application of a below-the-knee cast after surgery [12,13], therefore raising the possibility that postoperative immobilisation in a corrected position might improve the talonavicular angle. On the other side, a review by Suh et al. suggested that STA should be indicated only in FFF with mild abduction and that LCL [14] should be preferred to achieve better correction of the transverse plane deformity [6]. Unfortunately, the heterogeneity of studies included and the absence of direct comparative cohorts make difficult to establish if the morphological correction depends on the subtalar implant or on any additional procedure performed to achieve correction [6]. Noteworthy, the so-called Judet technique (consisting in restoring the talar position relative to the calcaneus and maintaining it using a temporary talocalcaneal screw through the sinus tarsi) has been proposed as alternative to achieve long-lasting correction of FFF, nevertheless its superiority compared to STA or LCL is yet to be proven [15]. Secondly, although both in our study and in historical literature two-dimensional radiographs present a good intra- and inter-observer reliability, also allowing to assess three-dimensionally the foot morphology [16], there are some biases inherently related to plain radiographs that may affect the accuracy of measurements. The adoption of cone beam standing computed-tomography might possibly help to provide objective and more reliable measurements in flatfoot [17], even if its application in paediatric population has never been investigated so far.

With regard to clinical outcome, we found a mean AOFAS score at 94.1 points even after 5 years which compares well with the 88–94 points reported in literature [6,13,18] and mean 9.1/10 among all VAS-FA items. When focusing on studies uniquely dealing with non-resorbable endo-orthesis for correcting paediatric FFF, authors report clinical and radiographic improvement in series from 27 to 112 feet, assessed at 18–40 months of mean follow-up and with complication and reoperation rate of 8–40% and 3–25%, respectively [7,8,11,13,18–20]. During the selection of patients we found unplanned removal of the implant in 24% (17/70) of our cohort for sinus tarsi syndrome, in line with numbers reported in literature (6–25%) [7,8,11,12,19] (Fig. 5). More important, comparison to a group of unaffected individuals highlighted patients in our cohort experienced some limitation in terms of pain at rest, difficulties when doing physical activity and standing on one leg. This has relevant implications for counselling before surgery since it could be said that a satisfactory functional level may be achieved after use of STA, but patients and their caregivers should be made aware that limitations might still exist after surgery.

We acknowledge that this study has limitations. First, the limited sample size. Nonetheless our power analysis suggested the study was sufficiently robust to support the conclusions reached. Secondly, the retrospective design meant no pre-operative clinical scores were available, however the clinical improvement associated with radiographic correction has been successfully documented by other study groups [7,8,11–13] and was not among the aims of our work. Thirdly, the evaluation of STA could have been ideally performed against children treated conservatively as a control group. While agreeing with this concept, we also believe that a comparison with a healthy population provided useful insights to judge the procedure. Fourthly, results from a single-surgeon cohort, as those reported here, may be not always generalizable across different centres. Although we reckon that this aspect allowed us to assess a more homogeneous group of patients, we advocate multicentric prospective studies to highlight potential differences among surgeons.

5. Conclusion

In this study, the use of STA with expanding non-resorbable Giannini implant as a standalone procedure significantly changed the paediatric FFF deformity, with radiographic correction of

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the longitudinal arch but no significant improvement of forefoot abduction in relation to the hindfoot. The complication rate in our series was not negligible, albeit in line with previous evidence. Although at 5 years patients report satisfactory pain and function level with a good range of motion at the ankle and hindfoot, they may still experience increased pain at rest, during physical activity and when standing on one leg compared to normal individuals. This must be considered when counselling patients and their caregivers about surgery, in order to realistically set their expectations.

Disclosure of interest

F.L. declares paid consultancy for Curvebeam and a patent for TALAS software, outside the submitted work.

The other authors declare that they have no competing interest.

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No funding has been received for the submitted work.

Contribution of authors

A.B. has worked on the study design, drafting of manuscript, acquisition and interpretation of data, statistical analysis, critical revision. C.I. has concentrated upon the study design, drafting of manuscript, acquisition and interpretation of data. R.D.A. has worked on the study design, drafting of manuscript, acquisition, analysis and interpretation of data.

F.L. and S.P. have both worked on the drafting of manuscript, analysis and interpretation of data, critical revision while F.S. has worked on the study design, drafting of manuscript, interpretation of data, and the critical revision.

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