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TESI DI DOTTORATO

Subtalar arthroereisis in treating flatfoot: clinical, radiographic and functional analysis

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TABLE OF CONTENTS

LIST OF FIGURES

on lateral view (A), ankle anteroposterior view (B) and foot dorsoplantar view (C). Implant is therefore advanced till optimal position on two projections (D and E). On dorsoplantar view (D), STA is advanced so that the proximal extremity has slightly overcome the lateral edge of the talar neck. Implant stability is finally checked manually with dorsiflexion/plantarflexion and inversion/eversion movements.

Figure 12: Example of stage IIb adult acquired flatfoot deformity with comparison between pre-operative (left and upper central images) and 11-month follow-up (lower central and right images) radiographs. Patient has been treated through calcaneal medialising osteotomy, flexor digitorum tendon transfer, spring ligament repair, Cotton osteotomy and STA implant.

Figure 13: Dorsoplantar foot view before (left) and after (right) flatfoot reconstruction. The abduction of the forefoot is improved by 13 degrees (going from 32 to 19) when measured as talonavicular coverage angle and by 4 degrees (going from 14 to 10) when measured as calcaneus-fifth metatarsal angle. This apparent discrepancy between the two measurements (of 9 degrees) may find its explanation in the derotation of the subtalar joint with a change of the talocalcaneal angle of about 7 degrees (going from 19 to 12). The remaining unexplained rotation (approximately 2 degrees) is probably a consequence of two-dimensional radiographs biases (i.e. projection and operator-related biases), which reduce the accuracy of measurements.

PART I

The role of subtalar arthroereisis for flatfoot in children and adults: a review of the literature

INTRODUCTION

Flatfoot (also called pes planus) is a complex multiplanar deformity that represents a very common referral in orthopaedic clinics, both in children and adults. As widely reported over the last decade, a clear definition of flatfoot is lacking and the limit between a physiological flatfoot (assumed as normal) and a pathological flatfoot (needing to be treated) is still uncertain[1,2].

However, a basic distinction is generally made between a rigid and a flexible flatfoot. The rigid form, usually painful, is related to underlying specific conditions such as tarsal coalition and treated by specific measures. By contrast, the flexible form is commonly asymptomatic, even though sometimes it may become painful and cause functional limitation in daily life. At present, no data are available to explain why a flexible flatfoot remains asymptomatic or become painful, with the exception of those (few) cases of advanced deformity and subsequent gait dysfunction. Foot kinematics in symptomatic and asymptomatic flatfeet do not significantly differ, therefore tenderness may depend on tissue wear and subjective pain thresholds[3]. However, the current trend is towards the treatment of the deformity when painful and limitating to provide relief from symptoms by restoring foot balance and alignement[1].

Another important basic difference has to be made between children and adult flatfoot. It is widely accepted that flatfoot is physiological in newborns, and related to the fat pad and to the laxity of musculoskeletal structures. A medial longitudinal arch may be seen at two years of age and is expected to further develop up to 6 to 10 years. Even though, is some children a flat shape may persist, being considered pathological if painful, as overmentioned[2].

On the other hand, adult flatfoot is mainly secondary to the posterior tibial tendon dysfunction (PTTD), causing the collapse of a preexisting medial arch with a progressive stiffening of the deformity[4,5]. This leads to disabling pain, footwear problems and difficulty with ambulation. Moreover, the rupture of the calcaneonavicular plantar (otherwise known as spring) ligament may follow, due to its inalbility to compensate the lack of an active support (the tibialis posterior), thus worsening the deformity and symptoms.

In regard to different treatments proposed for flatfoot, primary randomised high-quality studies are lacking whilst a number of case series have been published[6]. Some authors have documented the inconsistency of conservative treatment, on the contrary surgical approaches have provided encouraging results. In particular, most recent studies have focused on the efficacy and safety of subtalar arthoereisis, a worldwide spread surgical alternative considered mini-invasive and safer than soft-tissue and bony procedures (osteotomies and arthrodeses). Though the effort of some authors in analyzing literature and defining the place of such procedure in the treatment of children and adult flatfoot[7–9], a clear consensus is still missing[6].

In this context, we performed a critical review of the scientific literature in order to define the role of arthroereisis in the treatment of flatfoot based on recent evidence provided, thus resuming the current state of understanding and highlighting the areas where knowledge is still lacking.

FLATFOOT

Flatfoot is a common deformity characterized by medial rotation and plantar flexion of the talus, eversion of the calcaneus, collapsed medial arch, and abduction of the forefoot[6].

Most authors usually refer to the child-adolescent flatfoot and adult flatfoot as two different entities.

In children

As overmentioned, a distinction has to be made between a rigid and a flexible form. The former is mostly symptomatic and related to neurologic or neuromuscolar conditions, bone coalitions, rheumatoid or post-traumatic arthritis or other underlying causes[10,11]. The latter is idiopathic and clinically characterised by the possibility to restore a medial arch at physical examination when standing on tip toes or with the Jack's test (rise of the medial arch at the first toe passive dorsiflexion)[12]. The deformity may be isolated or associated to Achilles tendon shortening or to gastrocnemius contracture (investigated with the Silfverskiold test assessing the possible ankle dorsiflexion with extended and flexed knee)[12].

In most cases flatfoot is flexible and idiopathic, being considered a simple variation of the normal foot architecture. There is general consensus and evidence that within the first years of life a flat shape of the foot has to be considered physiological often spontaneously corrected by the age of ten[13]. Despite this, the abnormal foot shape often become a reason of concerns for parents and triggers subsequent medical referral[14]. Usually children are able to walk without symtpoms, but sometimes they may complain with pain located over the medial aspect of the heel, the sinus tarsi, the distal fibula, and the medial aspect of the midfoot[12].

A footprint-based classification of flatfoot was proposed by Denis in 1974, dividing flatfeet in grade 1 (in which support of the lateral edge of the foot is half that of the metatarsal support), grade 2 (in which the support of the central zone and forefoot are equal) and grade 3 (in which the support in the central zone of the foot is greater than the width of the metatarsal support)[15]. This method has been often used in epidemiological studies assessing the prevalence of the deformity in pre-school or school children, with results varying from 3% to 59%[16–18]. Other similar footprint-based methods were proposed in 1985 by Staheli who described the Plantar Arch Index (which is the division of the width of the foot at the median part of the foot in the arch, over the width of the heel)[19] and in 1987 by Cavanagh with his Arch Index (using the ratio of the area of the middle third of the footprint to the entire footprint area except toes)[20]. Over time, many flaws have been detected with footprint measurments, therefore they are not currently used in daily practice[9]. On the contrary, weightbearing radiographs have been deemed more adequate for detecting and quantifying flatfoot, such as they are usually requested as complementary to the clinical assessment and used in assessing flatfoot gravity and in making decisions about the treatment[9]. They are also used in postoperative assessment to verify alignement, even though their role and limitations in this context remain debated as well[21,22].

In adults

Among adults pes planus is more frequent in African American population than in Caucasians (38% vs 16%)[23], and is more frequently related to tibialis posterior tendon dysfunction [24], classified according to clinical and radiographic criteria by Johnson and Strom (implemented by Myerson)[25,26]. Causes may be divided in osseous (congenital or post-traumatic) articular (connective tissue disease, rheumatoid arthritis, degenerative primary midfoot and hindfoot arthritis) and neurologic or neuro-muscular disorders[5,27]. Generally, in adults, flatfoot represents an acquired deformity remaining permanently. When symptomatic (it is unknown in what percentage of cases) it may cause pain in daily activities, difficulties in footwear fitting and functional chronic dysfunction associated to a lack of propulsive gait, generally getting worse in abscence of treatment[5,21].

Treatments in children

The distinction between a 'normal' and a flat' foot is a current matter of debate, even though there is agreement upon the indication to treat flatfoot when painful and causing dysfunction.

Conservative treatment includes activity modifications, stretching, supportive footwear with medial arch supports, orthotics, mild analgesics or nonsteroidal anti-inflammatory drugs. The first choice usually consists in prescribing insoles, that in some case have been reported as a way to get relief from pain[28]. Their anti-pronation effect is reached through a medial navicular support together with a heel medial wedge one, more frequently using pre-fabricated models as to date custom-made devices have not proven superior[29]. Other more sophisticated orthotics have also been introduced among options, but children compliance may become an issue, thus their use is not diffused[30–32]. In case of equinus deformity, Achilles stretching exercises may also be proposed[32]. Corrective shoes also represent a common prescription from physicians to tackle severe hindfoot deformities [32]. All these solutions have been deeply criticised over the last thirty years. In fact, some studies on children have shown no difference between subjects treated and untreated, strenghtening the concept that the improvements documented in other studies were likely the result of the physiological longitudinal arch spontaneous development more than of medical treatments[33]. Additionally, even if some authors have documented beneficial effects of insoles [34] and foot exercises[35], a few recent systematic reviews have concluded that there were no evidence based recommendations in favour of orthotics, bracing and stretching exercises for children [14] neither of orthotics for adults[36]. Therefore, only in severe non-operable forms customized orthopaedic shoe-wear should be prescribed[5]. Notwithstanding this, a significant number of prescriptions and overprescriptions still exist in Western countries in current daily practice[16].

Regardless of the kind of treatement, after the failure of conservative measures, surgery is considered. Surgical approaches to children flatfoot consist of soft-tissue procedures, bony procedures (osteotomies or arthrodeses) or subtalar arthroereises, all being performed alone or combined and aimed to restore a well balanced foot.

Among soft-tissue procedures, an operative release of the gastrocnemius complex or of the Achilles tendon (a gastrocnemius recession and a tendo-Achilles lenghtening, respectively) is usually indicated in case of contracture[26,37,38]. The flexor digitorum longus tendon transfer may help to restore tibialis posterior tendon function while a spring ligament plication is aimed to renforce the medial contention of the talar head[24,38]. A peroneal tendon transfer is rarely indicated, in more advanced forms. Among bony procedures, the most common is the medializing calcaneal osteotomy (according to Myerson)[26], but the lateral column calcaneal lengthening osteotomy (Evans and reverse Dwyer osteotomies)[5] and the medial cuneiform opening wedge osteotomy (Cotton procedure)[24,38] are widespread procedures as well. Obviously, in case of accessory navicular bone a surgical excision is recommended[24]. Fusion procedures of the hindfoot and midfoot have a limited indication in children, as the preservation of joint motion during growth is one of the main goal to be achieved[32]. Therefore, when arthrodesis is required, selective procedures should be always preferred.

Treatments in adults

In adults, flatfoot generally corresponds to stage II, III and IV PTTD. In this case, the first issue is represented by misdiagnosis, as PTTD may remain long time unrecognised, therefore untreated. According to the litterature, flexible flatfoot (stage II PTTD) is firstly approached using orthotics, that have proven useful in some studies [39,40]. In case of failure, a minimally invasive tendoscopic synovectomy [41,42] with the possibility to reconstruct the calcaneonavicular plantar ligament[43] has also been proposed, but its efficacy is still not validated. Thus, traditional surgery become the choice. The most diffused way to restore a tibialis posterior function relies on the augmentation with the flexor digitorum longus tendon, a procedure that has been shown effective but not sufficient to solve the condition. Therefore, bone works is required dealing with calcaneus and, if required, medial cuneiform osteotomies. Regarding rigid flatfoot (stage III PTTD), joint-sparing correction become no more feasible, thus fusion of subtalar, talonavicular and calcaneocuboid joints (alone or combined) are needed, relieving from pain with the drawback of eliminating joint mobility and overloading the nearest articular compartments[5].

SUBTALAR ARTHROEREISIS

Generalities

Coming from the fusion of the Greek roots arthro- (joint) and -ereisis (the action of sustaining, supporting, pushing against something), *arthroereisis* indicates a surgical option in the treatment of flatfoot with the aim of re-establishing a medial foot arch and limiting the motion of the subtalar joint without blocking it[44]. The concept of 'manipulation' of the subtalar joint to approach flatfoot was firstly reported in 1946 by Chambers who described the impaction of a wedge-shaped bone block into the anterior border of the posterior facet of the calcaneus (a so called "abduction block") in order limit the excessive anterior displacement of the talus upon the calcaneus and correct the deformity[45]. Pursuing the same goal, some years later Baker proposed a lateral opening wedge osteotomy of the posterior joint surface[46], while Haraldsson firstly termed 'arthrorisis' the introduction of a wedge graft into the sinus tarsi[47,48]. It was only in 1970 that Lelievre coined the word arthroereisis to describe a similar procedure, as to say the insertion of a bone graft in the sinus tarsi fixed by a temporary staple[49]. Very soon the idea of placing an external synthetic implant in the sinus tarsi to sustain the talus on the calcaneus took place. Following the first device proposed in 1974 by Subotnik[50], a number of solutions have been introduced varying essentially in shape (block, sphere, screw, cap, cylinder), material (silastic, polyethylene, titanium, a combination of these latters, absorbable poly-L-lactic acid, poly lactic acid or poly glycolic acid) and mechanism of action.

The biomechanical classification currently used was introduced in 1987 by Vogler[51] who classified three types of implants (Fig.1):

- axis-altering prostheses, made up of a stem (vertically fixed in the sinus tarsi floor just anteriorly to the posterior subtalar surface) and by a superior head in contact with the talar lateral process, in order to modify the subtalar joint axis and to limit the internal rotation of the calcaneus;
- impact-blocking devices, similar to the former, but with the head place slightly more anterior so to impinge with the talar lateral process limiting its anterior gliding and, of consequence, its internal rotation;
- self-locking implants, inserted in the sinus tarsi along its main axis, sustaining the talar neck and avoiding the contact between the talar lateral process and the sinus tarsi floor, thus limiting the talar adduction and plantarflexion.

Regardless of the type of implant, all them are finalised to limit the subtalar joint motion.

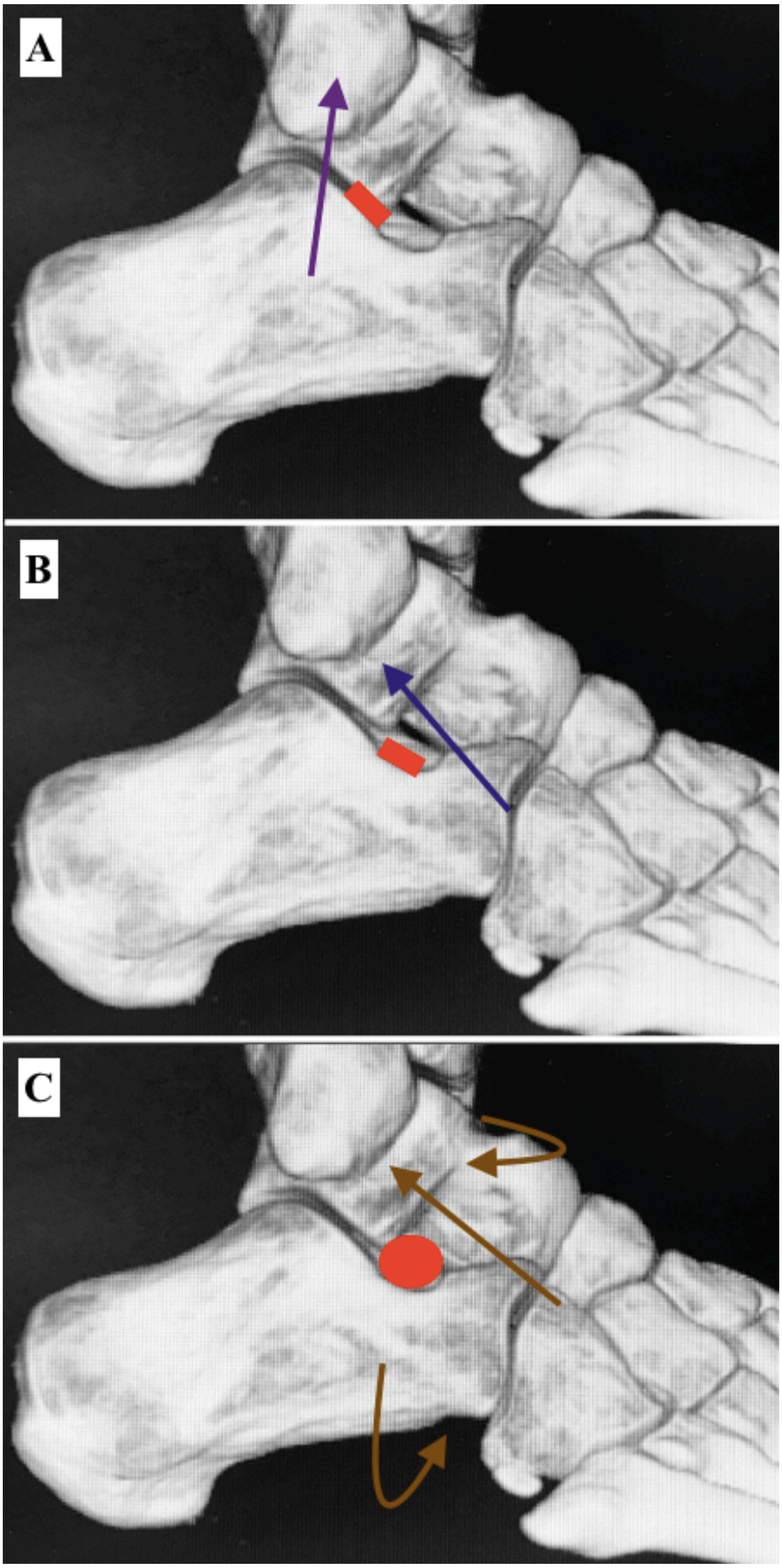


Fig. 1: The three types of subtalar implant (axis-altering in A, impact-blocking in B and self-locking in C) are illustrated with their position in the joint (in red) and the main force generated between the talus and the calcaneus (black arrows). Image adapted form BoneBoxTM - Foot (© 2014 iSO-FORM, LLC).

The recent state of understanding

Subtalar arthroereisis (STA) may be performed as a stand-alone or as an associated procedure in treating painful congenital flexible flatfoot, while is often realised as ancillary in the treatment of the tibialis posterior tendon dysfunction, tarsal coalition and accessory navicular bone syndrome[52]. Both in adolescents[53] and in adults[26], one of the most diffused procedures for treating tibialis posterior tendon dysfunction consist of flexor digitorum longus transfer and medializing calcaneal osteotomy. In this context arthroereisis has been documented as performed either before the osteotomy (if the correction reached is satisfying osteotomy may be avoided)[24,53] of after the osteotomy (to discharge the medial structures)[55], leading to satisfying results in both cases[24,53,54].

Technically, the surgical approach is common for all authors and minimally invasive, through a lateral 1 to 4 cm incision just anterior and inferior to the malleolus tip, parallel to the skin tension lines. After debridement of the sinus tarsi, the hindfoot is manually supinated and a correct position of the foot is restored. For self-locking implants, a blunt probe is used to find the tunnel direction and progressive trial implants are used to chose the proper size under fluoroscopy, then the permanent device is implanted (Figs. 2 and 3). For impact-blocking devices, a guide-wire in the calcaneus (anterograde technique) or in the talus (retrograde technique) is drilled, then the definitive screw is inserted (Fig. 2). Postoperative protocols vary depending on authors. When performed as stand-alone procedure, weightbearing may be allowed immediately with[55,56] or without cast[57] or at 5-10 days[58], while it is delayed for 6 weeks when associated to other procedures[24,53,54].

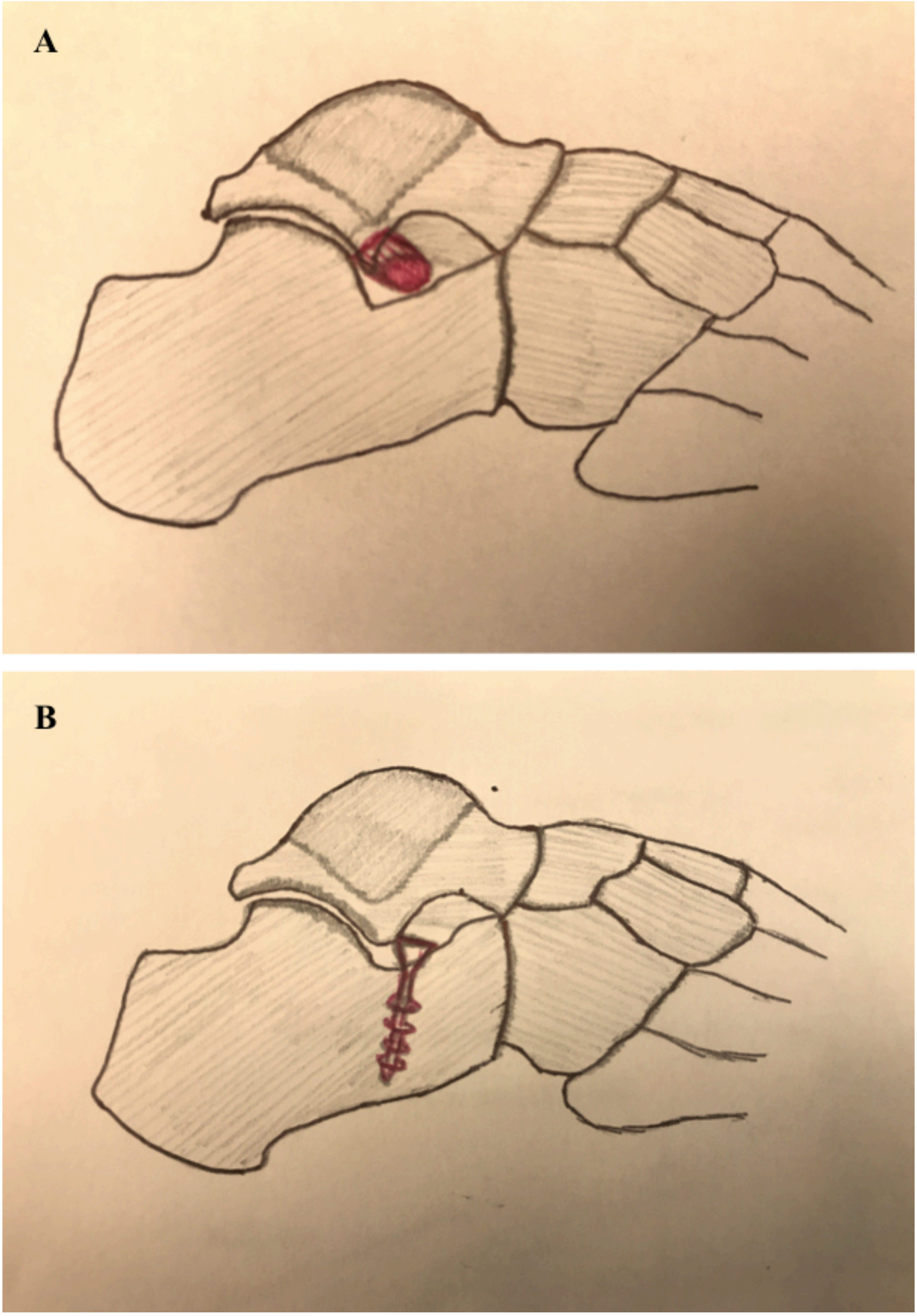


Fig. 2: The two drawings (lateral view of a hindfoot) show the difference in positioning between a self-locking (in A) and an impact blocking (in B) devices (in red), corresponding to the implants more frequently used worldwide.

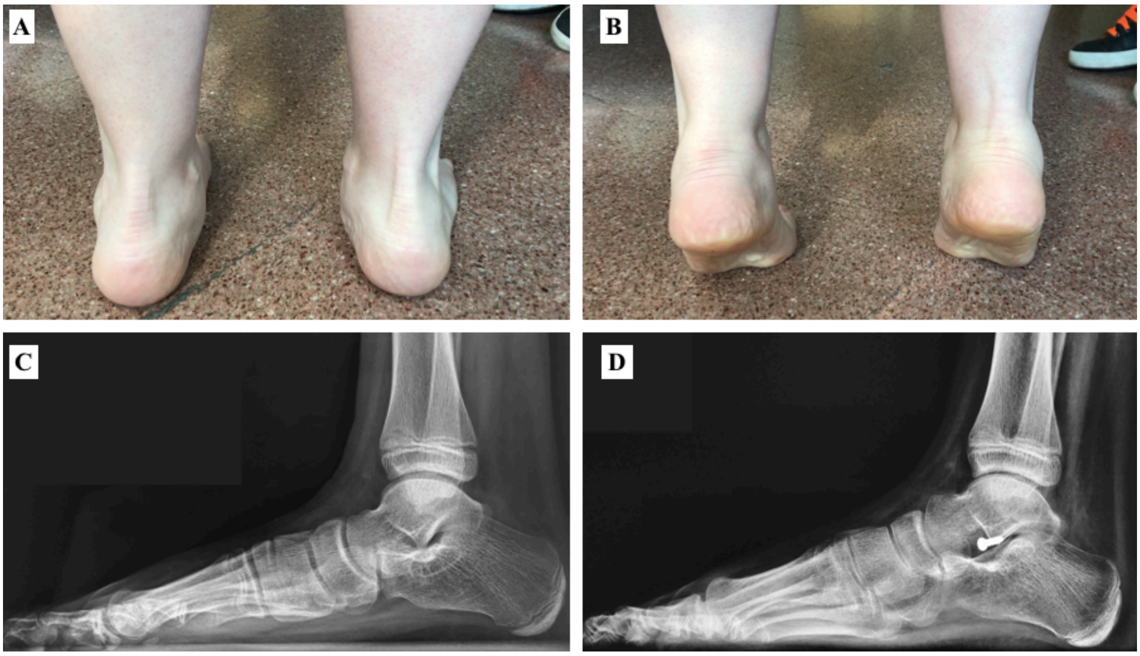


Fig. 3: The two clinical images reproduce two important phases of the clinical examination. The young patient (12 years old) is complaining of pain at the right foot. Visually, during weightbearing and from behind, a collapse of a medial arch and a valgus hindfoot may be noticed (A). The correction of the valgus to the heel rise test (B) helps to understand if the deformity is flexible (as in the image) or not. In C and D the preoperative and postoperative (3 months) weightbearing lateral views, respectively, where the improvement of the talometatarsal angle may be observed.

As showed in literature, STA induces a triplanar modification of the foot limiting pronation through its three components, i.e. calcaneal eversion, talar adduction and plantar flexion[59]. The implant technique has been widely described, but there is a lack of understanding about the precise mechanism of realignment. Apart from an obvious mechanical effect, a hyphotetical proprioceptive action of these prostheses (most of all impact-blocking) related to the density of receptors (mostly mechanoreptors) in and around the sinus tarsi has been long discussed[60]. Despite being attractive, this hyphotesis has never been proved by any basic or clinical study.

Globally, complications may be divided in 4 main categories, including the consequences of inappropriate indication (unstable midtarsal joint, arthritis or arthrosis, rigid equinus), technical error (extrusion, over or undercorrection) adaptation/irritation (painful sinus tarsitis, peroneal spasm, soft tissue entrapment) and biomaterial failure (wear or breakage)[61] (Fig. 4). Among these, the most common is undoubtedly sinus tarsi pain[6,24,52], even though the most of authors have reported its complete resolution after implant removal[61,62]. What actually remains unclear are the complication and the removal rates. Indeed, in a recent review including the whole litterature, they are reported from 4.8% to 18.6%and from 7.1% to 19.3%, respectively[4,6]. These figures are in contrast with the concept that not all complications require further surgery and may solve spontaneously, as shared by most authors. Some previous studies had also documented removal needed in up to 40% of patients[54], thus uncertainty in this field together with the lack of long-term analyses could be only addressed by future robust prospective designed works.

Fig. 4: A complication after STA. Foot weightbearing radiographs in a patient complaining of pain at 6 months from the implant of a subtalar device, showing a bilateral extrusion of the screw.

Looking at the literature, in performing subtalar arthroereisis surgeons usually rely on some personal experience or on some litterary suggestion rather than based on a structured scientific evidence. This is probably the main reason why nowadays the literature available on this topic looks so heterogeneous. A series of good results have been reported but it's extremely difficult to extract reliable data about the true role of a subtalar implant and its real contribution to final deformity correction.

In 2011 Metcalfe et al. analysed extensively the available evidence regarding subtalar arthroereisis in treating flatfoot[6]. Regardless of the type of implant, the authors found only 'ad hoc' case reports and retrospective case series. In terms of outcome, they underlined that few studies had applied validated clinical or patient reported outcome measures and that only one study had utilized a disease- and child-specific patient reported outcome measure. Also, they showed that despite a wide variation in radiological parameters used among studies and their unclear relationship with clinical status, radiographic measures were often adopted as markers of success after surgery. The most used were calcaneal inclination and talar declination angles, but several other parameters have been reported to indicate arch height increase and the improvement in the hindfoot-midfoot axis[6]. Globally, Metcalfe et al. concluded that arthroereisis appeared capable of correcting flatfoot, but that it was still an evolving technique based more on clinical experience than evidence-based data. Obviously, they suggested to use in further studies validated disease-specific patient outcome tools.

An overview of the recent years (2012-2017)

Our goal was to update the current state of art about the STA in treating flatfoot, therefore a review of the evidence produced during the last years (in English language) has been lead.

The first important consideration is that high-quality studies are still lacking both in children and adults. The only prospective nonrandomised comparative study (Level of Evidence II) was lead in 2015 by Chong et al. on 24 feet treated by arthroereisis or lateral column lenghtening (Evans osteotomy or calcaneocuboid fusion associated to gastrocnemius recession or peroneal tendon transfer)[56]. At about 12 months follow-up, authors found satisfying subjective (score) and objective results (radiographic mesures, kinematics and pedobarometry) together with a similar complication (15% vs 18%, respectively) and reoperation rate (15% vs 9%) between the two strategies. They concluded that subtalar arthroereisis may be considered a useful alternative, but the small sample size, the short term follow-up and the conflict of interest declared by the authors certainly make further robust comparisons unavoidable.

Apart from this, a few case series have been published. Some studies have reported excellent results in the treatment of pediatric[53,63,64] and adult[24,65,66] flatfoot with arthroereisis associated to other procedures, but – as also stated by Yen - it is hard to gather reliable informations from them about arthroereisis mainly due to the potential confounding effect of additional procedures[67].

When considering STA alone, all authors reporting results on different cohorts (non comparative studies) have concluded that this minimally invasive procedure was an optimal technique for the correction of the flexible flatfoot in children[57,58] and in adults[68] providing clinical and radiological satisfying outomes. Of note, what we found is that in clinical assessment they still use non-validated scores (for children) and radiographical parameters, not always related to the 'pathologic' flatfoot and, additionally, often affected by some bias[69].

What is more, some new rare but possible complications as post-operative subtalar fusion and talar fracture have been documented in case reports[70,71], however in more recent studies the overall complication rate was considered negligable, standing between 0% and 11%[57,68]. By contrast, surprising data emerge from a web-based survey performed in 2015 documenting that among the American Orthopaedic Foot and Ankle Society members that have performed subtalar arthroereisis over their carreer, one out of three (33%) has decided to abandone the procedure mainly because of the failure rate and the need of removal[52]. This may suggest that the publication bias related to the tendency to publish positive results may actually be underestimated in studies dealing with subtalar arthroereisis. Additionally, this survey states that there is a greater percentage of non-United States based surgeons performing arthroereisis than the United States counterparts, probably being influenced by problems with payments by health insurance companies.

Concerning the device removal, older studies had suggested that an implant should be maintened in place at least 2 years to allow adequate bone and soft-tissue adaptation[49,50]. In recent literature, when used as adjunctive procedure in adult flatfoot, a delay of 18 down to a minimum of 6 months have been reported in order to take advantage of the implant related discharge on the other surgical acts[24,54]. Anyway, no precise data are available about the minimum time requested to mantain long-lasting correction. Furthermore, due to considerable unplanned explantation rates up to 30-40%[8,54], a few investigations have focused on possible predictive factors of implants removal in adults[72,73], concluding that implant size (greater risk with greater implant)[73] and radiographic undercorrection of the deformity[72] could represent risk factors. Of note, in these studies arthroereisis was often performed as adjunctive procedure with several types of implant[72]; what is more, looking back even at the older literature, both the size and the radiographic parameters of correction do not seem to have always been related to a higher removal rate[72,74]. Therefore a clear relationship between the explantation risk and any possible risk factor has still to be determined (Table 1).

Table 1: Advantages and disadvatages of STA.

Advantages	Disadvantages
Compared to open traditional surgery	Quality of studies available is poor
lower invasivity (mini-incision)	Data uncertain regarding:
decreased postoperative edema	complication rate
shorter hospital stays	removal rate
possibility to associate soft-tissue and bony procedures	need (and timing) of removal in absence of symptoms
	comparison among implants
	long-term results

Practice recommendations from literature

In children

In 2017 (when this review has been lead), subtatalar arthroereisis is still a debated procedure. Different types of device (mostly self-locking and impact-blocking devices) are currently used worldwide for the treatment of flexible flatfoot as an isolated or complementary surgical procedure depending on each surgeon or school experience. Sometimes, in children it has been used even in rigid variants secondary to tarsal coalitions, being implanted after the resection of synostosis. In many case series arthroereisis is reported as simple, effective and low risk, but outcome assessment is heterogeneous and non standardized. At present, according to the A,B,C,I system[75], subtalar arthroereisis procedure should be assigned a grade C of recommendation, because of the poor-quality evidence (Level IV or V studies) of studies available in current literature. The unique Level II study is prospective but nonrandomised and deals with a little sample size and a short follow-up, therefore being inadequate to provide strong recommendations for or against the technique[54]. Lack of understanding has still to be addressed in terms of mechanisms, minimum time before removal, superiority compared with other surgical solutions or among implants. Additionally, some concerns about long term results and complications (osteoarthritis) are crucial in a procedure often performed in childhood or adolescence, therefore they need to be addressed by proper medical investigations and research.

In adults

In adults, there is a wide consensus regarding the usefulness of insoles in the first approach to flatfoot (secondary to PTTD), and in proposing surgery only in case of failure. However, adult foot is structured, therefore the rationale under the implant of whatever arthroereisis screw is different from children. In adults, the procedure is rarely performed alone, while it may be useful together with soft tissues and bony acts in order to strenghten the anti-pronation effect and to discharge the tibialis posterior tendon and the medial arch. Even in adulthood, the grade of recommendation for STA should be considered as C, due to the quality of studies published. At present, several experts'opinions are available in literature, and some of them suggest to use subtalar implants when the correction after traditional surgery is not deemed satisfactory. According to the data here shown, comparative and prospective studies are needed to elucidate the real advantages and indications of such devices.

PART II

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

AIM

In this study, we hypothesized that (1) STA provided significant radiographic correction of low longitudinal arch and forefoot abduction in paediatric flatfoot (FF) and that (2) mid-term clinical outcomes were satisfactory and comparable to a normal population.

METHODS

Study design

A retrospective review was carried out of patients diagnosed with FF and treated with STA at a single institution (Section of Orthopaedic Surgery, Department of Public Health, Federico II University, Napoli, Italy) by a single surgeon 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.

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 FF (collapse of the medial longitudinal arch associated with hindfoot valgus and forefoot abduction); flexible 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).

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[76]. 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. 5). Forty-eight feet from 24 healthy volunteers comparable by age at follow-up, sex, side and body mass index (BMI) were recruited (Table 2).

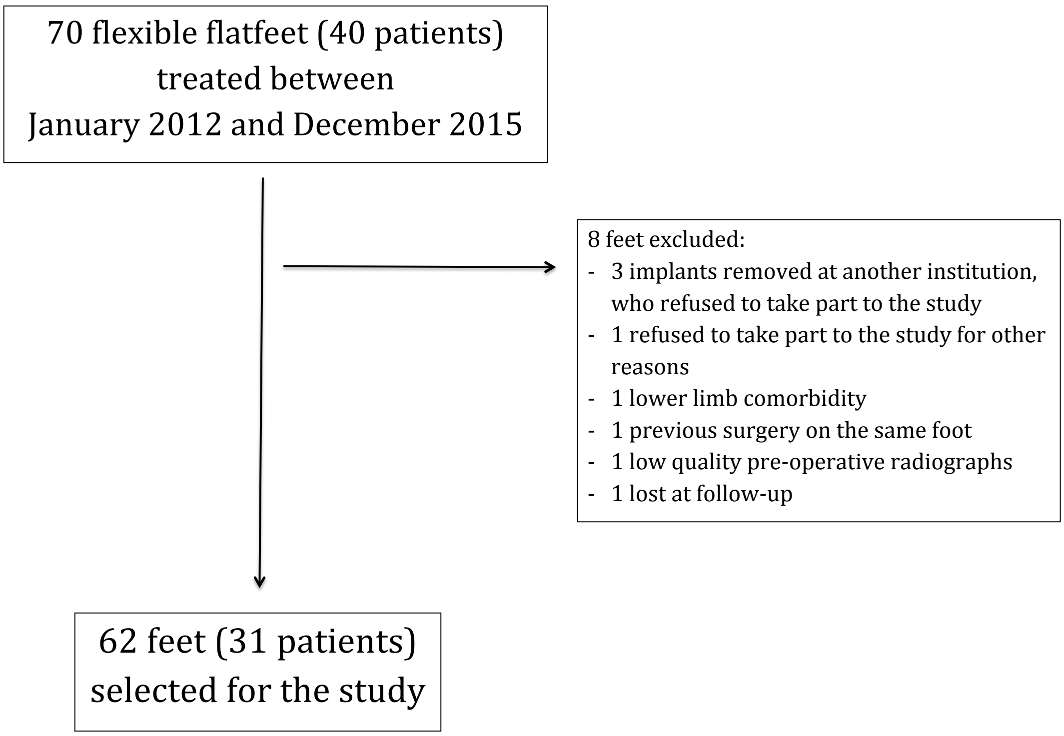


Figure 5: Flow chart showing selection of patients.

Table 2: Patients' demographics.

	STA	Controls	*p*-value
Feet (Patients)	62(31)	48(24)	1
Age at surgery, yr	10.5±1.6(8–15)	-	-
Age at follow-up* , 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*, kg/m^{2,}	23.4±4.1(15–35)	23.3±3.5 (17–27)	0.750**

STA: Subtalar arthroereisis
* mean±standard deviation, range in brackets
** unpaired T-Student test
*** chi-squared test

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. 6)[76].

Figure 6: 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).

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.

Outcome assessment

Radiographic outcome

Standardised weight-bearing dorsoplantar and lateral radiographs of the feet taken pre-operatively and at latest follow-up were assessed (Figs. 7 and 8). For patients requiring removal of the implant, radiographs from before and after surgery were retrieved. The variables investigated, gathered from literature[77,78], were talonavicular coverage angle (TNCA), talocalcaneal divergence angle (TCDADP) and calcaneo-fifth metatarsal angle (CFMA) 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.

Figure 7: Example of preoperative and 48-month follow-up lateral radiographs.

Figure 8: Example of preoperative and 48-month follow-up dorsoplantar radiographs.

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.

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 .05.

RESULTS

Radiographic outcome

Excellent inter and intra-observer reliability was confirmed for all angles (range, 0.81-0.97). The medial longitudinal arch was significantly heightened after STA ($p < .001$ 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 3). 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: Radiographic comparison between preoperative and last follow-up values in patients treated with STA (N 62).

	Preoperative	**Postoperative**	***p*-value**
	Mean ± SD (range)	*Mean ± SD (range)*	
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

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. As expected, STA patients showed less hindfoot inversion than controls (*p*=0.03) (Table 4a).

Table 4a: Clinical outcome (ROM and AOFAS score). Significant differences are outlined in bold.

	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**

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 4b).

Table 4b: Clinical outcome (VAS-FA). Among the items, one question (problems while driving a car) was not applicable because of age of patients, being therefore removed. Significant differences are outlined in bold.

VAS-FA *(points)*	STA (N 62)	Controls (N 48)	*p*-value
	Mean ± SD (range)		
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

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

In our series, subtalar endo-orthesis heightened the medial longitudinal arch in flexible FF which is in accordance with the results of other groups[56,63,76,79,80]. Bearing in mind the concept of calcaneopedal unit (CPU)[81,82], our results suggest STA leads to a re-positioning of CPU under the talo-tibiofibular unit (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 cohort. Although after STA an intraoperative 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 mantaining 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[56,79,80] and dorsoplantar talocalcaneal angle[76,79]. 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[56,80], 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 FF with mild abduction and that lateral column lengthening (LCL)[83] should be preferred to achieve better correction of the transverse plane deformity[84]. 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 perfomed to achieve correction[84]. Noteworthy, the so-called Judet technique (consisting in restoring the talar position relative to the calcaneus and mantaining it using a temporary talocalcaneal screw through the sinus tarsi) has been proposed as alternative to achieve long-lasting correction of FF, nevertheless its superiority compared to STA or LCL is yet to be proven[85]. 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[86], 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[87], 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[80,84,88] and mean 9.1/10 among all VAS-FA items. When focusing on studies uniquely dealing with non-resorbable endo-orthesis for correcting paediatric FF, 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[37,63,76,79,80,88,89]. 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%)[37,56,63,76,79] (Fig. 9).

Figure 9: Preopearative 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.

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[56,63,76,79,80] 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 centers. 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.

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

PART III

Subtalar arthroereisis as an adjunct procedure improves forefoot abduction in stage IIb adult-acquired flatfoot deformity

AIM

In a recent study, Walley et al. recently compared 30 feet that underwent medialising calcaneal osteotomy (MCO), flexor digitorum longus (FDL) transfer, spring ligament repair (SLR) and Achilles tendon lengthening for adult acquired flatfoot deformity (AAFD) against 15 feet which had the same procedure but with additional STA[91]. Similar good clinical outcomes were reported amongst both groups but STA was found to confer better radiographic correction[91]. Bearing in mind that the interplay between flatfoot deformity and gastrocnemius-soleus tightness is not yet completely clear[92], we undertook a similar analysis but excluding patients who underwent any soft tissue posterior release.

The primary purpose of this study was to compare the radiographic outcomes of AAFD correction with and without STA. The secondary purpose was to assess for complications of STA. Our hypothesis was that STA as adjunct procedure would improve the longitudinal medial arch and forefoot abduction with a low rate of complication.

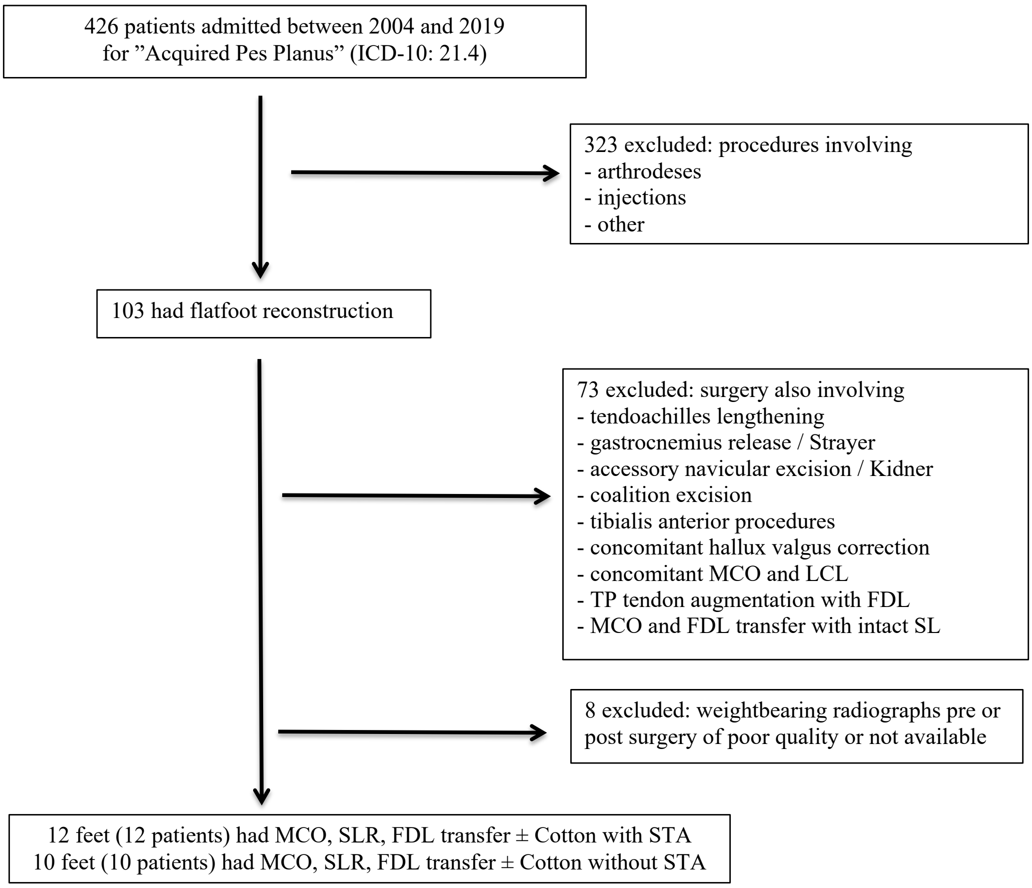
METHODS

Study design

A retrospective study was initiated of adult patients presenting to a single unit (Foot and Ankle Unit, Royal National Orthopaedic Hospital, Stanmore, UK) with diagnosis of acquired pes planus (ICD 21.4) between July 2004 and January 2019. All procedures were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Inclusion/exclusion criteria

Medical records were reviewed to only include those specifically with stage IIb AAFD (over 18 years of age) who underwent surgical correction using a medialising calcaneal osteotomy (MCO), flexor digitorum longus tendon (FDL) transfer, spring ligament repair (SLR) with or without plantarflexion osteotomy of the medial cuneiform (Cotton osteotomy) and with or without STA. Strict exclusion criteria included the use of concomitant bony or soft tissue procedures outside that previously described and inadequate or unavailable weightbearing pre and postoperative radiographs (Fig. 10).



Abbreviations: MCO: medialising calcaneal osteotomy; LCL: lateral column lengthening; FDL: flexor digitorum longus; TP: tibialis posterior; SLR: spring ligament repair; STA: subtalar arthroereisis

Figure 10: Flow chart showing selection of patients for the study on the adult cohort. In the final cohort, all patients were diagnosed with stage IIb (supple hindfoot valgus associated with forefoot abduction) adult acquired flatfoot deformity. One patient had bilateral surgery (one side with STA and one side without).

Study population

Out of 426 patients, 22 feet in 21 patients were finally selected, with the patient flow-chart for study entry being depicted in Figure 1. The average age ± standard deviation (SD) was 55.2 ± 2.4 years (range, 31 to 77). The average height and weight ± SD was 162.9 ± 2 cm (range, 150 to 183) and 85.3 ± 4.1 kg (range, 60 to 136.2), respectively. The average body mass index (BMI) ± SD was 31.4 ± 1.1 kg/m^2 (range, 23.1 to 42 kg/m^2). There were 11 (50%) males and 11 (50%) females. Five (23%) Cotton osteotomies and 12 (54%) STA procedures were performed.

Surgical technique

All surgeries were undertaken by one of three foot and ankle orthopaedic surgeons using a standard technique in the supine position with an ipsilateral buttock support initially to aid internal rotation of the leg. An extended lateral approach was used to approach the calcaneus and perform a medialising sliding osteotomy that was fixed with either cannulated partially threaded screws or a locked step-plate depending upon the practice of the surgeon. The choice of whether STA was performed was dependent upon a change in practice by two surgeons. STA was performed through an incision over the sinus tarsi. A guidewire was passed across the tarsi canalis and after sequential size increases in trial implants, a definitive Futura™ Conical Subtalar Implant (Tornier, Saint Ismier, France / Wright Medical Group, TN, USA) was placed under image guidance (Fig. 11).

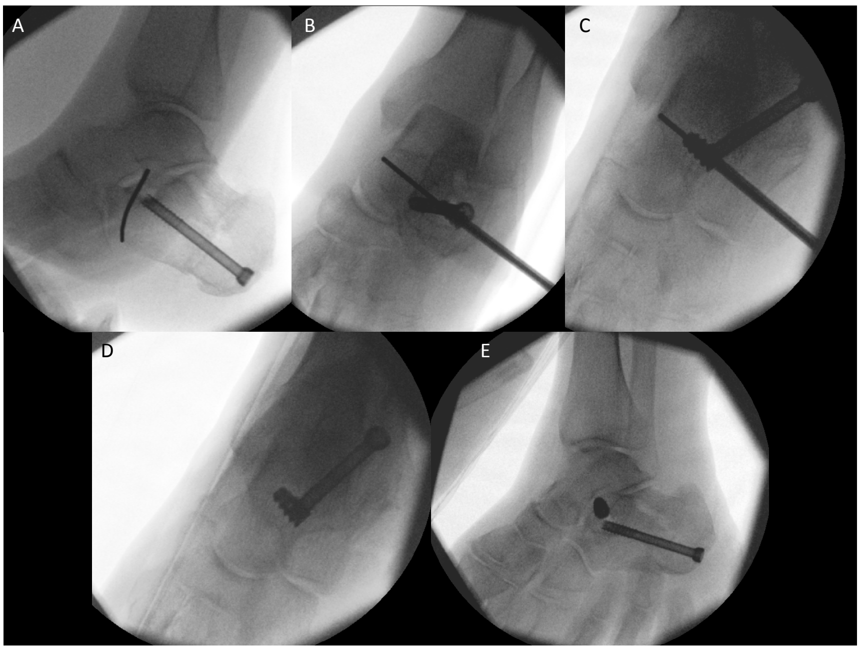


Figure 11: Implant of Futura™ Conical Subtalar Implant. Introduction of dedicated blunt guide wire into the canalis tarsi through the sinus tarsi, checked under image intensifier on lateral view (A), ankle anteroposterior view (B) and foot dorsoplantar view (C). Implant is therefore advanced till optimal position on two projections (D and E). On dorsoplantar view (D), STA is advanced so that the proximal extremity has slightly overcome the lateral edge of the talar neck. Implant stability is finally checked manually with dorsiflexion/plantarflexion and inversion/eversion movements.

After removal of the buttock support, attention was turned to the medial side, where the posterior tibial tendon was identified and the diseased segment was excised leaving a stump at the distal insertion. The spring ligament was then inspected and found in all cases to be either torn or stretched and defunctioned. All ligaments were incised to make complete tears and repaired by double breasting the ends with the talonavicular joint in reduced position (foot inverted). This repair was supplemented with the remnant tibialis posterior tendon distal stump. The flexor digitorum longus tendon (FDL) was identified at the ankle and traced distally till the knot of Henry where it was divided and passed through a 5 mm bone tunnel in the navicular where it was either sutured back on to itself (if length allowed) or fixed with an interference screw. In case of persistent rigid forefoot supination, a Cotton plantarflexion osteotomy of the medial cuneiform was performed through a dorsal approach and fixed with a wedge plate (Fig. 12). A below-knee plaster of Paris cast was applied postoperatively with the foot at 90 degrees relative to the tibia in the sagittal plane and 45 degrees supinated relative to the tibia in the coronal plane. This was changed after 2 weeks and 4 weeks with each plaster change bringing the foot sequentially to a plantigrade position. After week 6, the cast was removed and exchanged for a pneumatic walking boot in which weight bearing was allowed and physiotherapy commenced. Clinical and radiographic assessment was carried out at 6 weeks and also at 6 and 12 months, then yearly. Removal of STA implant was offered to all patients with persistent pain in the sinus tarsi at minimum 6 months from the index procedure.

Figure 12: Example of stage IIb adult acquired flatfoot deformity with comparison between pre-operative (left and upper central images) and 11-month follow-up (lower central and right images) radiographs. Patient has been treated through calcaneal medialising osteotomy, flexor digitorum tendon transfer, spring ligament repair, Cotton osteotomy and STA implant.

Radiographic measurements

Two observers not involved with surgical procedures independently examined pre and postoperative weightbearing plain radiographs and one of them repeated all measurements after six weeks. Postoperative radiographs were defined as being taken at a minimum of 6 months after surgery. The dorsoplantar view was used to measure: (1) talo-navicular coverage angle (TNCA); (2) talo-calcaneal divergence angle (DPTCA) and; (3) calcaneo-fifth metatarsal angle (CFMA). The lateral view was used to measure (1) talo-calcaneal divergence angle (LTCA); (2) talo-first metatarsal angle (TFMA); (3) Dijan-Annonier angle (DAA) and; (4) calcaneal pitch (CPA).

Statistical analysis

Data is reported as mean, standard deviation (SD) and range values. Inter and intraobserver reliability was assessed through intraclass correlation (ICC) calculation. Results were considered excellent if > 0.74; good, 0.60–0.74; fair, 0.40–0.59; and poor, < 0.40.[93] Normality of data was tested using the Shapiro-Wilk test, therefore Student t-test was used to compare normally distributed variables, Wilcoxon rank-sum test for non-normally distributed ones and Fisher test for categorical ones. A total of 20 patients were required to have a power of 80%, using a two-sided alpha set to 0.05 to show a radiographic difference of greater than 5 degrees in the mean TNCA[91] between the preoperative and postoperative value. Univariate analysis was conducted to compare patients with and without STA against radiographic variables. Association between continuous variables (age, height, weight and BMI) and change in radiographic angles was explored through Pearson's coefficient correlation, with a p-value of < .05 indicating statistical significance. Association between discrete variables (gender, side, Cotton osteotomy and STA) and change in radiographic angles was tested through Wilcoxon rank-sum test, using a p-value of < .10 as has been used in previous studies.[94,95] Predictors of correction of forefoot abduction or longitudinal medial arch were identified by including those variables found to be independently significant in the univariate analyses in a subsequent multivariable analysis. Multivariate linear regression modelling was developed to estimate the effect of STA on change in the angles found as predictors, adjusting for demographic and radiographic variables with statistical significance set at 0.05. All statistical analyses were performed using STATA statistical software package (version 12.0, StataCorp, College Station, TX, 2011).

RESULTS

Reliability of measurements

Mean radiographic follow-up was 11.2 months (range, 6 to 25). All radiographic measurements exhibited excellent interobserver and intraobserver reliability both before and after surgery (ICC range, 0.74 to 0.99).

Comparison between patients treated with adjunct STA versus without STA

Patients who underwent surgery with an adjunct STA did not differ from those who had surgery without STA by sex (p= 0.457), side (p=1), age (p=0.825), height (p=0.444), weight (p=0.896), BMI (p=0.95), number of Cotton osteotomies (p=0.193) and interval between surgery and last radiographic follow-up (p=0.644). All radiographic measurements were normally distributed ($p > 0.05$ in all cases). Preoperative and postoperative values did not differ between the two groups ($p > 0.05$ in all cases) (Table 5). All measurements revealed a significant improvement of the deformity after surgery, except for the CFMA in the group treated without STA (p=0.062) and the CPA in both groups (p=0.761 and p=0.704 with and without STA, respectively)

Univariate analysis

Age or BMI had no association with changes in radiographic angles (all $p > 0.10$). Interestingly, surgery undertaken on right feet revealed greater changes in LTCA (p=0.02) and TFMA (p=0.08) than the left. Cotton osteotomy was significantly associated with change in DPTCA (p=0.005) (Table 6 and 7). The addition of STA correlated with greater changes in the TNCA (p=0.04) and CFMA (p=0.01), being also associated with larger changes in males than females (p=0.05) (Table 6 and 7). Since STA significantly correlated with change in TNCA and CFMA, only these angles were included in the further analysis.

Table 5: Comparison of pre and postoperative radiographic angles in each group and between groups.

		Flatfoot reconstruction with STA (N 12)		Flatfoot reconstruction without STA (N 10)		*p-value**
RADIOGRAPHIC ANGLES *(degrees)*		*Mean value ± SD*	*95% CI*	*Mean value ± SD*	*95% CI*	
Dorsoplantar view						
TNCA	*preop*	35.4 ± 1.9	31.1 – 39.6	29.7 ± 3.6	21.3 - 38	0.101
	postop	16.5 ± 3.8	8.1 – 24.9	18.4 ± 3.7	9.9 – 26.8	0.632
	p-value	<0.001		0.02		
DPTCA	*preop*	27.8 ± 2.3	22.5 – 33.1	26.6 ± 2	22.1 – 31.1	0.353
	postop	20.5 ± 2.6	15.7 - 25.3	20.2 ± 2.4	14.6 – 25.7	0.46
	p-value	0.015		0.001		
CFMA	*preop*	18.1 ± 1.9	13.9 – 22.4	17.9 ± 2.4	12.3 - 23.5	0.472
	postop	11.2 ± 1.3	8.3 – 14.1	16.1 ± 2.4	10.6 – 21.6	0.959
	p-value	<0.001		0.062		
Lateral view						
LTCA	*preop*	51 ± 1.7	47.1 - 54.9	48.2 ± 1.6	44.4 – 51.9	0.118
	postop	41.2 ± 2.1	36.6 – 45.9	42.6 ± 1.4	39.2 – 45.9	0.684
	p-value	<0.001		0.003		
TFMA	*preop*	19.5 ± 2.2	14.5 - 24.4	19 ± 3	12 - 25.9	0.447
	postop	6.4 ± 1.6	2.8 - 10	9.5 ± 1.4	6.3 – 12.7	0.912
	p-value	<0.001		0.003		
DAA	*preop*	139.3 ± 2.1	134.6 - 144	137.2 ± 2.7	131 – 143.4	0.270
	postop	132 ± 2	127.5 – 136.6	131.4 ± 1.2	128.4 – 134.3	0.396
	p-value	<0.001		0.015		
CPA	*preop*	15.1 ± 1.2	12.3 - 17.9	13.1 ± 1.3	10.1 - 16.2	0.148
	postop	15.6 ± 1.4	12.4 – 18.8	13.9 ± 0.5	12.5 – 15.2	0.155
	p-value	0.761		0.704		

BMI: Bone mass index; STA: Subtalar arthroereisis; SD: Standard Deviation; TNCA: Talonavicular coverage angle; DPTCA: Dorsoplantar talo-calcaneal divergence angle; CFMA: Calcaneal-fifth metatarsal angle; LTCA: Lateral talo-calcaneal divergence angle; TFMA: Talo-first metatarsal angle; DAA: Dijan-Annonier angle; CPA: Calcaneal pitch; preop: preoperative; postop: postoperative

* Student T Test

Table 6: Univariate analysis (for change in radiographic angles on dorsoplantar view, reported in degrees).

	N		TNCA		DPTCA		CFMA	
CONTINUOUS VARIABLES								
			PCC	*p-value*	*PCC*	*p-value*	*PCC*	*p-value*
Age *	22		-0.20	0.35	0.18	0.41	-0.27	0.21
BMI *	22		-0.36	0.14	-0.23	0.31	-0.23	0.15
DISCRETE VARIABLES								
			Mean ± SD	*p-value*	*Mean ± SD*	*p-value*	*Mean ± SD*	*p-value*
Sex **	5	M	10.5 ± 3.7	0.41	3.8 ± 2.7	0.30	1.1 ± 1	0.05#
	17	F	17.4 ± 2.8		7.8 ± 2		5.6 ± 1.2	
Side **	11	R	17.6 ± 3.3	0.66	8.5 ± 3.2	0.71	5.2 ± 1.6	0.46
	11	L	14.2 ± 3.4		5.3 ± 1.3		3.9 ± 1.4	
Cotton **	5	Y	16.9 ± 3	0.36	8.7 ± 2	0.005#	4.5 ± 1.3	0.87
	17	N	12.5 ± 1		0.7 ± 0.5		4.6 ± 1.2	
STA **	12	Y	19.7 ± 3.4	0.04#	7.3 ± 2.9	0.59	6.9 ± 1.4	0.01#
	10	N	11.2 ± 2.7		6.4 ± 1.6		1.8 ± 1	

BMI: Bone mass index; STA: Subtalar arthroereisis; TNCA: Talonavicular coverage angle; DPTCA: Dorsoplantar talo-calcaneal divergence angle; CFMA: Calcaneal-fifth metatarsal angle; SD: Standard Deviation

(*): Pearson's correlation coefficients (PCC); (**): Wilcoxon rank-sum test

#: significant p-values at univariate analysis (<0.10)

Table 7: Univariate analysis (for change in radiographic angles on lateral view, reported in degrees).

	N		LTCA		TFMA		DAA		CPA	
CONTINUOUS VARIABLES										
			PCC	*p-value*	*PCC*	*p-value*	*PCC*	*p-value*	*PCC*	*p-value*
Age*	22		-0.29	0.17	-0.07	0.75	0.04	0.84	-0.26	0.23
BMI*	22		-0.27	0.23	-0.28	0.21	-0.19	0.39	-0.05	0.80
DISCRETE VARIABLES										
			Mean ± SD	*p-value*	*Mean ± SD*	*p-value*	*Mean ± SD*	*p-value*	*Mean ± SD*	*p-value*
Sex**	5	M	5.6 ± 1.4	0.48	9 ± 2.5	0.50	6.3 ± 1.6	0.90	0.5 ± 0.4	0.78
	17	F	8.6 ± 1.6		12.1 ± 2.2		6.7 ± 1.5		0.6 ± 0.8	
Side**	11	R	10.7 ± 1.9	0.02#	14 ± 2.1	0.08#	7.8 ± 1.2	0.12	-0.1 ± 0.7	0.33
	11	L	5 ± 1.4		8.6 ± 2.8		5.4 ± 2.1		1.3 ± 1.3	
Cotton**	5	Y	7.1 ± 1.4	0.25	10 ± 2	0.14	6.4 ± 1.5	0.45	0.5 ± 0.8	0.63
	17	N	10.6 ± 2.9		16 ± 3.4		7.4 ± 1.7		0.7 ± 0.8	
STA**	12	Y	9.8 ± 1.9	0.14	13 ± 2.4	0.26	7.2 ± 1.3	0.11	0.5 ± 0.8	0.81
	10	N	5.6 ± 1.5		9.4 ± 2.7		5.8 ± 2.2		0.7 ± 0.8	

BMI: Bone mass index; STA: Subtalar arthroereisis; LTCA: Lateral talo-calcaneal divergence angle; TFMA: Talo-first metatarsal angle; DAA: Dijan-Annonier angle; CPA: Calcaneal pitch SD: Standard Deviation

(*): Pearson's correlation coefficients (PCC)
(**): Wilcoxon rank-sum test
p value <.10 were included in the multivariable analysis

Multivariable analysis

Gender, side, Cotton osteotomy and STA were included in the multivariable analysis. Regression showed that STA was the only predictor of change in TNCA (R^2=0.31; p=0.03) and in CFMA (R^2=0.40; p=0.02) (Table 8). Mean radiographic improvement ± SD in TNCA was 19.7 ± 3.4 degrees (range, 3 to 44) for feet treated with an adjunct STA and 11 ± 2.7 degrees (range, 3 to 28) for feet treated without STA. The mean change ± SD in CFMA was 6.9 ± 1.4 degrees (range, -1 to 16) with STA and 1.8 ± 1 degrees (range, -4 to 7) without STA. Final modelling demonstrated that STA independently affected the TNCA angle by 10.1 degrees and the CFMA by 5 degrees (Table 8).

Table 8: Multiple linear regression models for change in TNCA and CFMA.

VARIABLE	TNCA*		CFMA**	
	Parameter estimate	*p*-value	Parameter estimate	*p*-value
Sex	3.73	0.51	3.45	0.15
Side	-6.31	0.19	-2.11	0.29
Cotton	-9.39	0.13	-1.66	0.51
STA	-10.1	0.03	-5	0.02

STA: Subtalar arthroereisis; TNCA: Talonavicular coverage angle; CFMA: Calcaneal-fifth metatarsal angle;
*Model information: N 22; p=0.04; R^2=0.31; adjusted R^2=0.15
**Model information: N 22; p=0.04; R^2=0.40; adjusted R^2=0.26

Complications

Four patients out of 12 who underwent STA complained of persistent pain in the sinus tarsi and all underwent the implant removal between 7 and 14 months after their index procedure. Immediate symptom relief was achieved in three patients but one patient described residual pain at the sinus tarsi which was did not resolve at final follow-up which was 8 months after the removal. Further investigation did not identify an independent pain generator.

DISCUSSION

This study identified that MCO, FDL transfer and SLR improves the deformity associated with the stage IIb adult flatfoot. Moreover the use of STA as an adjunctive procedure further reduces forefoot abduction, when assessed by TNCA and CFMA on weightbearing radiographs. We noted that one third of patients required their STA implant to be removed due to pain in the sinus tarsi and removal resolved these symptoms in the majority of patients.

Adult acquired flatfoot reconstruction is a complex procedure with multiple components. Authors have previously investigated the individual role of these components and found the MCO is a strong modifier of hindfoot lever arm [94] and Cotton osteotomy helps correct the collapse of the longitudinal arch [95]. A previous case-control study by Walley at al. compared MCO, FDL transfer, SLR and Achilles lengthening with and without STA [91]. They concluded that TNCA improved by 6 degrees without STA and by 10 degrees with it equating to a mean of 4 degrees [91]. Our results support STA improving TNCA but we believe it to be more powerful finding since approximately 10 degrees were gained in TNCA and 5 degrees in CFMA through its use (Fig. 13). Also, our analysis represents a step forward from Walley's study for at least three more reasons. First, although the premise that STA might improve transverse plane deformity is not new, through multivariable analysis we were able to quantify the contribution of STA as adjunct procedure in the treatment of AAFD. Second, all STAs in our series were performed with the same implant and on patients in the same substage (IIb) of the disease, which increased the homogeneity of the cohort. Third, we excluded patients who underwent any posterior soft tissue release, since the lengthening achieved might be difficult to quantify, potentially representing a confounding factor.

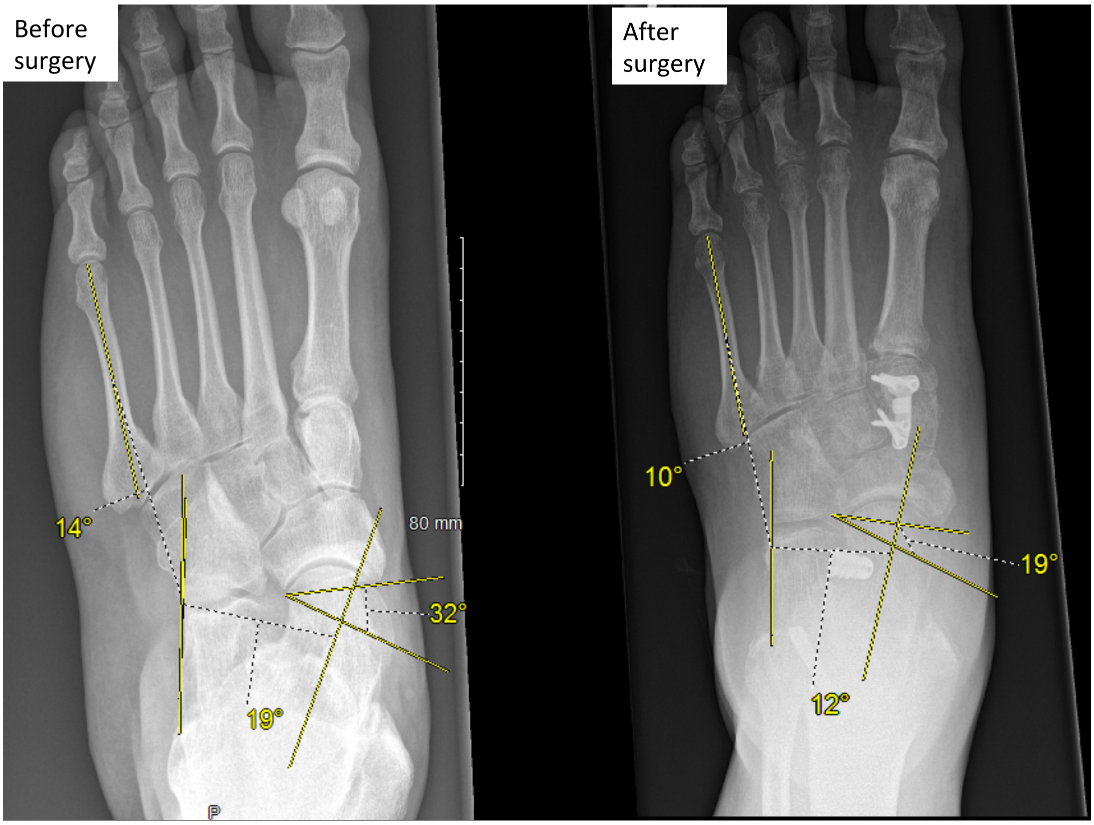


Figure 13: Dorsoplantar foot view before (left) and after (right) flatfoot reconstruction. The abduction of the forefoot is improved by 13 degrees (going from 32 to 19) when measured as talonavicular coverage angle and by 4 degrees (going from 14 to 10) when measured as calcaneus-fifth metatarsal angle. This apparent discrepancy between the two measurements (of 9 degrees) may find its explanation in the derotation of the subtalar joint with a change of the talocalcaneal angle of about 7 degrees (going from 19 to 12). The remaining unexplained rotation (approximately 2 degrees) is probably a consequence of two-dimensional radiographs biases (i.e. projection and operator-related biases), which reduce the accuracy of measurements.

Regarding complications of STA, we only observed one which was pain in the sinus tarsi. Although Walley et al. reported only a 6% incidence of sinus tarsi pain, this is much lower than the wider literature where pain ranges between 19% and 46% and re-operation rates range between 19% and 39% (Table 9) [73,96–98]. Our cohort was in keeping with this with approximately one third having sinus tarsi pain associated with STA. Although the implant was removed in all these patients, it is worth noting that one patient's pain continued even after removal.

Table 9: Demographics and surgical details from series published over the last 15 years (in English, with cohorts greater than 10 feet) reporting the use of non-resorbable (NR) subtalar arthroereisis devices (STA) to treat idiopathic deformities.

Author (year)	**LoE (design)**	**N of Feet (patients)**	**Age at surgery *(years)***	**Implant**	**Associated procedures**	**Follow-up *(months)***	**Complications**	**Re-interventions**
edleman 06)	(retr)	28 (23)	51 (28-74)	MBA	28 AchL or GR, 1 Br, 13 FDL, 2 Sp, 12 Cot, 2 Lap and McBr, 1 Chev, 1 Lesser toe surg	44 (7-76)	13 (46%) sinus tarsi syndrome	11 (39%) removal (of which 1 required triple arthrodesis for peroneal spasm)
ker 12)	r)	32	47 (11-80)	Kalix	8 TP repair, 5 AchL, 5 Cot, 7 Kid, 3 Calc Ost, 2 NCF, 1 Sp, 1 TA	> 12	6 (19%) sinus tarsi syndrome	6 (19%) removal
Zhu (2015)	IV (retr)	24 (22)	48.8 (23-74)	Kalix	19 FDL, 8 Calc Ost, 2 Lap, 6 Cot, 13 GR or AchL	29 (24-35)	7 (29%) - 6 sinus tarsi syndrome - 1 recurrence	14 (58%) implants removal (of which 6 symptomatic and 1 removal and arthrodesis)
Viladot Voegeli (2016)	IV (retr)	37 (35)	54 (40-80)	Kalix	16 AchL, 10 TP plasty, 9 FDL, 9 TP repair, 8 TP stripping, 2 FHL, 1 resection of accessory navicular	47.5 (14-75)	15 (40%) -13 sinus tarsi syndrome -1 CRPS -1 symptomatic overcorrection	13 (35%) removal
Walley (2019)	III (retr)	15 (15)	51.4 (66-94)	NEXA or ProSTOP Plus	In all cases: Calc Ost, FDL, Sp, AchL	28*	1 (6.6%): sinus tarsi syndrome	1 (6.6%): removal
This study	IV (retr)	12 (12)	55.2 (31-77)	CSI	In all cases: Calc Ost, FDL and Sp; 1 Cot	11.2 (6-25)*	4 (33%) sinus tarsi syndrome	4 (33%) removal

Data are reported as mean values ± SD and/or range in brackets, as reported by authors

LoE: Level of Evidence; retr: retrospective; MBA: Maxwell-Bracheau arthroereisis; GR: gastrocnemius recession; AchL:Achilles lengthening; Kid: Kidner's procedure; Br: Brostrom ligament repair; FDL: Flexor digitorum longus transfer; Sp: Spring ligament repair; Cot: Cotton osteotomy; Lap: Lapidus procedure; McBr: McBride procedure; Chev: Chevron procedure; TP: tibialis posterior tendon; Calc Ost: calcaneal osteotomy; TA: tibialis anterior transfer; NCF: naviculocuneiform fusion; FHL: flexor hallucis longus transfer; CSI: Conic Subtalar Implant.

* radiographic follow-up

Interestingly, a survey undertaken in 2013 of AOFAS members found 85% of surgeons removed implants for pain. One third of surgeons who performed STA no longer do and two-thirds of them did so since because they found it had a ‘low rate of success.’ In that study, success was not defined and it was not established if this was in paediatric or adult patients, nor whether STA had used as an adjunct or the sole procedure of flat foot correction[52]**.** However, because of both authors’experience and these literature findings, we strongly recommend that sinus tarsi pain and possible re-operation is appropriately discussed with patients before STA is undertaken.

At the same time, it should be emphasized that flatfoot reconstruction involving MCO and FDL transfer sometimes lead to radiographic undercorrection of the deformity[99–102]. As an alternative to achieve greater realignment and maintain it over time address residual forefoot abduction, lateral column lengthening (LCL) has been advocated [99,103], leading to a more powerful correction of talonavicular angle with a mean gain estimated at 17 to 24 degrees[99,103,104]. In a direct comparison between LCL and MCO with over 2-year mean follow-up, Bolt et al. found a mean improvement of talonavicular coverage at 17 and 7 degrees, respectively[99]. Some authors have also reported positive results after a combined calcaneal osteotomy involving LCL and MCO[105–108]. However, there is large consensus that LCL carries higher risk of non union (as compared to MCO), lateral pain, increased calcaneocuboid pressure and progression of joint osteoarthritis (up to 40% at 5 years)[99,104,105,107,109–111]. In light of these figures, we believe that STA can be considered a valid adjunctive step to other bony and soft tissue procedures, in order to restore adequate talonavicular coverage without increasing lateral columns pressure[112].

Our study has limitations, such as the small sample size and its retrospective design. However, surgeries described in previous studies have been heterogeneous which could be a strong reason in preventing clear conclusions being drawn about STA.

Consequently, we chose to apply strict selection criteria to increase the homogeneity between the two groups and therefore strength of our findings. Furthermore we calculated the minimum sample size needed to show a difference in radiographs and exceeded this. Secondly, whilst it may be felt that investigating radiographs taken between 6 and 12 months from surgery is a relatively short follow-up, there is evidence that 24 weeks radiographs for AAFD are already reliable with no significant difference compared to 2 years [94,113]. Thirdly, the different number of Cotton osteotomies in patients with (33%) and without (9%) STA may generate a potential treatment bias in our study. However, using a multivariable analysis, it was demonstrated that this part of the correction was not significantly associated with change in TNCA or CFMA. Lastly, in this analysis we did not consider any patient-reported outcome. While this was due to the original design of the study, we acknowledge that further investigations focusing on the correlation between clinical and radiographic are warranted in order to draw clear conclusions about STA.

In this part of the study, we found that STA improved forefoot abduction when used as an adjunct to correcting a stage IIb AAFD. In our series, STA-related complication and removal rates were 33%, with resolution of symptoms frequently observed after implant removal.

CONCLUSION

In 2020, subtalar arthroereisis remains a debated procedure. As mentioned above, although multiple series have documented positive results, comparative studies still represent a minority of the evidence available. As demonstrated in our results, while STA seems to mechanically contribute to the morphological correction of flexible flatfoot, the risk of complications (especially persistent pain) and the need of removal of the implant must be discussed at length during the preoperative counselling. Interestingly, the contraddicting findings in terms of improvement of the midfoot/forefoot abduction (which was lacking in children and present in adults) raise concerns about further variables potentially influent and not taken into account in our analysis. The use of different devices, implanted from different surgeons, in patient of different age, associated or not with other procedures might partially explain the discrepancy between the two clinical studies here performed. However, we do believe that other factors, such as anatomical variants of the sinus tarsi shape, the size of the implant (the choice is still arbitrary to date) and the type of implant (partially resorbable or not) are likely to play a crucial role in the final outcome. The use of recently-introduced imaging technology (cone beam weightbearing computed tomography) coupled with the developpment of automatic measurements of the bones of the foot and the use of the distance mapping analysis to investigate the joint spaces will probably help perform a volumetric analysis of the sinus tarsi and better understand the matching between the patient anatomy and the subtalar implants available on the market. We encourage further comparative and ideally randomised studies with larger cohorts with the aim of confirming our results.

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