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ORIGINAL ARTICLE • LOWER LIMB - PAEDIATRICS

Patient-perceived outcomes after subtalar arthroereisis with bioabsorbable implants for flexible flatfoot in growing age: a 4-year follow-up study

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Abstract

Purpose Results of subtalar arthroereisis in flexible flatfoot have been mainly reported in the literature using clinical or radiographical findings. However, the aim of this study is to evaluate the patient-perceived quality of life using self-reported questionnaires after subtalar arthroereisis using a bioabsorbable implant.

Methods Italian modified FFI and the SEFAS scores were submitted to a consecutive series of 173 patients who underwent surgical treatment for flatfoot deformity using a bioabsorbable endo-orthotic implant. Postoperative complication rates were assessed. Time needed to resume normal sports activities was recorded.

Results Mean population age was 11.2 years with slight variability between males and females. At a mean follow-up of 4 years, arthroereisis with bioabsorbable implants showed excellent results for the perception of the quality of life with an average result for FFI score of 4.5 and an average SEFAS score of 47.19. Time needed to resume sport activities was 4.7 months $\pm$ 0.2 with almost no difference between the groups. Four patients needed a second procedure for implant removal.

Conclusion Arthroereisis using a bioabsorbable implant offers good results in terms of satisfaction and quality of life with a negligible rate of failures and patient complaints based on self-reported questionnaires. The patient reported high degrees of satisfaction, and their quality of life was not compromised at all by the procedure.

Keywords Subtalar arthroereisis · Pediatric flatfoot · Bioabsorbable implants · Self-reported

Introduction

Flexible flatfoot (FF) is one of the most common deformities affecting children and adolescents [1–3]. The deformity is characterized by a reduction or absence of the medial arch, talar adduction and plantarflexion, valgus hindfoot during weight-bearing and various degrees of forefoot supination and abduction [2]. Despite often pauci-symptomatic, FF can cause limitations in daily activities such as early fatigue, low back pain, knee or heel pain and the development of calluses of the medial foot [4, 5]. Furthermore, a direct connection has been shown to exist between flatfoot and other foot conditions [3] such as Morton's neuroma, hallux valgus/rigidus [6], metatarsalgia, tibialis posterior tendon dysfunction, tarsal tunnel syndrome, subtalar or midtarsal osteoarthritis [7].

To date, the proper surgical indications and treatment for FF are still under debate [7–11]. Generally, surgical treatment is indicated in patients between 8 and 14 years of age with flatfoot and complaining of pain or other limitations [12]. Current surgical options include: soft tissues procedures, osteotomies, arthrodesis and arthroereisis. All procedures aim to restore the proper alignment between talus and calcaneus, and many studies have shown good results using all these techniques [13].

Arthroereisis represents the most commonly performed surgical treatment in Europe for flexible flatfoot in pediatric patients [10]. Several implant designs have been proposed over time [12, 14–17]. Regardless of the type of implant, the rationale of the procedure is based on

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Fig. 1 Preoperative hindfoot alignment in a 10 –year-old male patient

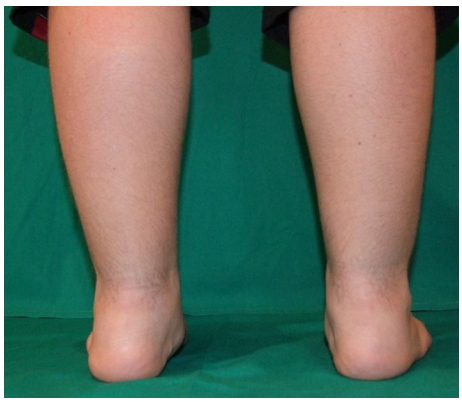

Fig. 2 Hindfoot alignment 2 years after surgery: correction of the hindfoot valgus is achieved

placing a motion locking device into the sinus tarsi in order to restore and maintain the physiological alignment between talus and calcaneus during bone remodeling, and to correct the deformity before it becomes fixed [8] (Figs. 1, 2). Normally, the implants should be removed after 2–3 years from the first procedure, once the growth phase has stopped [8, 10,18]. In recent years, bioabsorbable implants have been proposed [4, 8]. These have the great advantage of not needing a second surgical procedure for the removal of the implant.

The vast majority of the studies in the literature related to subtalar arthroereisis [6, 8, 10, 12] reported results based on clinical or radiographical findings. Considering that the indication to surgery is almost always dependent on the patient's symptomatology, the aim of this study is to evaluate the patient-perceived quality of life after undergoing an arthroereisis by means of a bioabsorbable implant using self-reported questionnaires.

Methods

The study was approved by the local ethical committee. Consent to participate in this study was given by parents after they were informed of the nature of this research.

An investigation was conducted to identify patients who underwent surgical treatment consisting of subtalar arthroereisis using polymeric endo-orthotic implants (BFFI® Novagenit S.R.L.) between 2010 and 2012. Inclusion criteria were represented by patients with flexible flatfoot between 8 and 15 years of age at the time of surgery. The exclusion criteria were neurogenic or neuromuscular disorders, the presence of synostosis, clubfoot sequelae, and joint hyperlaxity. The laxity level is assessed with medical history and clinical examination. The clinical evaluation assessed knee and elbow extension as well as thumb abduction. Furthermore, we excluded patients who underwent Achilles tendon lengthening or a medial navicular resection and tibialis posterior re-tensioning.

Surgical technique

The procedure was performed with a single 1-cm incision centered laterally on the sinus tarsi and the positioning of an 8-mm endo-orthotic implant. The surgical technique we used is the same described by Giannini et al. [8] in previous papers with a small lateral approach over the sinus tarsi, a careful dissection of the retinaculum, and the preparation of the sinus tarsi for the implant. The implant was then placed into the sinus tarsi, and a bioabsorbable screw was inserted to open and stabilize the implant. The retinaculum was sutured as well as the skin. A walking boot leg cast was then applied and worn for 2 weeks, and weight-bearing was conceded. Although in the literature several postoperative protocols have been proposed [5, 8, 19], in our experience, the use of a walking boot leg cast can represent an optimal solution after surgery. It provides pain relief and protection during deambulation after surgery; furthermore, it is cheaper than braces and does not have an economic impact on the patient.

The search yielded 182 patients who met inclusion criteria. The patients were divided according to demographics (including age and sex), side (mono- or bilateral), and eventual complications. Nine patients were lost during the follow-up, so the total patient number was 173. The patients were divided according to the treated side. Complications, failures of the implants, and second surgical treatments were documented and reported.

The patients were submitted the Italian Foot Function Index Questionnaire (FFI) modified score [20] and Self-reported Foot and Ankle Score (SEFAS) [21] by phone.

The Italian FFI modified score is a self-reported questionnaire that ranges between 0 and 162 [20]; the lower the score, the better the outcome. SEFAS score ranges from 0 to 48; the higher the score, the better the outcome. The time needed to resume a normal sports activity was also used as a parameter to evaluate the outcome.

Patients were contacted by phone replying to the two questionnaires chosen. The statistical analysis was performed using the Student *t* test, considering the distribution to be normal. The confidence interval was set to 95%. Correlation between series of data was searched with the Pearson test.

Results

The total number of patients analyzed was 173 (107 males and 66 females). In total, 283 flatfeet were treated. The mean population age was 11.2 years with slight variability between males and females. (Males had an average age of 11.3 years, while females had an average age of 11.0 years.) Of the total number of patients, 110 received a bilateral procedure, 15 underwent surgery at their right foot, and 48 at their left foot, as shown in Table 1. In all of the patients, an 8-mm bioabsorbable implant was used. If flatfoot is bilateral, the procedure is usually performed simultaneously.

Out of a total number of 173 patients, 4 needed a second surgery for removing the implant. (All these patients were male.) Three patients suffered from implant breakage, while one needed the revision surgery for persistent pain secondary to a local inflammatory response. A second procedure for implant removal was performed in one patient after 5 months, one after 8 months, and another one at 11 months, whereas the final patient underwent a second procedure 3 years after the original one. The need of a second procedure did not lead to a significant decrease in the scores reported (p value > 0.05).

The mean follow-up time was 49.5 months overall (range 36–70); in particular, the mean follow-up time was 50.7 months (range 36–70) in the male group, and 47.5 months (range 36–69) in the female group as shown in Table 1.

Table 1 Clinical records of the side affected and mean follow-up time

	Bilateral	Monolateral right	Monolateral left	Mean follow-up (months)	Range (months)
Males	70	9	28	50.7	36–79
Females	40	6	20	47.5	36–69
Total	110	15	48	49.1	36–70

The results were then evaluated using the Italian FFI score and the SEFAS score. Overall, the mean FFI score at follow-up was 4.5 and the mean SEFAS score was 47.2, well into the normal range. Specifically, the average FFI score in the male group was 5.3 ± 1.9, while in the female group it was 3.7 ± 2.1. The average SEFAS score in the male group was 47.0 ± 0.4, while in the female group 47.3 ± 0.5. These results are shown in Table 2. There were no statistically significant differences in the results between males and females (p value > 0.05).

Analyzing the data based on the side of the procedure, we identified 3 groups, respectively: bilateral, monolateral right and monolateral left as represented in Table 3. In particular, the average FFI and SEFAS were 4.4 ± 1.6 and 47.3 ± 0.3 in the bilateral group; 8.1 ± 8.8 and 46.1 ± 2.4 in the monolateral right; 4.2 ± 2.5 and 47.3 ± 0.6 in the monolateral left, respectively. There were no statistically significant differences in the results between the different groups: monolaterally right, monolaterally left, and those treated bilaterally (p value > 0.05). Although the side affected and treated does not seem to influence the outcomes, for clarity, we preferred to report them as they are.

Time needed for the normal recovery of sports activities was also estimated. In this study, we considered competitive sports and recreational activities alike because the physical activity they require, especially in this age group, is similar and the difference is minimal. For this reason, we simply asked each patient the main sport activity they performed after the surgery, no data on the preoperative period were available, but all patients complained of early fatigue and some degree of pain, especially after sports activities. A comparison of the mean months needed between female patients and male patients is shown in Table 4. The average time to resume sport activities was 4.5 ± 0.2 months, in particular 4.2 ± 0.2 months in male patients and 5.1 ± 0.2 months in females. Although this time was lower

Table 2 Results of mean SEFAS and FFI score in the population

	Males	Females
Total number of patients	107	66
Mean follow-up (months)	50.7	47.5
Mean FFI score	5.3 ± 1.9	3.7 ± 2.1
Mean SEFAS score	47.0 ± 0.4	47.3 ± 0.5

Table 3 Mean FFI and SEFAS based on the side of the procedure

	Mean FFI	Mean SEFAS
Bilateral	4.4 ± 1.6	47.3 ± 0.3
Monolateral right	8.1 ± 8.8	46.1 ± 2.4
Monolateral left	4.2 ± 2.5	47.3 ± 0.6

Table 4 Comparison of clinical results and recovery time

	Mean FFI	Mean SEFAS	Mean time to resume sport activities
Males	4.4 ± 1.6	47.3 ± 0.3	4.2 ± 0.2
Females	8.1 ± 8.8	46.1 ± 2.4	5.1 ± 0.2
Total	4.5 ± 5.2	47.2 ± 1.4	4.5 ± 0.2

Table 5 Summary of the sport activity practiced by the patient

Sport	Males	Females	Total	Recovery
Athletics	11	6	17	4,4
Badminton	2	0	2	4,5
Basketball	12	5	17	4,0
Cycling	2	0	2	4,0
Dancing	1	13	14	5,5
Fencing	1	0	1	5,0
Football	33	5	38	4,1
Gymnastics	0	9	9	4,3
Horse riding	3	0	3	5,0
Handball	3	1	4	5,3
Martial arts	6	2	8	5,0
Skiing	4	3	7	3,8
Swimming	9	8	17	3,7
Tennis	9	4	13	4,8
Volleyball	8	10	18	4,4
Waterpolo	2	1	3	3,8

in male patients when compared to female patients (Table 4), no statistical correlation has been found between the two groups. Furthermore, we classified the type of sports activity each patient referenced as being the predominant one as shown in Table 5.

Discussion

Flexible flatfoot is a common condition in pediatric patients [22]. Diagnosis is usually based on clinical evaluation [23] and on the finding of the characteristic radiographic abnormalities.

Despite the fact that diagnosis can be easily made, principles of treatment and indications for surgery are still under debate [9, 24]. Some authors highlighted the importance of treating only functional flatfeet [3, 12]. A functional flatfoot does not properly alternate pronation and supination during gait and is characterized by a prevalent or persistent pronation during all gate phases, thus causing limitations in daily activities and pathological alterations through the years [12]; vice versa, a morphological flatfoot presents with reduced medial arch and widening of the foot print with slight or no clinical symptoms; therefore, it is usually well tolerated by the patients and does not require any treatment [12].

However, the discernment between morphological and functional flatfoot is not always possible; more often surgical treatment is indicated when pain, discomfort, early fatigue, and limitations in normal activities are reported by the patient [8, 10].

Arthroereisis represents one of the most common procedures in Europe for the treatment of flexible flatfoot in pediatric patients [4, 5, 19]. The effectiveness of this technique has been reported by several studies in the literature, with good medium-term follow-up results for deformity correction, clinical and radiographic parameters [4, 5, 19]. Bioabsorbable implants for subtalar arthroereisis have been proposed in order to overcome the necessity of a second procedure for implant removal [6–8]. The results reported by the literature with the use of these implants are comparable to those observed with traditional devices [7].

Although the literature, irrespective of the type of implant, showed good clinical and radiographic results, no attention over the years has been paid to a patient's perception of the results after the procedure, and its impact on the quality of life. This assessment can be even more interesting when dealing with implants that are supposed to be reabsorbed with time; in the literature, there are some concerns about the possibility of transient inflammatory reactions during the re-absorbtion of the implant which could negatively influence the results.

Since the treatment choice is strongly dependent on the patient's discomfort, we believe that self-reported outcomes can represent a viable and useful tool for evaluating the procedure's efficacy, regardless of clinical and radiographic results that, although valuable in their own right, do not focus on the main reason needed to perform surgery for flexible flatfoot, which is its symptomatology. For this reason, self-reported outcomes can be used to widen the data available to the surgeon if used in combination with clinical and radiographic outcomes, or to focus the surgeon's attention on the crucial data needed when evaluating the results of surgical correction of flexible flatfoot. In previous studies, Giannini et al. [8] already evaluated, from a clinical and radiographic point of view, the procedure's ability to correct the deformity. The only parameter missing was the patient-perceived result, and this is what we analyzed in this study, granted that the clinical and radiographic points of view remain the most important parameters.

To date, there is increasing attention to perception of the results by the patient, and as a result, many self-reported questionnaires have been developed [20, 21].

In this study, we evaluate the patient-perceived quality of life using two of the most validated self-reported tests for assessing foot and ankle pathology, specifically SEFAS

and FFI [20, 21]. To eliminate possible confounding factors, patients treated with simultaneous procedures, such as Achilles tendon lengthening or accessory navicular resection, have been excluded from the study.

The results in our study were excellent in terms of life quality perception at a mean follow-up of 4 years. The bioabsorbable endo-orthotic implant showed a very low failure rate (1.41%) with a rare necessity for implant removal. The percentages reported in this study were similar to those previously found by Faldini et al. [6] with the use of the same implant (1.5% of failures).

However, some studies [4, 25–28] reported that even if the device is prematurely broken or removed, the position of the foot maintains a certain degree of correction and allows for good clinical results. This corroborates our findings that patients with implant ruptures showed good self-reported results, comparable to the other patients, even after having the implant removed.

Some concerns about the possible effects related to the implant bioabsorption are reported by the literature [29]. The device degradation process over time may result in some form of cellular response and transient inflammatory reaction [6, 8]. Nevertheless, the results of our study did not reveal any complications related to this issue, except in one case.

The average time to return to sports activities was also evaluated in this study, especially considering its social and psychological impacts. Patients are usually asked to avoid jumping, running or any other high-demanding physical activities for 3–4 months after surgery. This theoretically allows a better tissue healing which provides further stabilization to the implant. Moreover, a temporary intra-rotation and supination of the foot could occur during heavy load, causing possible instability, and leading to ankle sprains and early implant displacement; for these reasons, an early return to sports activities is not recommended.

The results of this study showed a return to sports activities after an average of 4–5 months with earlier sports resumption in males compared to females (4.2 vs 5.1). The lower compliance to the rehabilitation protocol may have affected the questionnaire's results considering that male patients reported lower outcomes compared to females. The time to resume sports activities described in our series, however, is similar to that reported by Martinelli et al. [30] using a metallic implant which described a 87% resumption of patient sport activities in the first 6 months after surgery.

Some limitations of the study need to be acknowledged; the absence of clinical and radiographic outcomes; the lack of a control group; and the follow-up of variable durations. On the contrary, the fact that the procedure was performed by the same surgeon in a relatively short time frame, guarantees good homogeneity of the surgical technique.

In conclusion, subtalar arthroereisis using a bioabsorbable implant offers good results based on self-reported questionnaires, with negligible failures rates, and patient complaints. The patients reported high degrees of satisfaction, and their quality of life was not compromised at all by the procedure. Since the main indication for FF surgical treatment is based on the perceived discomfort [8], treatment results should also be evaluated from a self-reported point of view. Further studies comparing the results of self-reported questionnaires with clinical and radiographic parameters are required to investigate any possible correlations between them.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and animals rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. This study was approved by the local ethical committee.

Informed consent Informed consent was obtained from all the parents of the individual participants included in the study, since it was performed on underage patients.

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