The Journal of Foot & Ankle Surgery 56 (2017) 776–782

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Bioabsorbable Calcaneo-Stop Implant for the Treatment of Flexible Flatfoot: A Retrospective Cohort Study at a Minimum Follow-Up of 4 Years

Sandro Giannini, MD [1], Matteo Cadossi, MD, PhD [2], Antonio Mazzotti, MD [3], Valentina Persiani, MD [2], Giuseppe Tedesco, MD [2], Matteo Romagnoli, MD [2], Cesare Faldini, MD [4]

[1] *Professor Emeritus, Istituto Ortopedico Rizzoli, Bologna University, Bologna, Italy*
[2] *Orthopaedic Surgeon, II Clinic of Orthopaedic and Traumatology, Istituto Ortopedico Rizzoli, Bologna University, Bologna, Italy*
[3] *Medical Doctor, II Clinic of Orthopaedic and Traumatology, Istituto Ortopedico Rizzoli, Bologna University, Bologna, Italy*
[4] *Professor and Director, II Clinic of Orthopaedic and Traumatology, Istituto Ortopedico Rizzoli, Bologna University, Bologna, Italy*

ARTICLE INFO

Level of Clinical Evidence: 4

Keywords:
arthroereisis
pediatric
pes valgus
subtalar joint

ABSTRACT

Arthroereisis of the subtalar joint is a common surgical technique in Europe for the management of flexible flatfoot in the pediatric population. In most cases, it is performed using a calcaneo-stop metallic screw. Despite the good clinical results, screw removal is always advised after 2 to 3 years. The use of a bioabsorbable screw might overcome the need for a second operation to remove a nonabsorbable device. We report the results of a biodegradable calcaneo-stop screw at a minimum of 4 years of follow-up. Eighty-eight procedures were performed on 44 children. All patients were clinically and radiologically evaluated preoperatively and at a minimum 4-year follow-up period. Patient satisfaction and plantar collapse using Viladot's classification were recorded. Meary's talus–first metatarsal angle and talocalcaneal angle were measured on radiographs preoperatively and at the last follow-up visit. The presence of the device at the last follow-up examination was assessed by magnetic resonance imaging. The mean follow-up duration was 56 months. Of the 44 patients, 33 (75%) reported excellent clinical outcomes, 9 (20.5%) good outcomes, and 2 (4.5%) poor. Foot print improvement was registered for all patients. The mean Meary's talus–first metatarsal angle had improved from 160.6° ± 7.7° preoperatively to 170.6° ± 6.5° at the last follow-up visit ($p < .001$). The talocalcaneal angle had decreased from 39.9° ± 5.2° preoperatively to 29.4° ± 4° at the last follow-up examination ($p < .001$). At the 4-year follow-up point, the implant could be seen to have almost completely biodegraded on magnetic resonance imaging. Two screw breakages occurred. The bioabsorbable calcaneo-stop screw seems to be an effective solution for flexible flatfoot in pediatric patients. Also, owing to its biodegradable composition, the need of a second operation for implant removal will not always be necessary.

Flexible flatfoot in pediatric patients is a common orthopedic condition, with an incidence of approximately 5% (1,2). The deformity is characterized by a reduction or absence of the medial arch, medial protrusion of the talar head, and valgus hindfoot with weightbearing (3).

Flatfoot can be asymptomatic or symptomatic and rigid or flexible. The clinical examination must address not only the deformity but also the functional aspects (4–8). Foot morphology should be examined with the patient both non-weightbearing (to evaluate the presence of subtalar or midtarsal synostosis, ligamentous laxity, and shortening of the Achilles tendon) and weightbearing (standing; to analyze the foot print and hindfoot axis). The functional examination should be performed with the patient walking. Radiographs under weightbearing should always be performed to complete the diagnosis (9).

In some cases, flatfoot will present with a reduced medial arch and widening of the foot print, with only slight or no clinical symptoms. Therefore, flatfoot is usually well tolerated by patients. If flatfoot does not properly alternate between pronation and supination during gait, with a prevalent or persistent pronation during all gait phases (10), it can cause limitations in daily activities such as early fatigue and medial foot calluses (11) and can lead to severe pathologic alterations over time (10).

Persistent subtalar joint pronation during gait can have important consequences in adulthood, including metatarsalgia, posterior tibialis tendon dysfunction, tarsal tunnel syndrome, Morton's neuroma,

Financial Disclosure: None reported.
Conflict of Interest: None reported.
Address correspondence to: Antonio Mazzotti, MD, II Clinic of Orthopaedic and Traumatology, Istituto Ortopedico Rizzoli, Bologna University, Bologna 40136, Italy.
E-mail address: antonio.mazzotti2@studio.unibo.it (A. Mazzotti).

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http://dx.doi.org/10.1053/j.jfas.2017.02.018

Fig. 1. Images showing photopodographic flatfoot grade according to Viladot.

hallux valgus, and, in more advanced stages, subtalar and/or midtarsal osteoarthritis (4,12–14).

Conservative treatment with the use of insoles (15) to support the medial arch and to stabilize the hindfoot axis, suppressing the eversion of the talocalcaneal joint, can reduce the discomfort in symptomatic patients aged 4 to 8 years (16). Surgical treatment is recommended for cases of symptomatic flatfoot after 8 years of age.

Arthroereisis is a widely used technique in Europe with several methods and implant designs available (12–14,17–19). The calcaneostop (CS) procedure uses a metallic cancellous screw inserted in the calcaneus at the lateral entrance of the sinus tarsi to block the excessive subtalar eversion. This procedure has been commonly adopted in Europe in recent years owing to the good results obtained in deformity correction by reduction of the subtalar joint pronation (13,20–23). Despite these good results, the need for a second surgery for screw removal represents an issue for both patients and the National Health System in the interests of reducing costs.

Recently, a poly-L-lactic acid (PLLA) screw, RSB® Calcaneo Stop (RSB-CS; CE approved; Lima Corporate SpA, Villanova, Italy), has been proposed to overcome the necessity for implant removal. PLLA is a biocompatible and biodegradable polymer that degrades in carbon dioxide and water within approximately 4 years (24–27). This new device might balance clinical innovation with economic sustainability, thus avoiding the need for a second surgery for implant removal.

We report the clinical and radiographic results of a consecutive series of RSB-CS cases at a minimum 4-year follow-up period.

Patients and Methods

The local ethics committee approved the study. The data were abstracted by 3 of us (M.C., A.M., C.F.), the clinical and radiologic results were assessed by 3 of us (G.T., V.P., M.R.), and the statistical analysis was performed by 1 of us (V.P.). From September 2010 to January 2012, 88 RSB-CS procedures were consecutively performed by the senior surgeon (S.G.) on 44 children.

The indications for surgical correction were idiopathic, flexible, and symptomatic flatfeet in patients aged 8 to 14 years. The exclusion criteria were joint hyperlaxity; post-traumatic, neurogenic, or neuromuscular disorders; the presence of foot synostosis; and clubfoot sequelae.

The diagnosis was made from the clinical and radiographic examination findings by the surgeon (S.G.) who performed the procedure. The clinical diagnosis was based on restriction of dorsiflexion of the ankle joint after manual correction of the deformity, increased heel valgus at rest and during the tip-toe standing test, footprint enlargement according to Viladot's classification (28) (Fig. 1) and the presence of discomfort or other symptoms (pain, early fatigue during sports activity). Weightbearing lateral and dorsoplantar radiographs of the feet were taken before surgery. Additional computed tomography or magnetic resonance imaging (MRI) studies were performed when the presence of a coalition was in doubt.

Implant Characteristics

The RSB-CS can be cannulated or noncannulated. The noncannulated screw has a 7 mm diameter and 18 mm length. It is usually indicated for load stresses and anatomic

Fig. 2. Cannulated RSB® Calcaneo Stop screw, with 9-mm head diameter and 18-mm threaded length. Shown with permission of Lima Corporate SpA.

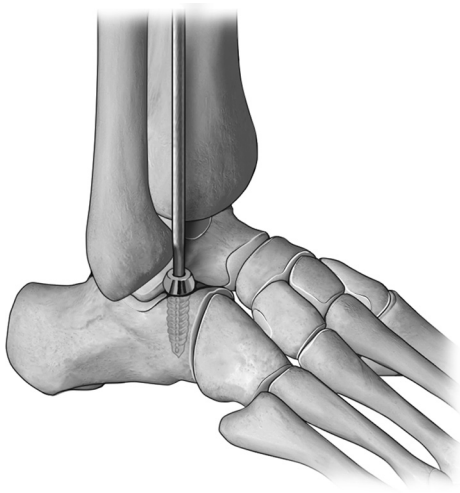

Fig. 3. Anatomic site of implant position.