Surgical Technique

Medial Column Arthrodesis in Rigid Spastic Planovalgus Feet

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Abstract

Background Treatment of spastic planovalgus feet is challenging, especially in patients with severe and rigid deformities. The available techniques do provide some correction but not at the site of the deformity and sometimes the correction is lost over time. We describe a new surgical approach at the site of the deformity.

Technique Indications for the surgery included adolescents or young adults with severe and rigid planovalgus deformities of the feet resulting from cerebral palsy. Through a medial approach, arthrodesis of the talonavicular, navicular-medial cuneiform, and medial cuneiform first metatarsal joints was internally fixed using a single-molded plate over the plantar surface of the foot, recreating the longitudinal arch.

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All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research* editors and board members are on file with the publication and can be viewed on request. Each author certifies that his or her institution approved the human protocol for this investigation, all of the investigations were conducted in accordance with ethical research principles, and informed consent for participation in the study was obtained. This work was performed at the Neuromuscular Clinic, Department of Orthopaedics and Traumatology, Santa Casa Medical School and Hospitals, São Paulo, Brazil.

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Methods We retrospectively reviewed 21 patients (35 feet) with spastic cerebral palsy in whom the new technique was indicated for severe and rigid deformity, gait dysfunction, and pain (mean age, 190 months; range, 96–345 months). The mean age of the patients was 16 years (range, 8–29 years). We analyzed the patients clinically and radiographically. The minimum followup was 2.5 years (mean, 58 months; range, 2.5–7.5 years).

Results At last followup, 34 of the 35 feet (97%) had radiographic improvement of the deformity with no difficulties wearing shoes; one patient had persistent pain despite bone union. Union was achieved initially in eight patients (17 feet) and in another eight (10 feet) after revision surgery, of 27 of the 35 feet. The radiographic calcaneal inclination angle improved an average of 13°. The lateral talocalcaneal angle decreased from a mean of 43° to 26° after surgery. Four patients (five feet) had revision surgery for pseudoarthrosis, and another four patients (five feet) had revision surgery for other problems.

Conclusions Based on our preliminary observations, we believe stabilization of the medial column is a reasonable option for treating selected patients with severe and rigid planovalgus feet by providing a stable and pain-free foot, recreating the anatomy, and allowing the use of braces or regular shoes. Further studies with longer followup periods will be required to confirm these initial results and to verify if these findings persist over time.

Level of Evidence Level IV, case series. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Planovalgus is the most common deformity in patients with cerebral palsy (CP) and the spastic diplegia and quadriplegia

patterns [10, 14]. It is a complex deformity occurring in different planes and joint levels of the foot. Muscular imbalance, abnormal forces, bone malalignment, capsule-ligamentous laxity, and racial and genetic patterns are all causal factors [14]. Muscular imbalance often occurs as a result of weakness of the tibialis posterior muscle with extensive pull of the spastic peroneal muscles; however, planovalgus can also be caused by weakness of both the tibialis posterior and peroneal muscles with medial collapse of the foot as a result of capsule and ligamentous laxity. Poor muscle control leads to inadequate shock absorption and excessive transmission of energy to the bones, capsules, and ligaments, leading to even worse collapse of the foot [14].

The etiology of planovalgus deformity in ambulatory patients is distinct from that observed in nonambulatory children, although the natural history is similar. According to Miller [14], three evolutionary stages can be defined in the development of the planovalgus foot in ambulatory patients. The first stage is characterized by valgus external rotation of the foot and dorsiflexion relative to the talus. As this deformity evolves, the head of the talus becomes uncovered medially and downward. As the foot dorsiflexes relative to the talus, the condyle of the posterior facet subluxates out of the plateau of the talus, allowing posterior movement of the calcaneus on the talus, which leaves space for more external rotation and dorsiflexion of the foot. The plateau of the talus tends to open up in the posterior facet and become dysplastic on the posterior lateral aspect, allowing the condyle of the calcaneus to subluxate posteriorly and medially. The calcaneocuboid joint also subluxates with the cuboid, moving upward and laterally relative to the calcaneus [14]. The deformity is mild and can be reduced with manipulation. In the second stage, the calcaneus presents with substantial dorsiflexion relative to the talus. The talus itself is in a severe equinus position relative to the tibia, and the calcaneus is in the equinus position relative to the tibia. This equinus position of the hindfoot may be the result of overactivity of the triceps, but it may also be an adaptation developed in response to the progressive collapse that occurs in planovalgus deformity. Consequently, the medial column is lengthened relative to the lateral column. In the third stage, physeal arrest of the distal tibia results in valgus of the ankle in adolescence, which is often associated with external tibial torsion. The collapse of the navicular-medial cuneiform joint leads to dorsal dislocation of the medial cuneiform. The hallux valgus worsens and is a common source of pain in these feet in addition to the prominence of the talus. A rigid deformity is established [14].

Spastic peroneal muscles are believed to be the primary cause of planovalgus deformity in nonambulatory patients [14]. According to that report, the natural history is similar to that of ambulatory patients, and the disorder develops as

described in the second and third stages of ambulatory patients. However, midfoot collapse and equinus of the hindfoot are often more severe.

The treatment for these spastic planovalgus feet is challenging, especially in adolescent and young adults with severe, rigid, unbraceable, and painful deformities. Whether in ambulatory or nonambulatory patients, the goals of surgery are to achieve a stable and plantigrade foot, reduce the medial pressure, relieve the pain, and facilitate the use of braces and footwear. The usual treatment is triple arthrodesis without major foot correction [1, 2, 6, 9–14, 16, 17, 19, 20, 22]. An alternative approach to the collapsed foot is medial column arthrodesis to ensure the correction is maintained until bone union internal fixation is applied. The procedure is performed at the apex of the deformity, recreating the medial contour of the foot. The purposes of this procedure are to achieve stabilization of the foot and provide stable support for walking and standing for transfers of weight, to recreate the longitudinal arch and relieve medial pressure, and to provide a foot that can be fitted for braces or shoes.

We describe this procedure and determine whether it was successful in (1) correcting bone alignment and the deformity; (2) achieving bone union; (3) relieving pain; and (4) reducing or eliminating difficulties with the wearing of braces or shoes.

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The surgical indications were rigid planovalgus deformity (Fig. 1A–C), gait dysfunction and instability, pain during weightbearing, and difficulty or impossibility in wearing a brace or shoes. The procedure was contraindicated in the presence of skin lesions or ulcers on the foot.

With a tourniquet applied to the thigh, we approached the medial column of the foot through a medial incision from the sustentaculum tali to the proximal third of the first metatarsal. The retromalleolar tendons were identified and retracted. The periosteum was removed from the medial and inferior aspects of the medial column along the distal talus, navicular, medial cuneiform, and first metatarsal bones. The talonavicular joint capsule, navicular-medial cuneiform, and medial cuneiform were opened to the first metatarsal joints, and the cartilage was removed from the articular surfaces. After reducing the navicular on the talus, a plantar closing wedge was removed from the talonavicular joint, and the longitudinal arch was reestablished. A single plate was then contoured to adapt to the corrected talonavicular joint and to the plantar aspect of the medial column to recreate the longitudinal arch (Fig. 2). We used a small fragment dynamic compression plate (DCP) AO/ASIF (Paoli, PA, USA) in the first 24 feet and a low contact

Fig. 1 The images are preoperative radiographs of a female patient, aged 15 years 2 months. (A) AP view; (B) lateral view of the right foot; (C) lateral view of the left foot showing a severe hindfoot valgus and the collapsed longitudinal arch.

plate (LCP) AO/ASIF in the 11 remaining feet. Both plates had seven or eight holes and were manually molded. Care was taken not to overcontour the plate so as to create a cavovarus deformity. The plate was fixed proximally in the sustentaculum tali with two cancellous partially threaded (16 mm) screws. If the plantar aspect of the sustentaculum tali was not denuded of soft tissue or periosteum, it was shaved to enable correct placement of the plate. Distally, the plate was fixed in the first metatarsal with two cortical screws, ensuring that the holes of the plate were in a

Fig. 2 Immediate postoperative radiographs of the same patient as shown in Fig. 1, aged 15 years 2 months, are shown here. (A) AP view; (B) lateral view of the right foot; (C) lateral view of the left foot. The images show the longitudinal arch restored, hindfoot neutral, and the plate placement.

horizontal position to prevent the first metatarsal drop. In the midfoot, the plate was fixed with cortical screws. After placement of the plate, the length of the Achilles tendon

was accessed, and in three feet, a “Z” lengthening was performed to allow the foot to achieve a plantigrade position. In the last eight patients (nine feet) in the series, a compression screw was added in the talonavicular joint to compress both bone surfaces. The mean operating time was 60 minutes (range, 50–80 minutes).

The foot was placed in a short leg cast for 8 to 12 weeks with no weightbearing until bone union was achieved. After bone union, the patient was referred to physiotherapy under supervision with gradual weightbearing and walking/transfer training for at least 6 months, after which unrestricted activities were permitted.

Patients and Methods

We retrospectively reviewed all 21 patients (35 feet) with spastic CP and planovalgus deformities who underwent medial column arthrodesis between March 2003 and April 2008. The study group included 13 males and eight females. The mean age at the surgical procedure was 16 years (range, 8–29 years). Ten patients had diplegia, 10 had tetraplegia, and one had hemiplegia; functionally, six patients were classified as Type II in the Gross Motor Function Classification System (GMFCS) [15], eight were classified as GMFCS III, and seven were classified as GMFCS IV.

Table 1. Previous surgeries

Procedure	Number
Adductor tenotomy	6
Femoral derotation osteotomy	3
Hamstring lengthening	7
Tibia derotation osteotomy	2
Tendon Achilles lengthening	9
Gastrocnemius resection	1
Subtalar arthrodesis	2
Grice procedure + subtalar arthrodesis	2
Evans osteotomy	4

Table 2. Radiographic data and concordance between observers

Parameters		Mean value (minimum to maximum)	ICC (consistency)	95% CI	CCC	95% CI
ICA	Preoperative	−1.0° (−26° to 15°)	0.91	0.84–0.95	0.91	0.83–0.95
	Postoperative	15° (0–35°)	0.83	0.69–0.91	0.82	0.68–0.90
	Final	12° (−4° to 26°)	0.84	0.71–0.91	0.82	0.68–0.90
TCA	Preoperative	43° (18°–59°)	0.82	0.68–0.90	0.77	0.61–0.87
	Postoperative	29° (17°–52°)	0.75	0.56–0.86	0.75	0.56–0.86
	Final	26° (10°–40°)	0.69	0.47–0.83	0.65	0.45–0.79

ICA = angle of inclination of the calcaneus; TCA = talocalcaneal angle; ICC = intraclass correlation coefficient; 95% CI = 95% confidence interval; CCC = concordance correlation coefficient.

Fourteen patients had bilateral surgery and seven unilateral. All the patients had undergone previous operations on the lower limbs (Table 1). No patients were lost to followup. The minimum followup was 2.5 years (mean, 5 years; range, 2.5–7.5 years). No patients were recalled specifically for this study; all the data were retrieved from medical records and radiographs during followup in outpatient clinics.

After surgery, the patients were seen every month for clinical evaluation. AP and lateral radiographs were taken monthly until bone union was achieved and every 6 months thereafter. We assessed the surgical correction by clinical examination, determining whether the foot was plantigrade, with normal alignment. We also asked the patient or caregiver about the presence of persistent pain in the foot after surgery and about difficulties in the use of shoes or braces. We considered major complications to be pseudarthrosis or any subsequent operation to relieve pain or treat secondary deformities.

Two observers (PMF, HHY) independently evaluated all of the radiographs taken in three periods: preoperative, immediately postoperative, and final. Specific measurements included the calcaneal inclination angle (CIA) and talocalcaneal angle (TCA) [3, 21] assessing the weight-bearing lateral view on the foot radiographs, the mean values, the range intervals, the interclass correlation coefficient, and the concordance correlation coefficient (MedCalc[®] Version 11.5.1.0, ©1993–2011; MedCalc Software, Mariakerke, Belgium) (Table 2). Bone union was assessed on the postoperative radiographs. The criterion for bone union assessment was consolidation in the three cortices on two radiographic views.

Results

Radiographically, the CIA had an improvement of 13° (range, −1.0° preoperatively to 12° postoperatively). The TCA ranged from a mean of 43° preoperatively to a mean of 26° postoperatively.

In the 21 patients at last followup, eight (17 feet) had bone union (Fig. 3), improvement of the deformity, and no difficulties in wearing shoes; one patient had pain as a result of the primary operation. After reoperation for various reasons, four patients (five feet) presented with foot correction and no pain. Among the nine patients with pseudarthrosis, five patients (eight feet) were still asymptomatic with improvement of the deformity and did not require a second procedure; the other four patients (five feet) had improved foot position, no pain, and no problems with wearing shoes after a second operation (Table 3). Eight patients (10 feet) required a reoperation. Of these, four patients (five feet) were reoperated on for pseudarthrosis and four (five feet) for various other reasons. Pseudarthrosis was radiographically present in nine patients (13 feet) located in the talonavicular joint in eight feet, naviculocuneiform in five, and cuneo-first metatarsal in four. Of this group of nine patients, five (eight feet) were asymptomatic and had not been reoperated on as of the last followup. The mean age of these patients was 16 years 4 months, and they were graded functionally; two patients were classified as GMFCS II, two GMFCS III, and one GMFCS IV. In the other four patients (five feet), we reoperated at a mean time of 2 years 3 months after the initial surgery (Fig. 4). In all cases, the implant was changed to LCP, and a compressive screw was added to the pseudarthrosis site. In two feet, the pseudarthrosis was at the talonavicular joint alone; in one foot, it was associated with the naviculocuneiform joint; and in one foot, it was associated with the metatarsocuneiform joint (Fig. 5). The mean age of these patients was 15 years 1 month, and two patients were functionally GMFCS II and two GMFCS III.

We also reoperated on four of the 21 patients (35 feet) for reasons other than pseudarthrosis. One patient (GMFCS II) had worsening hallux valgus deformity after surgery, and the foot had collapsed, losing the correction previously obtained. It had also become painful 17 months after the initial surgery. In this case, a calcaneus and midfoot osteotomy and hallux arthrodesis were performed. After the reoperation, the deformity was corrected, and at the last followup at 49 months, the patient was pain-free. A second patient (GMFCS IV) developed pain on the plantar surface of both feet (midfoot, there was no pain in the forefoot), which was unrelated to the documented bone union. The plates were removed on the right side at 21 months postoperatively and on the left at 24 months. After the removal, the patient became pain-free, and the foot correction was maintained until last followup at 4.5 years. In a third patient (GMFCS III) who had bilateral operations, one foot developed an equinus deformity at 2 years after surgery, and his plate was substituted with a better contoured one. After reoperation, the pain was resolved and the deformity

Fig. 3 This is the postoperative radiograph taken 3 years 9 months after surgery of the same patient as shown in Figs. 1 and 2, now aged 18 years 11 months. (A) AP view; (B) lateral view of the right foot; (C) lateral view of the left foot. The imaging shows bone union and maintenance of the correction.

Table 3. Patients' demographic and clinical data

Patient number	Side	Sex	Age (months)	GMFCS	Implant	TN screw	Complication	Pseudoarthrosis (site/symptoms)	Reoperation	Postoperative time to reoperation (months)	Followup (months)
1	R	M	161	IV	DCP	No	No				59
	L		161		DCP	No	No				59
2	R	M	192	III	LCP	Yes	No				30
3	L	M	278	IV	DCP	No	No				66
4	R	F	188		LCP	No	No				53
	L		188		LCP	No		TN/symptomatic	Pseudoarthrosis repair + implant change to LCP	33	53
5	R	F	206	IV	DCP	No	No				74
	L		183		DCP	No	No				77
6	R	M	189	II	LCP	No		TN/symptomatic	Pseudoarthrosis repair and implant change to LCP	16	52
	L		189		LCP	No		TN/symptomatic	Pseudoarthrosis repair and implant change to LCP	16	52
7	R	M	96	III	LCP	Yes	No				39
	L		96		LCP	Yes	Pain				39
8	R	F	345	II	DCP	No	No				56
	L		345		DCP	No	No				56
9	L	M	197	II	DCP	Yes			Plate removal + midfoot osteotomy + calcaneal osteotomy + pan arthrodesis + arthrodesis of the first metatarsal-phalanx joint	17	66
10	L	F	210	IV	DCP	Yes		CM/asymptomatic			91
11	R	F	166	IV	DCP	No	No				55
	L		166		DCP	No	No				55
12	R	M	232	II	DCP	No		TN/asymptomatic			58
	L		232		DCP	No		TN + CM/asymptomatic			58
13	R	M	158	III	DCP	No		TN/asymptomatic			71
	L		165		DCP	No		NC/asymptomatic			64
14	R	M	252	II	LCP	Yes		NC + CM/asymptomatic			30
15	R	F	146	III	LCP	Yes	No				39
16	R	M	166	III	DCP	No	Equinus		Change the plate (better molded)	25	78
	L		187		DCP	No	No				57
17	R	F	194	IV	DCP	No	Pain		Plate removal	21	78
	L		191		DCP	No	Pain		Plate removal	24	75

Table 3. continued

Patient number	Side	Sex	Age (months)	GMFCS	Implant	TN screw	Complication	Pseudoarthrosis (site/symptoms)	Reoperation	Postoperative time to reoperation (months)	Followup (months)
18	R	F	163	III	DCP	No	Equinus	NC/asymptomatic	Tendon Achilles lengthening	14	74
19	L		160		DCP	No		TN + CM/asymptomatic			77
	R	F	182	III	LCP	No	No				49
	L		182		LCP	No	No				49
20	R	M	173	III	DCP	Yes					64
	L		173		DCP	No	No	NC/symptomatic	Pseudoarthrosis repair + change implant to LCP	13	64
21	L	M	164	II	DCP	Yes		TN + NC/symptomatic	Pseudoarthrosis repair + implant change to LCP	27	45

GMFCS = Gross Motor Function Classification System; TN = talonavicular site; M = male; F = female; DCP = dynamic compression plate; LCP = low contact plate; CM = cuneo-first metatarsal site; NC = navicularcuneiform site.

Fig. 4 These are the preoperative radiographs of a female patient, aged 17 years 6 months, with only the left foot treated. (A) AP view; (B) lateral view. The patient had a severe planovalgus deformity.

correction was maintained until last followup at 4.5 years. In a fourth patient (GMFCS III), one foot developed an equinus deformity at 14 months and was submitted to tendon Achilles lengthening. At last followup at 4.5 years after the primary procedure and 2 years after the Achilles lengthening, the deformity was corrected.

No general or local complications occurred; no patient had infection or avascular necrosis.

Discussion

The treatment of spastic planovalgus feet is recognized as challenging by many authors [10–14, 17, 22, 24], especially with rigid and unbraceable deformities. The surgeon has to face a patient with pain, difficulty with walking, and

Fig. 5 This image shows the radiograph taken 6 years 11 months after surgery of the same female patient as shown in Fig. 4, now aged 24 years 5 months, with (A) AP view and (B) lateral view, showing pseudarthrosis cuneo-first metatarsal site and breakage of the implant.

a progressing deformity; triple arthrodesis is not capable of solving the problem in all patients [22, 24–26]. We describe a procedure at the main site of the intended to provide permanent correction and evaluated patients to see whether foot alignment was maintained.

We acknowledge limitations to our study. First, given the retrospective design, we did not have a standard protocol or outcomes. However, all patients were operated on by the same staff and we lost no patients to followup. Second, we had no control group. However, given that our objective was to report a case series involving a homogeneous population (all patients with planovalgus feet resulting from CP) operated on using a standardized technique, we believe the results, in terms of alignment, correction of deformity, bone union, pain relief, and functional recovery, are promising. A comparative study with a control group (triple arthrodesis versus medial column arthrodesis in comparable patients) would help confirm whether this new approach better achieved its aims. Third, there is a question as to whether the clinical versus the radiographic findings better reflect outcome. We believe the clinical appearance of the foot, the ability to wear braces or shoes, and the absence of pain are more important to the patient than specific radiographic changes, because some of the patients without “good” radiographic results were pain-free and satisfied. Fourth, followup time was short and we cannot say whether the deformity correction will be maintained long-term.

The correction of bone alignment and the foot deformity in our patients with CP, our first objective, involved the challenge of dealing with planovalgus feet, which are generally recognized as being more difficult to correct than

equinovarus feet. Increased recurrence and residual deformity are the major long-term concerns [22, 24–26]. Our approach from the medial side was based on the intention to correct the bones at the site of the main deformity, and internal fixation was used to maintain the “new arch” until bone union was achieved. The preference for the medial approach is shared by Turriago et al. [23], although the medial arthrodesis performed by them was more limited. A high incidence of failure to correct the deformity is reported in 23.5% [23] to 52% [22] of cases undergoing triple arthrodesis, which clearly shows the difficulty in achieving and maintaining correction of the deformity in these rigid feet. Radiographic evaluation of these severe deformities is difficult, and it is usually hard to obtain good images in the weightbearing position in a nonambulatory patient. Still, we observed a distinctive increase in the CIA values related to the equinus correction. In our patients, the CIA and TCA values improved by an average of 12.75° and 17.5°, respectively, showing the surgical procedure proposed here was able to restore the anatomy of the longitudinal arch. The small changes in the TCA values between pre- and postoperative radiographs were, however, within the range of normality, which is wide for this parameter [3, 21]. The radiographic measurements achieved during surgery persisted in most patients, but further followup will allow us to correlate the outcome with radiographic improvement on a longer-term basis.

Our second objective was to evaluate bone union, which was achieved in eight patients (17 feet) (50%). Nine patients (13 feet) presented with pseudoarthrosis; of these, five patients (eight feet) were asymptomatic and were not reoperated on. The most frequent site was the talonavicular

in triple arthrodesis [1, 2, 20], which also appears to be the case with medial column arthrodesis; most of our patients with pseudoarthrosis (61%) were on the talonavicular site. Some of our patients required revision surgery. However, the rate of successful correction among our patients was 50% after the first operation and 78% after the second. Although comparison of the rate of pseudoarthrosis between the two techniques was not the objective of this study, reports from the literature show rates of pseudoarthrosis in the triple arthrodesis between zero [11] and 36% [22]. However, most studies on the subject include very few patients with CP, which makes comparison difficult. Besides, it has been reported that pseudarthrosis and residual deformity are correlated with unsatisfactory results in the long term [14]. The cause of pseudarthrosis in our patients is still unknown and requires ongoing investigation with this technique. Factors that may influence the rate have not yet been identified in our patients. The pseudarthrosis rate still needs to be reduced, but it may still be possible to postpone triple arthrodesis in these patients, especially those who are asymptomatic. Adelaar et al. [1] found pseudarthrosis was not correlated with pain and 60% of patients' pseudarthrosis was asymptomatic. Even the patients in our sample who presented with pseudoarthrosis and did not require reoperation were asymptomatic with a good capacity for wearing braces or shoes.

The evaluation of pain was the third objective of our study. Only one of our patients had pain after the first surgical procedure, even after radiographic bone union, and we were unable to identify any source of pain.

There appears to be a link between the deformity evolution and the loss of functional ability. Therefore, by providing a stable and aligned foot, the technique can restore, at least partially, the patient's ability to walk [11, 14]. Improvement in the surgical technique, through the use of more rigid internal fixation with compression screws and a plate, helped the correction, decreased the immobilization period, and allowed for earlier rehabilitation. The procedure proposed here was indicated mainly for adolescents and young adults. Arthrodesis or blockage of the subtalar joint (indicated when the valgus hindfoot deformity is the most predominant deviation) and anterior calcaneal lengthening (indicated when abduction is the most predominant deviation [7]) implies that the deformity is flexible and can be corrected by subtalar joint reduction [5, 8, 18]. When the deformity becomes less flexible, in the adolescent years, these techniques are unable to correct and maintain the foot position in the long term. We believe salvage procedures such as triple arthrodesis [1, 4, 6, 9, 11, 13, 14, 19, 20, 22, 24] are indicated in patients with moderate to severe rigidly deformed feet with increased pressure over the talar head with callosities and/or skin breakdown with feet too unstable

for walking or transfer of weight or unbraceable, particularly in patients with poliomyelitis.

The goal of all treatments, therefore, is to achieve a stable, plantigrade foot, to reduce medial pressure, and to facilitate the use of braces or shoes. In our study, at the last followup, 34 feet (97%) showed improvement of the deformity and were free of pain and difficulties with wearing shoes with only one patient with persistent pain (and without pseudoarthrosis). The absence of change in the functional status of the patients was expected. With this procedure, the foot becomes stable, the anatomy of the longitudinal arch is restored, and there is a decrease in medial pressure and pain enabling the patient to wear braces and/or regular shoes. Thus, in the short term, the primary goals of the method were achieved in these patients.

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