

# Complex Clubfoot Treatment With Ponseti Method: A Latin American Multicentric Study

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**Background:** Complex clubfoot is a term used to describe those feet that present after treatment with a short first metatarsal, severe plantar flexion of all metatarsals, rigid equinus, and deep folds through the sole of the foot and above the heel. Ponseti has described a modification of his original technique for the treatment of the deformity. Few series have reported the treatment outcomes of this group of patients. The purpose of this study is to analyze mid-term results and complications of a large multicenter cohort.

**Methods:** Patients with complex clubfoot treated at 6 tertiary-care institutions with a minimum of 1-year follow-up were retrospectively analyzed. Demographic data, previous treatment, number of casts, Achilles tenotomy, recurrences, complications, and additional procedures were documented. The patients were clinically evaluated at the time of presentation, after treatment, and at the last follow-up according to the Pirani score. All variables had a nonparametric distribution and are thus described as median (interquartile range (IQR), minimum-maximum). A comparison between the variables was performed using a Mann-Whitney *U* test, the change within each group was performed with a Wilcoxon-designated range test. A *P*-value <0.05 was used to indicate statistical significance.

**Results:** One hundred twenty-four feet (79 patients) were evaluated. The median age at initial treatment was 7 months (IQR, 15; min-max, 1 to 53 mo). The mean follow-up was 49 months (IQR, 42; min-max, 12 to 132 mo). A median of 5 casts (IQR, 5; min-max, 3 to 13) was required for correction. Percutaneous tenotomy of the Achilles tendon was performed in 96% of the feet. One hundred twenty-two feet (98%) were initially corrected; 2 feet could not be corrected and required a posteromedial release. The Pirani score improved significantly from

a pretreatment mean of 6 points (IQR, 1; min-max, 4.5 to 6) to 0.5 (IQR, 0.5; min-max, 0 to 2.5) at the last follow-up (*P* <0.001). Seven feet (6%) presented minor complications related to casting. Relapses occurred in 29.8% (37/124). In this subgroup, the number of casts required at initial treatment was higher (6; IQR, 5; min-max, 1 to 12 vs. 4 IQR, 4; min-max, 1 to 13; *P* <0.001), and follow-up was significantly longer (62 mo; IQR, 58; min-max, 28 to 132 vs. 37 mo; IQR, 48, min-max, 7 to 115; *P* <0.001).

**Conclusions:** Ponseti method is safe and effective for the correction of complex clubfeet. Early diagnosis and strict adherence to the Ponseti principles are key to achieve deformity correction. Patients with complex clubfoot require frequent follow-up because of a higher recurrence rate.

**Level of Evidence:** Level III—therapeutic study.

**Key Words:** complex clubfoot, Ponseti method, deformity, children (*J Pediatr Orthop* 2019;00:000–000)

## BACKGROUND

Congenital talipes equinovarus, also known as clubfoot, is the most frequent congenital deformity of the foot, with an incidence of 1 to 2 per 1000 live births.<sup>1</sup> It is characterized by 4 components of foot deformities: hindfoot equinus, hindfoot varus, midfoot cavus, and forefoot adduction, not spontaneously correcting with growth. Nowadays, conservative treatment is generally accepted as the first line of treatment. Ponseti method, which consists of serial manipulations, specific casting along with or without an Achilles tenotomy, and bracing to maintain the correction has shown excellent results in the long-term follow-up.<sup>2–4</sup>

In 2006, Ponseti et al<sup>5</sup> described a subset of patients who are very severe and resistant to manipulation (so-called “complex clubfoot”). Those patients have distinctive features: present after treatment with severe equinus, with short first metatarsal, hyperextended big toe, severe plantar flexion of all metatarsals, and deep folds through the sole of the foot and above the heel (Fig. 1). This type of clubfoot is difficult to treat and requires a modification of the standard technique. Ponseti et al<sup>5</sup> reported good outcomes on 50 patients treated with his modifications in the manipulation and casting technique. Few other studies have evaluated the efficacy<sup>6,7</sup> and durability of this technique.<sup>8</sup>

In the past years, because of the growing popularity of the Ponseti method, we have treated several patients

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**FIGURE 1.** Clinical appearance of a complex clubfoot. Note the characteristic transverse crease in the sole of the foot, a short hyperextended first toe, and rigid equinus with a deep crease above the heel.

managed with inadequate manipulations and casting technique, which resulted in complex clubfoot. Eight pediatric orthopaedic surgeons from 6 different centers across Latin America applied the modified technique described by Ponseti et al.<sup>5</sup> The purpose of this study is to analyze mid-term results and complications of this large multicenter cohort.

**METHODS**

**Study Design: Therapeutic Study (Level of Evidence: III)**

Regional institutional review board requirements were complied to identify patients with a diagnosis of complex clubfoot. We retrospectively evaluated patients treated between January 2007 and January 2016 at 6 reference institutions of Latin America, with a minimum of 1-year follow-up. Patients with atypical clubfoot (no previous treatment), nonidiopathic (syndromic or neuromuscular pathology) and patients with incomplete clinical records were excluded. Demographic data, previous treatment, cast number, tendo Achilles tenotomy (TAT), relapses, complications, and additional procedures were documented and analyzed. Patients were evaluated clinically at initial presentation, after treatment, and at the final follow-up with the Pirani score.<sup>9</sup> This score consists of 6 points and evaluates 3 morphologic aspects of the hindfoot (rigidity of equinus, severity of posterior fold, and emptiness of the heel pad) and midfoot (severity of medial fold, curvature of the lateral edge, and reducibility of the lateral side of the head of the talus). Score 1 corresponds to a severe deformity, 0.5 in the case the deformity is moderate, and if there is no deformity, no point is assigned. The total score ranges between 0 and 6 points. The higher the score, the more severe the degree of pathology. The lower the score after treatment, the better the correction of the deformity.

**Technique**

All patients were treated by pediatric orthopaedic surgeons trained in the Ponseti method. Manipulation and

casting were performed on a weekly basis according to the detailed description from Ponseti et al.<sup>5</sup> Equinus was corrected with percutaneous TAT when the foot could not achieve 15 degrees of dorsiflexion. After correction of the deformity, patients continued treatment with abduction brace (Mitchell-type or standard abduction brace depending on the availability) with the shoes in 30 to 40 degrees of abduction to prevent relapses. Bracing was started as soon as the final cast was removed. Braces were worn 23 hours/day for 3 months following treatment and then 12 to 14 hours/day (while the child is sleeping) until the child was 4 years old. The brace abduction could be changed and set to the regular 60 to 70 degrees as soon as the feet gain flexibility, usually at the end of the 23-hour period.

**Statistic Analysis**

Numerical variables were tested for normality (Shapiro-Wilk). All variables had a non-normal distribution and are thus described as median (interquartile range (IQR), minimum-maximum). A comparison between variables was performed used a Mann-Whitney *U* test, change within each group was performed with a Wilcoxon signed-rank test. A *P*-value ≤ 0.05 was considered statistically significant. The analysis was carried out with R 3.40 (A language and environment for statistical computing. R Foundation for Statistical Computing. Vienna, Austria. ISBN 3-900051-07-0).

**TABLE 1.** Patient Demographics

Characteristic	
Patients (feet)	79 (124)
Age (mo)	7 (15, 1-53)
Sex (male/female)	44/35
Side (right/left)	59/65
Follow-up (mo)	49 (42, 12-132)
Casts required for correction	5 (5, 3-13)

Values are median (IQR, min-max). IQR indicates interquartile range.



**FIGURE 2.** Manipulation of complex clubfoot with the 2 thumbs pushing under the head of the first and fifth metatarsals, whereas the forefoot is mildly abducted.

**RESULTS**

Ninety-five patients were identified for potential inclusion. After an additional independent review, 17 patients were excluded because of missing or inconsistent data. This left a cohort of 79 patients (124 feet) with complex clubfeet treated at 6 institutions from January 2007 and January 2016. Demographic data are shown in Table 1. All patients had received previous treatment, with manipulation and casting (between 5 and 25 casts) (Fig. 2). A median of 5 casts (IQR, 5; min-max, 3 to 13) was required for correction. Percutaneous tenotomy of the Achilles tendon was performed in 96% of the feet. One hundred twenty-two feet (98%) were initially corrected (Fig. 3). Two feet could not be corrected and required a posteromedial release. The Pirani score improved significantly from a median pretreatment of 6 points (IQR, 1; min-max, 4.5 to 6) to 0.5 (IQR, 0.5; min-max, 0 to 2.5) at the last follow-up ( $P < 0.001$ ). Median ankle dorsiflexion at the last follow-up was 20 degrees (IQR, 10 degrees; min-max, -5 to -30 degrees). Seven feet (6%) presented minor complications related to casting

(erythema, mild swelling, and allergic contact dermatitis). Minor complications did not affect the outcomes.

Thirty-seven feet (29.8%) had a relapse after initially successful treatment (Table 2, Fig. 4). Twenty-two cases developed dynamic supination of the forefoot and were treated with remanipulation, casting, and transference of anterior tibialis tendon (ATT). Four cases had equinus and underwent a second TAT. Two cases had equinus and forefoot adductus and required casting and second TAT. Two cases had equinus/dynamic supination and required TAT and ATT. One case had equinus/dynamic supination/mild cavus and required casting+TAT+ATT and plantar fascia release. One case had equinus/dynamic supination/rigid adductus and required casting+TAT+ATT+cuboid decancellation. One case had forefoot adductus and was corrected only with manipulation and casting. Four patients decided not to continue with treatment. One patient had a first recurrence at 17 months that required bilateral repeated percutaneous Achilles tenotomy, and second relapse at 54 months that required bilateral casting and tibialis anterior



**FIGURE 3.** The patient’s foot alignment after 2 years of clinical follow-up.

**TABLE 2.** Characteristics of Relapse and No-relapse Groups

Characteristic	Relapse (n = 37)	No Relapse (n = 85)	P*
Age (mo)	8 (23, 1-79)	7 (10, 1-57)	0.138
Pirani pretreatment	5.5 (1, 1.5-6)	6 (1, 2-6)	0.532
Follow-up time (mo)	62 (58, 28-132)	37 (48, 7-115)	<0.001
No. casts	6 (5, 1-12)	4 (4, 1-13)	<0.001

Values are median (IQR, min-max).  
 \*Mann-Whitney U test.  
 IQR indicates interquartile range.

**TABLE 3.** Change in Pirani Score After Treatment

Group	Pirani Pre	Pirani Post	Change	P*
Relapse (n = 37)	5.5 (1, 1.5-6)	0.5 (0, 0-3)	5 (1.5, 1.5-6)	<0.001
No relapse (n = 85)	6 (1, 2-6)	0.5 (0.5, 0-2.5)	5.5 (1.5, 1.5- 6)	<0.001

Values are median (IQR, min-max).  
 \*Wilcoxon signed-rank test.  
 IQR indicates interquartile range.

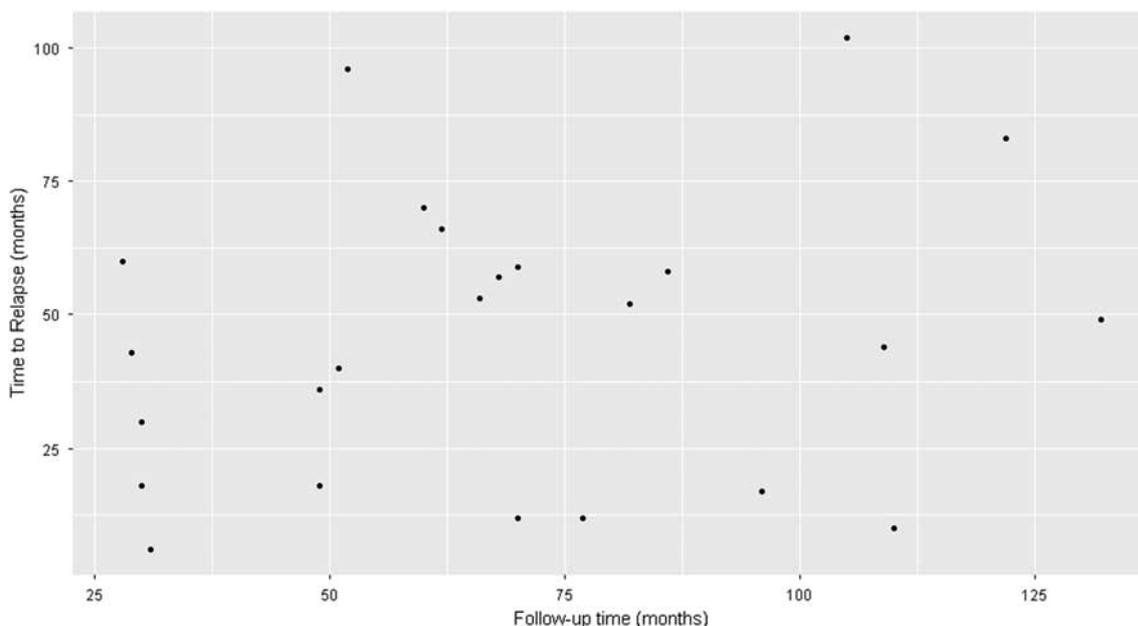
tendon transfer. This subgroup of patients required a significantly higher number of casts to achieve initial correction compared with the nonrelapse group (6 casts; IQR, 5; min-max, 1 to 12 vs. 4 casts; IQR, 4; min-max, 1 to 13;  $P < 0.001$ ). Also, the relapse group had a significantly longer follow-up (62 mo; IQR, 58; min-max, 28 to 132 vs. 37 mo; IQR, 48; min-max, 7 to 115;  $P < 0.001$ ). There were no statistically significance difference in the Pirani score at last follow-up in both subgroups (0.5; IQR, 0.5; min-max, 0 to 2.5 vs. 0.5; IQR, 0; min-max, 0 to 1.5;  $P 0.2908$ ) (Table 3).

**DISCUSSION**

Although most patients with idiopathic clubfoot treated with the Ponseti method have excellent long-term outcomes with minimal pain or disability,<sup>10-12</sup> some fail to respond to initial treatment or develop recurrent deformities requiring further treatment. Complex clubfoot represents a subgroup of patients with unique features that are difficult to treat. This form should be differentiated from the atypical clubfoot. Although both present with similar features, the complex received previous treatment while atypical does not. It is our belief that complex

clubfoot can be produced by an incorrect fulcrum, an incorrect molding, or a combination of both. When casting is poor, the feet slip in the cast, smashing the calcaneus fat pad, and diminishing adequate venous drainage in the dorsum of the foot. As a result of this, babies usually present with foot edema, erythema, and irritability similar to a reflex sympathetic dystrophy syndrome. In this scenario, we recommend waiting a few weeks until the swelling diminishes, before starting the modified protocol.

Although idiopathic clubfoot treatment with the Ponseti method has been reported extensively,<sup>4,13-18</sup> there is a paucity of literature that evaluates the results of complex clubfoot patients with the modified protocol.<sup>5-8</sup> Ponseti et al<sup>5</sup> evaluated 50 patients with 75 feet with these anatomic characteristics. The authors did not differentiate between those considered complex or atypical, but 62% of their patients were initially treated elsewhere. Fourteen percent of the series had relapses (mean follow-up, 23 mo) that were treated with casting, and 2 patients required a posteromedial release. Gupta et al<sup>7</sup> evaluated 16 patients with similar features. Although the authors described the deformities as “atypical” clubfoot, some of the patients were managed with 4 to 18 below-knee casts before they



**FIGURE 4.** Scatterplot depicts the pattern of relapse in patients with complex clubfoot during the longitudinal follow-up period.

were treated with the correct technique. The average age of the patients at the start of treatment was 3.2 months (range, 1 to 5 mo). The mean number of the cast that was applied to obtain correction was 7 (4 to 9 casts) and all required TAT. The average follow-up was 2 years (range, 1 to 3 y). At the last follow-up, all feet were well corrected with mean ankle dorsiflexion of 15 degrees (range, 10 to 20 degrees). Goksan et al<sup>6</sup> reported the outcomes of 134 feet (92 patients) with Dimeglio grade 2, 3, or 4 deformities treated with the Ponseti method. Seven patients (11 feet) had complex clubfoot with iatrogenic deformity because of incorrect casting technique. A complete correction was achieved in 97% of the whole series, however, relapses were significantly more frequent in the complex group ( $P=0.019$ ).

In our series, the modification of the manipulation and casting technique introduced by Ponseti was very effective, allowing initial correction in 98% of cases with a mean of 5 casts. However, almost 1 of 3 patients had a relapse (29.8%). This number is significantly higher than Ponseti's series and can be related to our longer follow-up (49 mo). A recent study with long-term follow-up<sup>8</sup> confirmed that patients with complex clubfoot are associated with a higher risk of relapse. Matar et al<sup>8</sup> published their results in 17 feet (11 patients), with a mean follow-up of 7 years. After an average of 7 casts and percutaneous TAT, the authors achieved initial correction in all cases. However, the overall relapse rate at the final follow-up was 53% (9 feet). Five relapses were managed successfully with casting and 4 feet required a second TAT. Four feet required extensive surgical releases. At the final follow-up, 13 of 17 feet presented a satisfactory outcome.

Our study has some limitations. First, this study was a retrospective analysis of the clinical records. Second, most patients were treated previously elsewhere, therefore, we cannot ascertain if they were originally an atypical clubfoot or became a complex clubfoot after treatment. Moreover, because we relied mainly on information from the parents, a precise number of manipulations and casting performed is uncertain. Finally, bracing compliance was not consistently recorded, and this variable could not be analyzed. Despite methodological limitations inherent to the study design, this is the largest series that evaluates results and complications of patients with complex clubfoot. This study sheds new light on the efficacy of the Ponseti method for complex clubfoot, and recurrence rate on this group of patients.

In conclusion, early identification of complex clubfoot and a change in the standard protocol, as described by Ponseti, can achieve a high rate of initial correction. However, these feet have a higher recurrence rate as reported

for the idiopathic clubfeet that could be possibly associated with muscular atrophy and permanent lesions and requires careful follow-up until maturity. Because of that, it is very important to promote strategies for adequate medical training in the Ponseti method, which will prevent a higher number of these difficult to treat clubfeet.

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