

# Outcomes of the Clubfoot Treatment with the Ponseti Method: Recurrence and Prognostic Factors

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## Abstract

**Background:** Clubfoot is a multifactorial disease with the prevalence of one in 1000 live births. The presentations of clubfoot are forefoot adductus, hindfoot varus, cavus, and equinus. Ponseti method is an efficient nonoperative clubfoot treatment containing manipulation, serial casting, and Achilles tendon tenotomy if necessary. Our prospective observational study assessed the outcome and probability of recurrence in the treated clubfoot with the Ponseti method.

**Methods:** This prospective observational study was performed in Akhtar Hospital in Tehran, Iran. 27 patients with 38 feet of idiopathic clubfoot in our study were treated with the Ponseti method. The patients were assessed before and after treatment and demographic characteristics, Dimeglio scores, number of recurrences, and need for tenotomy were recorded.

**Results:** All patients (38 feet) successfully achieved complete deformity correction, but 13 feet had a relapse. The mean age of cases with relapse was more than cases without relapse. Cases with a higher initial Dimeglio score had a higher recurrence rate after Ponseti method treatment. Eight feet (five patients) out of 38 feet did not use Denis Browne (DB) splint as our protocol; all of them had a relapse. On the other hand, only 5 of 30 feet (16.7%) that used splint had recurrence.

**Conclusion:** The treatment should be started as soon as possible because it is more effective at a younger age. Severe cases at the initial visit had more recurrence rate. Besides, the recurrence rate in cases that used DB orthosis improperly, irregularly, and incorrectly was higher than others.

**Keywords:** Clubfoot; Congenital Talipes Equinovarus; Treatment; Recurrence

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## Background

One of the most common pediatric congenital foot deformities is clubfoot or congenital talipes equinovarus (CTEV). Prevalence is one in 1000 live births (1-4). This foot deformity contains the forefoot adductus, hindfoot varus, cavus, and equinus (5, 6). About 80 percent of clubfoot cases are isolated (idiopathic or noncomplex), while the least of them are associated with other congenital deformities. Nearly half of them are unilateral, and others are bilateral (6).

A nonoperative common clubfoot treatment is Ponseti method, in which it is necessary to use orthoses for two to four years (4). This method includes manipulation, serial and persistent casting, almost always percutaneous Achilles tenotomy, and then bracing (5). To correct the equinus deformity, Achilles tenotomy is needed, and orthosis usage helps to maintain corrected foot in the right position (7, 8). Patients have to wear the foot abduction brace full time (23 of 24 hours) for the first three months and then during night sleep for three years (9). The main goal of the clubfoot treatment is to obtain permanent correction, painlessness, and a complete functional foot (10).

Untreated children walk on the sides and/or tops of their feet which results in callus formation, potential skin and bone infections, inability to wear standard shoes, and substantial limitations in mobility and further social challenges such as disability in employment (10). Clubfoot is mostly isolated, but it may present with comorbidities like spina bifida, myelomeningocele, or arthrogyposis

(11). Clubfoot is a multifactorial disease, and genetic factors play a major role, as suggested by the fact that identical twins have 33% concordance, and almost a quarter of all cases are familial (12, 13).

There are two classification systems that are widely used in the primary evaluation of clubfoot deformities. The first one was developed by Dimeglio et al. (14) and the second by Pirani et al. (15). Both of them have a point score algorithm based on different clinical findings, and their total score describes clubfoot severity. These two systems have a significant correlation, as reported previously (16). The frequent plastering and the necessity for tenotomy can be predicted by both Dimeglio et al. (14) and Pirani et al. (15) scoring systems quite accurately in most cases, but in predicting both steps of the Ponseti method treatment, the Dimeglio score was slightly more precise (13).

To treat congenital idiopathic clubfoot, the Ponseti method is a safe and effective way. The rate of extensive corrective surgeries in clubfoot patients is reduced with this method hugely. Two years of age is limitation for this method, and also it is effective after the other previous nonsurgical treatments (17).

## Methods

This prospective observational study was performed from May 2020 until November 2021 in Akhtar Hospital, Tehran, Iran. All participants provided written informed consent. The protocol and consent forms were approved by the Institutional Review Board at Shahid Beheshti

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University of Medical Sciences, Tehran. In this study, 27 children (39 feet) who had idiopathic clubfoot (unilateral or bilateral) were evaluated, and the diagnosis was made based on clinical examination. After the initial evaluation, to correct foot deformity, manipulation and serial casting with Ponseti method was performed. If ankle dorsiflexion range was smaller than 15 degrees, Achilles tenotomy would be necessary at the last casting. Questionnaire registration and initial assessment included: age at the start of treatment, sex, familial history, unilateral or bilateral involvement, and severity of disease based on the Dimeglio score. The Dimeglio score less than six was considered as benign and did not need treatment; therefore, it was excluded from the study. Dimeglio score between six to 10 was considered as moderate group, the score between 11 to 15 as severe group, and the score between 15 to 20 as very severe group (13).

Inclusion criteria included idiopathic clubfoot deformities which were treated in children less than 1 year old. Exclusion criteria included age more than one year old, underlying diseases such as dysplasia, syndromes, cerebral palsy or myelomeningocele, patients who have been previously treated, Dimeglio score less than six (which is not a real clubfoot deformity), incomplete treatment process, and failure to follow up treatment. Patients were initially evaluated and treated by a Ponseti method performed by a pediatric orthopedic fellowship surgeon.

Patients were visited weekly, and manipulated for five minutes, and then deformity casting was done by the Ponseti method. Paris plaster was used for casting. Cavus was corrected in the first casting with forefoot supination and first metatarsal base reduction. After that, forefoot adduction and heel varus were corrected in the subsequent casting, and at last, equinus deformity was corrected.

At the end of week one of casting, the parents opened the cast, and the child was brought to the clinic the same day for re-casting. Plaster casts were performed in a classic clubfoot from the fingertips to the proximal 1/3 of the thigh. After correcting other deformities, if ankle dorsiflexion was less than 15 degrees, percutaneous Achilles tenotomy would be conducted after topical lidocaine injection. Then casting was performed after tenotomy, and the affected limb was kept in plaster for two weeks after tenotomy.

After complete recovery and completion of the treatment period, immediate use of Denis Browne (DB) orthosis was started. The affected limb position was kept to 70 degrees of external rotation and the healthy limb position was kept to 40 degrees of external rotation. The size of the distance between the two heels was adjusted to the width of the patient's shoulder and was held using the connective bar between the two splints, right and left (Figure 1).



Figure 1. Denis Browne (DB) orthosis

The DB orthosis was used 23 of 24 hours daily for the first trimester, then 16 hours daily for the second trimester, and it was continued during sleep (nap time and night) for three years. Finally, re-evaluation was performed using the Dimeglio scoring system at the end of our study period (follow-up: six months after opening the cast).

We assessed some parameters such as the initial Dimeglio score, age at the time of first casting, the indication of Achilles tenotomy, the number of castings required prior to Achilles tenotomy, method of admission, use of DB orthosis, and recurrence.

All initial assessments and procedures, casting, tenotomy (if needed), final evaluation, and questionnaire completion were administered by a pediatric orthopedic fellowship surgeon. If any deformities such as cavus, forefoot adduction, heel varus, and equinus were returned, it would be considered a recurrence.

## Results

In this study, 32 patients with clubfoot were included. Due to lack of follow-up and incomplete treatment, four patients were excluded from the study, and due to the underlying disease, one patient was excluded from the study. Finally, 27 patients (38 feet) remained in the study that 17 (63%) patients were less than one month old, and 10 (37%) patients were more than one month old at the initial visit. The minimum age was one day, the maximum age was 73 days, and the mean age of patients was  $25 \pm 21$  days. Four patients were female (14.8%), and 23 were male (85.2%). Out of 27 patients, 11 cases (40.7%) had bilateral involvement, 13 cases (48.1%) had right involvement, and three patients (11.1%) had left involvement (Table 1).

16 feet were subjected to 4 manipulations and casts, in which no recurrence was observed. Another 16 feet were manipulated 5 times with two recurrences, and six feet were manipulated and plastered six times with three recurrences (Table 2).

Table 1. Characteristics of patient and distribution of relapse and tenotomy						
Item	n (%)	Relapse		Tenotomy		
		No	Yes	Not done	Done	
Age (month)	≤1	17 (63.0) P	17 (73.9) F	6 (26.1) F	4 (17.4) F	19 (82.6) F
	>1	10 (37.0) P	8 (53.3) F	7 (46.7) F	2 (13.3) F	13 (86.7) F
Sex	Male	23 (85.2) P	22 (64.7) F	12 (35.3) F	6 (17.6) F	28 (82.4) F
	Female	4 (14.8) P	3 (75.0) F	1 (25.0) F	0 (0) F	4 (100) F
Side	Right	13 (48.1) P	10 (76.9) F	3 (23.1) F	0 (0) F	13 (100) F
	Left	3 (11.1) P	3 (100) F	0 (0) F	0 (0) F	3 (100) F
	Bilateral	11 (40.7) P	12 (54.5) F	10 (45.5) F	6 (27.3) F	16 (72.7) F
Dimeglio score	Moderate	7 (18.4) F	7 (100) F	0 (0) F	2 (28.6) F	5 (71.4) F
	Severe	18 (47.3) F	12 (66.7) F	6 (33.3) F	2 (11.1) F	16 (89.9) F
	Very severe	13 (34.2) F	6 (46.2) F	7 (53.8) F	2 (15.4) F	11 (84.6) F

F: Feet; P: Patient

**Table 2.** Distribution of tenotomy, orthosis use, and correlation with recurrence

Item		n (%)	Recurrence	
			No	Yes
Tenotomy	Not done	6 (15.7) F	6 (100) F	0 (0) F
	Done	32 (84.2) F	19 (59.4) F	13 (40.6) F
Use orthosis	Yes	30 (78.9) F	25 (83.3) F	5 (16.7) F
	No	8 (21.0) F	0 (0) F	8 (100) F
Number of casts	4	16 (42.1) F	16 (100) F	0 (0) F
	5	16 (42.1) F	6 (37.5) F	10 (62.5) F
	6	6 (15.7) F	3 (50.0) F	3 (50.0) F

F: Feet

The average number of plasters in moderate, severe, and very severe cases was, respectively, 4.57, 4.55, and 5.07 (Table 3). The average number of plasters in cases of recurrence was  $5.23 \pm 0.48$  and in cases without recurrence was  $4.48 \pm 0.71$ .

**Table 3.** Correlation of the Dimeglio score with the number of casts

Item		Number of casts			Mean of casts	Total
		4	5	6		
Dimeglio score	Moderate	4 (57.1) F	2 (28.6) F	1 (14.3) F	4.57	7 F
	Severe	9 (50.0) F	8 (44.4) F	1 (5.6) F	4.55	18 F
	Very severe	3 (23.1) F	6 (46.2) F	4 (30.8) F	5.07	13 F
<b>Total</b>		16 F	16 F	6 F		38 F

F: Feet

6 of 38 feet were corrected by casting without Achilles tenotomy, and the remaining 32 cases were treated by casting with Achilles tenotomy (Table 2). 19 of 23 cases aged under or equal to one month and 13 of 15 cases aged over one month needed Achilles tenotomy (Table 1).

Seven cases had a moderate Dimeglio score, in which tenotomy was indicated for five cases, and no relapses were observed in the moderate group. 18 cases with severe Dimeglio scores were in this study; tenotomy was performed for 16 cases, and six recurrence cases were reported. 13 cases had a very severe Dimeglio score; Achilles tenotomy was performed for 11 cases, and 7 of these 11 cases had relapses (Table 1).

Out of the 38 affected feet, two feet developed soreness in the talar head area during casting. Both of them were superficial sores; the casting was continued after dressing, and they were healed completely.

Two of the 28 patients had a positive familial history. Out of 38 feet, in 13 cases (34.2%), the deformity had recurrences.

In the remaining 25 cases (65.8%), no recurrence was observed, and the results were satisfactory. Initial age was equal to or less than one month in 23 feet; six of them (26.1%) had a relapse. On the other hand, 7 of 15 feet (46.7%) that were initially treated after 30 days had recurrences (Table 1).

The primary Dimeglio score of the patients (38 feet) was  $14.65 \pm 3.77$ . Clubfoot deformity relapsed in 13 feet with the primary Dimeglio score of  $16.46 \pm 3.15$  although 25 feet without recurrence had an initial Dimeglio score of  $13.52 \pm 3.61$  (Table 4).

**Table 4.** Correlation of Dimeglio scores with relapse

Item	Relapse	Number of feet	Mean $\pm$ SD	P-value
Dimeglio score	Yes	13	16.84 $\pm$ 3.15	0.008
	No	25	13.52 $\pm$ 3.61	
Age (day)	Yes	13	37.61 $\pm$ 26.38	0.046
	No	25	20.20 $\pm$ 17.71	

SD: Standard deviation

## Discussion

One of the most common congenital lower limb anomalies is clubfoot. A nonsurgical therapy that includes

serial manipulation and casting by the Ponseti method is the best treatment for clubfoot and, if required, Achilles tenotomy (3, 6, 11).

In our study, the mean age of patients at the time of starting treatment was  $25 \pm 21$  days, between 1 and 73 days. In the study of Hoque et al., the mean age of patients was  $60.0 \pm 24.0$  days and their age was between 4 and 120 days (18). In addition, the mean age of patients in Lampasi et al. study was  $28 \pm 15$  days and their age was between 5 and 68 days (13), which was similar to our study. In another study by Gao et al., the mean age of patients at the first visit for treatment was 18 days, and the patients were between 2 and 40 days old (19).

11 cases (40.75%) of our patients had bilateral involvement, 13 cases (48.14%) had right involvement, and 3 cases (11.11%) had only left involvement. In Smythe et al. study, 52% of bilateral clubfoot and 48% of unilateral clubfoot (including right or left) were reported, which the conflict on the right was greater than on the left (9). Lee et al. reported 42.6% of bilateral cases, and the rest of the cases (57.4%) were unilateral (3), which was similar to our study. In another study by Zhao et al., the percentage of bilateral cases was 48% and that of unilateral cases was 52% (20).

In our study, if a patient required four times casting for treatment, recurrence was not observed, but if five or six times casting was required, the probability of recurrence was higher; however, no significant difference was found. Although cases with a higher number of initial Dimeglio scores required a higher number of cast time, there was no significant relationship considering the initial Dimeglio scores and number of cast times. In the study of Lampasi et al., it was found that the number of casts required in clubfoot treatment was directly related to the Dimeglio score at the initial referral and could predict the number of casts required (13).

In another study by Zhao et al., a positive relationship was reported between Dimeglio initial score and the number of times plastering required (20), which is similar to our study. Jayasomeswar et al. reported that the higher the degree of deformity, the more time plaster was needed to correct it (21).

In our study, in 32 of 38 cases (84.2%), Achilles tenotomy was performed, and tenotomy in six cases (15.79%) was not required. Besides, patients with higher Dimeglio scores had a higher risk factor for Achilles tenotomy in the last casting, but this relation was not significant. However, two feet in the very severe group of Dimeglio scores did not require tenotomy. In a study by Lampasi et al., in 82.4% of clubfoot cases, Achilles tenotomy was performed, which is similar to our study. A high correlation was found between Dimeglio score in the initial visit and indication of Achilles tenotomy at the last casting course (13). Smythe et al. showed that 79.7% of clubfoot cases required Achilles tenotomy, and more severe clubfoot in the initial visit would indicate the possibility of more need for tenotomy during treatment (9), and Hoque et al. showed that 92.32% of the feet needed tenotomy (18).

In this study, in the last clubfoot cast after percutaneous Achilles tenotomy, 70 degrees foot abduction and 15 degrees ankle dorsiflexion were maintained, and because all the cases were under one year old, the duration of the last cast was two weeks. We did not have any calcaneal deformity in this observation period. In the study of Smythe et al., the duration of long leg cast in

the corrective position after Achilles tenotomy in patients younger than two years was three weeks, and in patients older than two years was 4-6 weeks (9). Since we perform Achilles tendon lengthening in patients older than one year, they were excluded from this study. In a study by Lampasi et al., the age of inclusion was less than three months, and the duration of casting after Achilles tenotomy was considered to be twenty days (13).

According to table 4, the mean age in cases with recurrence was  $37.61 \pm 26.38$  days and in cases without recurrence was  $20.20 \pm 17.71$  days, which had a significant relationship ( $P < 0.05$ ) and indicates that recurrence is negatively related to initial casting age. However, Lee et al. suggested that if treatment was started before one month, there would be no significant difference in recurrence with patients whose treatment was started after one month (3). Moreover, Sud et al. (22) and Selmani (23) showed that age did not affect the recurrence rate. In some studies, it has been recommended that clubfoot cases should be treated by the Ponseti method as soon as possible after birth, to prevent relapse of clubfoot (24-26), which is in line with our research results on the relationship between age and clubfoot recurrence.

13 cases of recurrence were reported in our study in which the mean score of Dimeglio was  $16.84 \pm 3.15$  and the mean score of Dimeglio of patients without recurrence was  $13.52 \pm 3.61$ . These findings showed a significant difference in Dimeglio score between the cases with and without recurrence ( $P < 0.05$ ). Therefore, cases with a higher initial score of Dimeglio had a higher recurrence rate after Ponseti casting. In the study of Elgohary and Abulsaad, cases of clubfoot recurrence (14.7%) were reported, of which 90% had high clubfoot severity and high Pirani score during the initial visit (27). In a study by Zhang et al., a strong correlation existed between Dimeglio score with outcome after clubfoot treatment by Ponseti method. The higher initial Dimeglio score had a worse outcome in the final foot condition after two years (28). A study by Brazell et al. showed that clubfoot was more likely to recur in cases with a higher score of Dimeglio than in cases with a lower score (29). In Dobbs and Gurnett's study, it was reported that the initial severity of clubfoot did not indicate a higher risk of recurrence (10).

In our study, eight feet (five cases) did not use DB splint as our protocol; all of them had a recurrence. On the other hand, only 5 of 30 feet (16.7%) that used splint had a recurrence; the difference between two groups was significant ( $P < 0.05$ ) and it was revealed that not using brace was a risk factor for recurrence. Porecha et al. observed that the main cause of recurrence in clubfoot after complete treatment by the Ponseti method was the lack of proper acceptance of DB splint (30). Lee et al. (3) and Zions et al. (31), and Colburn and Williams (32) showed that the main cause of recurrence in clubfoot patients was the rejection of the use of abduction orthosis by the patient's family.

### Conclusion

Even in patients with severe clubfoot deformities, the Ponseti method is a sufficient treatment that includes serial manipulation and casting every week. Before the last casting, if ankle dorsiflexion was not achieved with manipulation, Achilles tenotomy would be performed. This method can be quite effective for all clubfoot deformities. However, it is recommended that the treatment be started as soon as possible because it is more

effective at a younger age. Severe cases at the initial visit had more recurrence rate. Further, the recurrence rate in cases who used DB brace improperly, irregularly, and incorrectly was higher than others.

**Limitations:** Limitations of this study included the small number of patients and the short follow-up period, that was six months, which was relatively less than other studies; moreover, acceptance and correct and regular use of DB splint was subjectively assessed based on the statements of parents.

### Conflict of Interest

The authors declare no conflict of interest in this study.

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