Ponseti Treatment for Idiopathic Clubfoot

Minimum 5-year Followup

Noam Bor MD, Julie A. Coplan DSc, PT,
John E. Herzenberg MD, FRCSC

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Abstract Ponseti clubfoot treatment has become more popular during the last decade. We reviewed the medical records of 74 consecutive infants (117 club feet) who underwent Ponseti treatment. Minimum followup was 5 years (mean, 6.3 years; range, 5–9 years). We studied age at presentation, previous treatment, the initial severity score of the Pirani scoring system, number of casts, need for Achilles tenotomy or other surgical procedures, and brace use. We measured final ankle motion and parents' perception of outcome. Late presentation and previous non-Ponseti treatment were associated with lower initial severity score, fewer casts, and less need for tenotomy. Forty-four percent of patients had poor brace use. We observed better brace use (75%) in babies who presented late for treatment. Good brace use predicted less need for extensive surgical procedures. Twenty-four (32%) babies

underwent additional surgical procedures other than tenotomy, including 21% who underwent tibialis anterior tendon transfer. At followup, 89% of feet had adequate dorsiflexion (5° or greater). Parents indicated high satisfaction with the treatment results. Ankle motion was not associated with parents' satisfaction. The Ponseti method is effective, even if treatment starts late or begins after failure at other centers. Brace use influenced the success of treatment.

Level of Evidence: Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Initial treatment of idiopathic congenital clubfoot is non-operative with manipulation and serial casting. Patients who eventually require extensive open surgical release might have poor outcomes [10]. During the last decade, there has been renewed interest in the Ponseti method of clubfoot treatment. A recent questionnaire reported that 65% of the Pediatric Orthopaedic Society of North America members used the Ponseti method [16]. However, all recently published reports describe only short-term followup of 1 to 2 years [1, 2, 4, 6, 8, 9, 17, 19, 21].

The Ponseti treatment has been used since 1997 by the two senior authors at centers in Baltimore (JEH) and Afula (NB) [25, 26]. We asked (1) if the populations were comparable at our two centers (to justify combining them); (2) if the number of casts required was associated with age at presentation (28 days or younger or older than 28 days); (3) if the number of casts applied was associated with the severity of the initial Pirani severity score [12, 13] at presentation; (4) if the need for additional surgery was

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

N. Bor
Pediatric Orthopedic Unit, Emek Medical Center, Afula, Israel

J. A. Coplan
Department of Rehabilitation, Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore, Baltimore, MD, USA

J. E. Herzenberg (✉)
Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore, 2401 West Belvedere Avenue, Baltimore, MD 21215, USA
e-mail: jherzenberg@lifebridgehealth.org

associated with the initial severity; and (5) if the results were different for early versus late presenters. Finally, we used an outcome tool to gauge parent satisfaction with the treatment.

Materials and Methods

We retrospectively studied the medical records of 88 babies (31 girls, 57 boys) with idiopathic clubfoot who began treatment at either the Baltimore or Afula center between 1997 and 2002. We did not call back patients for clinical followup specifically for this study. Of the 88 patients, we excluded 14 because they were lost to followup or they were unable to return for followup. Seventy-four patients (33 from Afula, 41 from Baltimore) with 117 clubfeet (59 left feet, 58 right feet) were included in the study. Twenty-six patients were girls and 48 were boys. Forty-three patients had bilateral clubfoot, and 31 had unilateral clubfoot (15 right feet, 16 left feet). The minimum followup was 5 years (mean, 6.3 years; range, 5–9 years).

Overall, the mean age at presentation for treatment was 67.1 days (median, 7.5 days; range, 1–630 days). The mean age (mean age, 11.2 days; range, 1–165 days; median, 1 day) of the 33 babies who presented for treatment at Afula was lower ($p = 0.001$) than the mean age (mean age, 112 days; range, 2–630 days; median, 42 days) of the 41 babies who presented for treatment at Baltimore. Presentation was categorized as either early or late. Early presentation was defined as 28 days or younger, and late presentation was defined as older than 28 days. Thirty-one (93.9%) of 33 babies who presented for treatment at Afula were 28 days or younger versus 20 (48.8%) of 41 babies who presented for treatment at Baltimore. Altogether, there were more ($p = 0.001$) late presenters than early presenters with 68.9% (51 of 74 babies) 28 days or younger and 31.1% (23 of 74 babies) older than 28 days.

The club feet were treated with strict Ponseti protocol [25, 26]. At the time of presentation, the clubfoot deformities were graded with the Pirani six-point initial severity score [12, 13]. The score was obtained at initial evaluation for 101 of the 117 total feet in the series. The 16 feet with missing initial scores were excluded from those analyses requiring the score. Information obtained from the medical records included ankle range of motion (ie, dorsiflexion, plantar flexion) measured by the senior investigators (NB, JEH) with a handheld goniometer, any previous treatment, tolerance to the brace (ie, foot abduction orthosis), need for percutaneous Achilles tenotomy, number of pretenotomy casts applied, and need for additional surgical procedures. Additional surgical procedures were classified as minor (eg, tibialis anterior tendon transfer [TATT] with or

without tendo-Achillis lengthening), moderate (eg, posterior release), or major (eg, posteromedial release [PMR], correction with external fixation). We defined a good outcome as requiring no surgery or minor surgery. During routine followup visits, we asked the parents whether they followed the strict brace protocol. We defined good brace use as full-time use for at least 3 months followed by at least 9 months of nighttime use [14, 29]; anything less was considered poor brace use. We made this assessment based on questioning the parents during followup examinations.

All babies were examined to determine ankle range of motion. Ankle dorsiflexion measurements were categorized as either inadequate (less than 5°) or adequate (5° or greater).

We measured parents' satisfaction regarding their children's feet using a 10-item clubfoot Disease Specific Instrument (DSI) as described by Roye et al. [28] (Appendix 1). The parents of 68 patients answered the clubfoot DSI. The parents of eight patients who were included in the study did not complete the questionnaire. However, the parents of two patients who were considered lost to clinical followup completed the questionnaire. To assess the reliability of the satisfaction summated scale, Cronbach's alpha coefficient was computed for the scale components.

The association between categorical variables (eg, initial severity scores of babies presenting at the two centers, presenting early and late, without or with tenotomy, without and with previous treatment, good and poor brace use) was examined using the chi square test. Mann-Whitney tests were used to compare continuous variables (eg, number of casts, range of motion) between two independent study groups. Data analysis was performed using the SPSS 14 statistical package (SPSS Inc, Chicago, IL). All statistical tests were two-tailed. P values of less than 0.05 were considered statistically significant.

Results

The mean initial severity score of the babies who presented early for treatment (28 days or younger) was similar ($p = 0.093$) between the two centers (Table 1). The Baltimore and Afula groups were similar in regard to the need for Achilles tenotomy (108 feet) (Table 2).

The babies who presented late had lower initial severity scores, presumably because they had some previous treatment (Table 3). Fewer casts were required to treat children who presented at an older age. Babies who underwent previous treatment needed fewer casts (Table 4). We observed an association between the total number of casts applied and the need to undergo additional surgery (other than percutaneous Achilles tenotomy) (Table 5). Of 108

Table 1. Pirani scores obtained at each center of babies who presented for treatment when they were 28 days or younger

Group	Mean	Number of feet	Standard deviation	Median	Minimum	Maximum
Afula	5.3214	42	1.06394	6.0000	3.00	6.00
Baltimore	4.7813	32	1.5010	5.5000	1.50	6.00
Total	5.0878	74	1.29040	6.0000	1.50	6.00

$p = 0.093$ (not significant).

Table 2. Comparison of the number of Achilles tenotomies performed at Baltimore and Afula

Group	Location		Total
	Afula	Baltimore	
No tenotomy performed, number (percent within group)	3 (6.8)	12 (18.8)	15 (13.9)
Tenotomy performed, number (percent within group)	41 (93.2)	52 (81.3)	93 (86.1)
Total	44	64	108

$p = 0.078$ (not significant).

Table 3. Pirani scores of babies older than 28 days who underwent previous treatment compared with those who had no previous treatment

Previous treatment	Mean	Number of feet	Standard deviation	Median	Minimum	Maximum
No	5.1876	72	1.15730	6.000	2.00	6.00
Yes	4.1207	29	1.54489	4.000	1.00	6.00
Total	4.8812	101	1.36180	5.500	1.00	6.00

$p = 0.001$ (significant).

Table 4. Total number of casts required to achieve correction for patients who underwent previous treatment compared with those who had no previous treatment

Previous treatment	Mean number of casts	Number of feet	Standard deviation	Median	Minimum	Maximum
No	6.69	74	2.177	6.50	3	14
Yes	5.43	30	2.300	5.00	2	10
Total	6.33	104	2.275	6.00	2	14

$p = 0.010$ (significant).

Table 5. Need for additional surgery (excluding Achilles tenotomy) according to the number of casts required to achieve correction

Surgical procedure	Mean number of casts	Number of patients	Standard deviation	Median	Minimum	Maximum
No	6.00	48	1.946	6.00	2	10
Yes	7.13	23	2.616	7.00	3	14
Total	6.37	71	2.231	6.00	2	14

$p = 0.045$ (significant).

feet, 15 (13.9%) did not require Achilles tenotomy. Higher initial severity scores at presentation were associated with the need for tenotomy (Table 6).

Brace use was evaluated in 70 babies and was almost evenly distributed: 31 (44.3%) had poor brace use and 39 (55.7%) had good brace use. Of 50 babies who presented early for treatment (28 days or younger), 26 (52%) had poor brace use and 24 (48%) had good brace use

($p = 0.093$) (Table 7). However, in 20 babies who presented late, a larger percentage ($p = 0.040$) had good brace use (15 babies) than poor brace use (five babies). Brace-intolerant patients might still avoid additional surgery. No additional surgery was required for 55% of the brace-intolerant patients. Good brace use led to a 20.5% risk of additional surgery, whereas deviating from the brace protocol led to a 45.2% risk of additional surgery.

Table 6. Need for tenotomy based on Pirani scores obtained at initial presentation

Tenotomy	Mean Pirani score	Number of feet	Standard deviation	Median	Minimum	Maximum
No	3.3636	11	1.45071	3.0000	1.50	5.50
Yes	5.0667	90	1.23605	5.7500	1.00	6.00
Total	4.8812	101	1.36180	5.5000	1.00	6.00

$p = 0.001$ (significant).

Table 7. Brace use of babies who presented for treatment when they were 28 days or younger

Compliance	Location		Total
	Afula	Baltimore	
Poor, number of babies (percent within group)	19 (61.3)	7 (36.8)	26 (52)
Good, number of babies (percent within group)	12 (38.7)	12 (63.2)	24 (48)
Total	31	19	50

$p = 0.093$ (not significant).

Table 8. Final ankle dorsiflexion for babies who presented early for treatment at the two centers

Dorsiflexion	Number of feet (%)
Adequate (5° or greater)	97 (89%)
Inadequate (less than 5°)	12 (11%)
Total	109

Final dorsiflexion was adequate for 97 (89%) of 109 feet (Table 8). The final ankle motion (ie, plantar flexion, dorsiflexion) was no different between early and late presenters (Tables 9, 10).

Ninety-nine feet (89.2%) achieved a good outcome (required no surgery or minor surgery). Of 111 feet, 23 feet (20.7%) had TATT, eight feet (7.2%) had posterior

capsulotomy, and four feet (3.6%) had major surgery (PMR, two feet; application of the Taylor spatial frame [TSF], two feet). Five feet (4.5%) required more than one procedure (not at the same time): TATT plus PMR (two feet), TATT plus posterior release (two feet), and posterior release plus application of the TSF (one foot). Twenty-four (32.4%) of 74 babies underwent additional surgical procedures (percutaneous Achilles tenotomy not included) during followup. Poor brace use was associated with the need to undergo additional surgical procedures (Table 11).

We found no association between the need for additional surgery and the initial severity score ($p = 0.113$), age at presentation for treatment ($p = 0.557$), prior treatment before presentation ($p = 0.284$), and ankle range of motion (ie, dorsiflexion) at the last visit ($p = 0.408$).

The DSI questionnaire was reliable (Cronbach's $\alpha = 0.676$). Nine of 10 answers are included

Table 9. Ankle dorsiflexion of babies who presented when they were younger versus those who presented when they were older

Age at presentation	Mean dorsiflexion	Number of feet	Standard deviation	Median angles	Minimum	Maximum
28 days or less	10.2°	74	6.477	10°	0°	25°
Greater than 28 days	10.7°	36	4.061	10°	5°	18°
Total	10.4°	110	5.784	10°	0°	25°

$p = 0.534$ (not significant).

Table 10. Final ankle plantar flexion of babies who presented when they were younger versus those who presented when they were older

Age at presentation	Mean	Number of feet	Standard deviation	Median angles	Minimum	Maximum
28 days or less	45.3	74	11.974	50°	10°	65°
Greater than 28 days	42.1	36	11.597	45°	18°	60°
Total	44.3	110	11.896	45°	10°	65°

$p = 0.183$ (not significant).

Table 11. Need for additional surgery (excluding percutaneous Achilles tenotomy) relative to brace tolerance

Brace tolerance	Variable	Additional surgery		Total number of babies
		No	Yes	
Poor	Number of babies (percent of poor brace tolerance group)	17 (54.8%)	14 (45.2%)	31
Good	Number of babies (percent of good brace tolerance group)	31 (79.5%)	8 (20.5%)	39
Total	Number of babies	48	22	70

$p = 0.027$ (significant).

Table 12. Disease specific instrument results per number of patients and percentages

Questions			Responses				Total number of patients
			1	2	3	4	
Satisfied	1	N	54	12	1	1	68
		%	79.4	17.6	1.5	1.5	
Cosmesis	2	N	49	17	2	0	68
		%	72.1	25	2.9	0	
Teasing	3	N	67	1	0	0	68
		%	98.5	1.5	0	0	
Shoes fit	4	N	59	11	6	1	68
		%	73.5	16.2	8.8	1.5	
Shoes liked	5	N	56	9	1	2	68
		%	82.4	13.2	1.5	2.9	
Pain	6	N	9 (yes)	57 (no)	0	0	66
		%	13.6	86.4	0	0	
Walking	7a	N	61	7	0	0	68
		%	89.7	10.3	0	0	
Running	7b	N	58	7	2	1	68
		%	85.3	10.3	2.9	1.5	
Pain with heavy exercise	8	N	47	19	2	0	68
		%	69.1	27.9	2.9	0	
Pain with moderate exercise	9	N	60	8	0	0	68
		%	88.2	11.8	0	0	

(excluding Question 6, which was a yes-or-no question about pain). The satisfaction index, which is the mean of the nine answers, was 1.2 (range, 1–4) (Table 12). We observed no association ($p = 0.425$) between brace use and parents' (62 patients) satisfaction according to the questionnaire. We also observed no association ($p = 0.514$) between dorsiflexion (classified as adequate or inadequate) and parents' (67 patients) satisfaction according to the questionnaire.

Discussion

The Ponseti technique has been available for more than 50 years, but only Ponseti and colleagues have reported

long-term followup [7, 20]. The literature otherwise contains primarily short-term followup studies. The goal of this study was therefore to evaluate midterm results with a minimum 5-year followup from two diverse centers. We specifically asked (1) if the populations were comparable at our two centers (to justify combining them); (2) if the number of casts required was associated with age at presentation (28 days or younger or older than 28 days); (3) if the number of casts applied was associated with the severity of the initial severity score at presentation; (4) if the need for additional surgery was associated with the initial severity; and (5) if the results were different for early versus late presenters. Finally, we used an outcome tool to gauge parent satisfaction with the treatment.

One of the limitations of the study is the reliance on parent-reported data such as brace use. When we believed the brace was not used correctly, we talked to the parents and they normally confirmed our suspicions. Another limitation is the variability of measuring ankle dorsiflexion. To lessen measurement variability, only the senior authors (NB, JEH) measured the range of motion. Our study included two centers, and although some of the data were similar between the centers, there were differences. Equal initial scores were obtained for babies who presented younger than 28 days, and no difference was observed between the numbers of babies who underwent Achilles tenotomy. Ankle plantar flexion at the last visit was also similar between the two centers. The brace tolerance for babies who presented for treatment at 28 days of age or younger was similar. There were some minor differences between the two centers such as the initial score (lower in Baltimore) and the age at presentation for treatment (older patients presented at Baltimore). Baltimore patients were often referred after failing initial treatment elsewhere. Babies who were partially but unsuccessfully treated at other centers had lower initial scores (Table 3), required fewer Ponseti casts (Table 4), and required slightly fewer percutaneous Achilles tenotomies. This indicates the previous treatment had some positive effect on the initial deformity. If patients fail Ponseti treatment at one center, it does not preclude success at another center that strictly follows the Ponseti protocol. Although the Baltimore and Afula groups were not identical at initial presentation, we believe it is justified to combine them because we are reviewing their response to our strict Ponseti treatment.

Our data show that even non-Ponseti manipulation and cast techniques have some favorable effect on the deformed feet, making subsequent Ponseti treatment both possible and easier. However, it should be noted that the number of Ponseti casts, although fewer in our late presenters, did not include the cumulative number of non-Ponseti casts applied elsewhere. Based on our experience, we believe some treatment is better than none, but we prefer to have the children referred to us as early as possible because the overall treatment time is shorter for children who are treated by us from birth.

The initial severity score was associated with the need to perform tenotomy. In the literature, approximately 90% of children undergoing Ponseti treatment need a tenotomy [17]. We found the number of Ponseti casts applied predicted the need to perform additional surgical procedures; a foot that requires many casts for the initial correction is more likely to require future additional surgery.

In our study, the Ponseti method proved successful with 89.2% of feet (99 feet) achieving a good outcome. Other authors have reported short-term results with the Ponseti technique. Ippolito et al. [18] compared babies treated with

different protocols (Ponseti and the Marino-Zuco method). In the Ponseti group, 78% of the feet had excellent or good results as compared with only 43% feet in the non-Ponseti group. Ippolito et al. [19] also reported excellent results in 18 of 49 feet treated with the Ponseti method and only two of 47 feet treated with the non-Ponseti technique. In another study [2], only two of nine feet treated with the Ponseti method required major surgery, whereas 13 of 19 feet treated with the Copenhagen technique required major surgery. A study from Romania [8] compared results of a local Romanian treatment protocol and the Ponseti method. At 18 months, only four (5.1%) of 78 feet treated with the Ponseti method required PMR, whereas 13 (17.6%) of 74 feet treated with the Romanian method required PMR for the completion of treatment [8]. Colburn and Williams [6] found only three of 57 feet treated by the Ponseti method required extensive surgical correction. This pattern of good short-term results has been replicated in many recent studies [1, 2, 4, 6, 8, 9, 17, 19, 21].

Relapses are associated with deviating from the Ponseti brace protocol [4, 14, 23, 29]. However, strictly following the brace protocol seems to be the major challenge of the Ponseti method. Many authors report brace intolerance rates of 30% to 49% [1, 7, 11, 14, 21]. Our brace intolerance rate was as high as 44.3%. Brace protocol deviation might occur for a number of reasons. Possible reasons can include the feet either (1) not being fully corrected before being placed in a brace or (2) the development of a relapse despite brace wear making continued brace use impossible. Various authors have suggested modifying the brace to improve brace tolerance [5, 15, 22, 27]. In our study, late presenters were more brace-tolerant. Children who were late presenters failed initial treatment at other centers and the parents might have felt motivated to strictly follow the Ponseti brace protocol while undergoing treatment at our centers. Dobbs et al. [11] reported better brace tolerance when the parents had more than a high school education.

Not strictly following the Ponseti brace protocol does not always preclude a good result. For example, five of 11 brace-intolerant patients in the study of Lehman et al. [21] had a good result. In another study [1], 30 brace-intolerant patients required no additional surgery. In our study, 55% of the brace-intolerant patients required no additional surgery. However, we have no way to reliably predict which brace-intolerant patients are more or less likely to relapse. Therefore, physicians should strongly recommend that all patients use the brace according to the strict Ponseti protocol.

Several authors have studied whether the initial age at presentation impacts the results of treatment. Abdelgawad et al. [1] reported a 6.6% failure rate in patients who presented late for treatment (mean age, 36.3 weeks). Lehman et al. [21] reported failure in five feet that presented late for

treatment (mean age, 34 weeks). Other studies have suggested age at presentation does not affect the end result of treatment; 19% of patients were older than 6 months in the Morcuende et al. study [23], all 17 patients who presented for treatment after walking age achieved full correction in the Lourenco et al. study [22], and good results were achieved in our previous study [3] that consisted of babies whose average age was 5 months. We found no relation between the final ankle dorsiflexion or plantar flexion and the patients' age at presentation for treatment. Age at presentation was not associated with the need to perform additional surgery. Dobbs et al. [11] reported the prevalence of recurrence was not dependent on the age at presentation for treatment (even if older than 1 year), the initial severity of the deformity, or whether the baby had any previous treatment, mainly casting, before referral. However, in our study, babies who had undergone previous treatment before referral had advantages in terms of fewer cast changes needed and better initial scores.

The initial severity score did not predict the need for additional surgery. This was also reported by Haft et al. [14] and Lehman et al. [21]. Overall, we found that 20.7% of feet required TATT; this is similar to results by Ponseti et al. [27], but the need for TATT was statistically lower in patients who followed the Ponseti brace protocol.

Assessment of pediatric quality of life is challenging. A parent must often be used as a proxy [28]. Dobbs et al. [10] used the SF-36 questionnaire [24]. We used the previously validated Royce et al. [28] DSI to measure satisfaction outcomes. Our questionnaire showed major satisfaction of the parents with the results of treatment at average followup of 6.3 years. The parent questionnaire clearly shows parents' satisfaction with the Ponseti treatment is not dependent on physical parameters such as range of motion or appearance of the feet.

The Ponseti method is a simple and effective method for treating idiopathic clubfoot. Adhering to the Ponseti brace protocol is a major challenge of the method, and it has a direct effect on the success of treatment. In our series, deviating from the Ponseti brace protocol essentially doubled the need for additional surgery. Because we do not have reliable criteria to foresee which patients who deviate from the brace protocol will still achieve correction, all parents should be strongly encouraged and properly educated to use the brace according to the Ponseti protocol.

Most children with clubfoot have a normal quality of life and behave and function at a level that is not dissimilar to children born with normal feet. Although our data show the Ponseti method provides reproducible results with midterm followup, it will be important to continue following these cohorts into adolescence and adult life to affirm Ponseti's long-term studies.

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Appendix 1. Disease Specific Instrument (DSI) of Royce et al. [28]*

Factor	Question
Satisfaction	1. How satisfied are you with the status of your child's foot?
	2. How satisfied are you with the appearance of your child's foot?
	3. Rate the amount of teasing your child has related to the clubfoot.
	4. Rate problems finding shoes that fit your child.
	5. Rate problems finding shoes that your child likes.
Function	6. Does your child complain of pain in the foot that was operated on?
	7. Rate your child's limitations in the following activities: A. Walking B. Running
	8. How much does your child complain of pain during heavy exercise?
	9. How much does your child complain of pain during moderate exercise?

* Parents were asked to answer nine items on a scale from 1 to 4 points with 1 representing the best possible outcome and 4 the worst; one item asked about pain and was in a yes-or-no format; it was scaled so answering "no pain" was recorded as 1 point and answering that the patient experienced pain was recorded as 2 points; we translated the original DSI into the native language of each family.

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