

# Early Clubfoot Recurrence After Use of the Ponseti Method in a New Zealand Population

By Geoffrey F. Haft, MD, Cameron G. Walker, PhD, and Haemish A. Crawford, FRACS

*Investigation performed at Starship Children's Hospital, Auckland, New Zealand*

**Background:** Nonoperative treatment of idiopathic clubfoot has become increasingly accepted worldwide as the initial standard of care. The Ponseti method has become particularly popular as a result of published short and long-term success rates in North America. The purpose of the current study was to examine the early rate of clubfoot recurrence following the use of the Ponseti treatment method in a New Zealand population and to analyze patient characteristics to identify factors predictive of recurrence.

**Methods:** Fifty-one consecutive babies with a total of seventy-three clubfeet treated by the Ponseti technique were followed prospectively for a minimum of two years from the start of treatment. Recurrence, defined as the need for any subsequent operative treatment, was analyzed with respect to the severity at presentation, the time of presentation, the number of casts needed to obtain the initial correction, any family history of clubfoot, ethnicity, and the compliance with postcorrection abduction bracing. Recurrence was classified as minor, defined as requiring a tendon transfer or an Achilles tendon lengthening, or major, defined as requiring a full posterior or posteromedial surgical release to achieve a corrected plantigrade foot.

**Results:** Twenty-one (41%) of the fifty-one patients had a recurrence, which was major in twelve of them and minor in nine. The parents of twenty-six babies (51%) complied with the abduction bracing protocol, and only three of these children had a major recurrence. Compliance with abduction bracing was associated with the greatest risk reduction for recurrence (odds ratio, 0.2;  $p = 0.009$ ). When the parents had not complied with the bracing protocol, the patient had a five times greater chance of having a recurrence. With the numbers studied, no significant relationships were found between recurrence and the severity at presentation, the time of presentation, the number of casts needed to obtain correction, ethnicity, or a family history of clubfoot.

**Conclusions:** Compliance with the postcorrection abduction bracing protocol is crucial to avoid recurrence of a clubfoot deformity treated with the Ponseti method. When the parents comply with the bracing protocol, the Ponseti method is very effective at maintaining a correction, although minor recurrences are still common. When the parents do not comply with the bracing protocol, many major and minor recurrences should be expected.

**Level of Evidence:** Prognostic Level II. See Instructions to Authors for a complete description of levels of evidence.

Nonoperative correction is commonly accepted today as the standard initial treatment for idiopathic clubfoot. In a recent questionnaire sent to the membership of the Pediatric Orthopaedic Society of North America, 99% of the respondents indicated that they initially treat clubfoot with serial cast applications and 65% of the respondents

reported that they used the Ponseti technique<sup>1</sup>. This method has gained widespread popularity in recent years for several reasons. The Ponseti method is inexpensive and is easy to teach. The results have been good, with numerous published studies demonstrating short-term success with a minimal need for surgery. In a review of the results at an average of twenty-

**Disclosure:** The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical practice, or other charitable or nonprofit organization with which the authors, or a member of their immediate families, are affiliated or associated.



six months, Morcuende et al. reported that only 5% of 157 patients required surgery of any kind<sup>2</sup>. In another study, by Dobbs et al., three of fifty-one patients required surgery because of relapse at an average of twenty-six months<sup>3</sup>.

Clubfoot is a common problem in New Zealand. While the entire population of New Zealand is 4 million, 750,000 people claimed a Polynesian ethnic background in the 2001 census<sup>4</sup>. With an estimated incidence of 6.8 clubfeet per 1000 in Polynesian populations<sup>5</sup>, compared with one per 1000 in white European populations, pediatric orthopaedic surgeons in New Zealand encounter an unusually high number of clubfeet.

In recent decades in New Zealand, the definitive treatment of idiopathic clubfoot has been primarily surgical. Following several months of manipulation and strapping of the feet, most babies were treated with a complete posteromedial soft-tissue release. Disappointment with surgical results combined with the promising published outcomes of the Ponseti technique prompted us to explore other treatment options. After a year of training with Dr. Ponseti in Iowa City, Iowa, the senior author (H.A.C.) implemented this method at Starship Children's Hospital in Auckland, New Zealand.

We performed a retrospective study using prospectively gathered data to determine the rate of early recurrence of clubfoot deformity at a minimum of two years after the start of treatment with the Ponseti method in a New Zealand population. We analyzed the outcomes in an attempt to identify risk factors related to recurrence. Specifically, we analyzed recurrence with respect to severity at presentation, timing of presentation, number of casts needed to obtain correction, family history of clubfoot, and compliance with abduction bracing. We hypothesized that the genetics underlying the high incidence of clubfoot in the Polynesian population might translate to a more severe form of clubfoot and a higher rate of recurrence. Therefore, we also analyzed the recurrences with respect to ethnicity.

Previous studies have indicated that failure to comply with the abduction bracing protocol following cast treatment is the greatest risk factor predicting recurrence<sup>3,6</sup>. We hypothesized that compliance with abduction bracing is related to the severity of the clubfoot. In other words, we wondered whether families were unable to keep their babies in the abduction brace as a result of an intrinsically recalcitrant clubfoot. Thus, we also analyzed bracing compliance with respect to each of the above variables.

### Materials and Methods

At the time of referral to Starship Children's Hospital, a patient's family met with a dedicated clubfoot nurse coordinator and was given a choice between an operative treatment pathway and the nonoperative Ponseti pathway. The advantages and disadvantages of each method were discussed in detail. The importance of strict compliance with the abduction bracing protocol following cast treatment with the Ponseti technique was strongly emphasized. The family was given informational handouts describing each clinical pathway and was directed to appropriate web sites. Once they arrived at

a decision, the family contacted the nurse coordinator, who then scheduled the patient to be seen in the appropriate doctor's clinic. The senior author (H.A.C.) treated all of the patients with idiopathic clubfoot whose families chose the Ponseti pathway. The appropriate regional ethics committee approved the use of patient records for this study.

Between November 1999 and November 2003, the parents of fifty-five babies with a total of seventy-seven clubfeet chose the Ponseti technique. During the same period, the parents of eighty babies with a total of 115 clubfeet chose the operative pathway. Four babies, each with a unilateral clubfoot deformity, were lost to follow-up after the completion of the cast treatment. We believe that these patients probably left New Zealand because, with a national health care system, maintaining contact with families throughout the country is quite easy. After being unable to contact these four babies' families for several years, we excluded them from this analysis, leaving fifty-one babies with a total of seventy-three clubfeet. All data for the study were collected prospectively with use of a templated data sheet at each clinic visit.

At the time of presentation, the clubfoot deformities were graded with the validated 6-point scale of Pirani et al.<sup>7</sup>. One examiner (H.A.C.) graded all of the feet. Other information that was routinely obtained at the initial treatment session included the patient's age, any previous treatments, family history, and ethnicity. A positive family history was defined as any first or second-degree relative with a history of clubfoot. Ethnicity was classified as Polynesian or non-Polynesian. Polynesian ethnicity was defined as having parents or grandparents who were Maori natives of New Zealand or natives of any Polynesian island.

The clubfeet were treated at weekly intervals as described by Ponseti<sup>2,8,9</sup>. In an effort to strictly reproduce the Ponseti method as it is practiced at the University of Iowa, all cast and orthotic supplies were ordered from the University of Iowa's suppliers in the United States. At the completion of cast treatment, all babies were placed in an abduction orthosis to help prevent recurrence of the clubfoot deformity. Open-toed, high-top shoes were fitted by the clubfoot nurse coordinator and attached at shoulder width to a Denis Browne bar. The patient's family was emphatically instructed to ensure that the baby wore the brace full-time for three months, followed by nighttime and naptime wear until the age of two years. All families were given a card with the nurse coordinator's telephone number to schedule any necessary clinic visits to ensure compliance. Following fitting with braces and shoes, all patients were routinely scheduled to return to the clinic at one month, three months, six months, and thereafter at semiannual intervals.

At the time of follow-up visits, compliance with bracing was ascertained on the basis of the parents' report. Compliance with brace use at the two-year point was so infrequent that statistical comparisons were not possible. For the purposes of this review, compliance was defined as full-time brace use for three months followed by at least nine months of nighttime and naptime use. Anything less was considered non-

TABLE I Odds Ratios for Recurrence

Variable	Recurrence of Deformity		Odds Ratio (95% Confidence Interval)	P Value
	Yes	No		
Pirani score				
Mild	0	3	1.00	
Moderate	2	6	2.00 (0.07, 59.62)	0.69
Severe	19	21	5.43 (0.26, 115.50)	0.28
Cast changes				
1-5	14	24	0.5 (0.14, 1.79)	0.29
>5	7	6	1.00	
Weeks to 1st cast				
<3	15	24	0.625 (0.17, 2.30)	0.48
≥3	6	6	1.00	
Family history				
Yes	10	14	1.04 (0.34, 3.18)	0.95
No	11	16	1.00	
Ethnicity				
Polynesian	10	22	0.33 (0.10, 1.07)	0.07
Other	11	8	1.00	
Brace compliance				
Yes	6	20	0.2 (0.06, 0.67)	0.009
No	15	10	1.00	

compliance. When early recurrence was identified during the first year of follow-up, reapplication of casts with the Ponseti technique was recommended to the families. The goal of the repeat cast treatment was to return the recurred deformity to an overcorrected position identical to the foot position at the end of the primary cast treatment. For the purpose of the current study, recurrence was defined as any deformity requiring surgical intervention. Recurrences were categorized as minor or major. Minor recurrences were those requiring an extra-articular procedure such as repeat Achilles tenotomy, open Achilles tendon lengthening, or tibialis anterior transfer to the lateral cuneiform. Major recurrences were defined as those requiring more extensive intra-articular surgical intervention—either a posterior capsular release<sup>10</sup> or a complete posteromedial release<sup>11,12</sup>.

#### Statistical Analysis

The effects of the Pirani score, number of casts, age at presentation, family history, ethnicity, and brace compliance on the risk of recurrence of the deformity were analyzed with use of odds ratios. For the statistical analysis of the ordinal data, age at presentation was categorized as less than three weeks or greater than three weeks; the number of casts, as five or fewer, or more than five; and the Pirani score, as mild (0, 1, or 2 points), moderate (3 or 4 points), or severe (5 or 6 points). For patients with bilateral clubfoot, the mean of the two Pirani scores was used for statistical purposes. P values and 95% confidence intervals were calculated with a retrospective power analysis conducted at the 50% and 80% levels for any nonsig-

nificant results. Reference categories were indicated with an odds ratio of 1.00.

#### Results

The average duration of follow-up of the fifty-one patients (seventy-three clubfeet) was thirty-five months (range, twenty-four to sixty-five months). Thirty-three (65%) of the patients were male. Thirty-two patients (63%) were of Polynesian descent, and nineteen (37%) were white. Twenty-four patients (47%) had a family history of clubfoot. Six (32%) of the nineteen white babies and eighteen (56%) of the thirty-two Polynesian babies had a family history of clubfoot. The majority of the patients (forty; 78%) were classified as having a severe initial deformity according to the Pirani classification. The mean Pirani score was 4.6 points for the Polynesian babies and 5.0 points for the white babies. We tend to see patients, through referral, very early after birth, and none of the babies had had previous treatment of the clubfoot. Thirty-nine (76%) of the babies were seen and treated with the first cast within three weeks after birth. The mean age at the application of the first cast was fifteen days (range, five to forty-two days). Thirty-eight patients (75%) required five casts or fewer to achieve correction. The mean number of casts was 4.5 (range, three to ten). Only four patients did not have a percutaneous Achilles tenotomy, and each of them had a Pirani score of ≤4 points. Compliance with bracing was evenly split, with only twenty-six (51%) patients using the brace as prescribed for at least one year.

The deformity recurred in twenty-one patients (41%).

TABLE II Odds Ratios for Minor Recurrence

Variable	Recurrence of Deformity		Odds Ratio (95% Confidence Interval)	P Value
	Yes	No		
Pirani score				
Mild	0	3	1.00	
Moderate	2	6	2.00 (0.07, 59.62)	0.69
Severe	7	33	1.27 (0.06, 28.34)	0.88
Cast changes				
1-5	8	30	3.2 (0.36, 28.42)	0.34
>5	1	12	1.00	
Weeks to 1st cast				
<3	7	32	1.09 (0.19, 6.14)	0.92
≥3	2	10	1.00	
Family history				
Yes	5	19	1.51 (0.36, 6.44)	0.58
No	4	23	1.00	
Ethnicity				
Polynesian	5	27	0.69 (0.16, 2.99)	0.62
Other	4	15	1.00	
Brace compliance				
Yes	3	23	0.41 (0.09, 1.88)	0.25
No	6	19	1.00	

All patients with bilateral clubfoot and a recurrence had recurrence in both feet. All patients with bilateral clubfoot and a minor recurrence had a minor recurrence in both feet, and all patients with bilateral clubfoot and a major recurrence had a major recurrence in both feet. Every procedure was a primary surgical treatment for recurrence; no patient had secondary surgical procedures within the follow-up period. Early reapplication of a series of above-the-knee casts, as described in the Materials and Methods section, was attempted for five patients. The parents of each of these patients had been completely noncompliant with the bracing protocol following the initial cast treatment and continued to be so subsequent to the reapplication of the casts. In the end, the effort proved fruitless, with recurrences requiring major surgical correction developing in all five patients who had had repeat cast treatment. Nine patients (18%) had a minor recurrence and twelve (24%) had a major recurrence. The parents of only three of the twelve patients with a major recurrence had complied with the bracing protocol. These three patients were also the three of the twenty-six whose parents had complied with the bracing protocol but had a major recurrence. Recurrence was less common in Polynesian patients than in white patients. Ten (31%) of thirty-two Polynesian babies compared with eleven (58%) of nineteen white babies had a recurrence.

The procedures done in the nine patients with a minor recurrence included repeat percutaneous Achilles tendon lengthening (one), open Achilles tendon lengthening combined with a tibialis anterior tendon transfer (two), and an

isolated tibialis anterior tendon transfer (six). Of the twelve patients with a major recurrence, ten underwent a full posteromedial release and two had an isolated posterior release.

Odds ratios with respect to recurrence are reported in Tables I, II, and III. In Table I, the odds ratios for any recurrence are listed for the patient variables of interest. With the numbers studied, there was not a significant association between recurrent deformity and the initial Pirani score, number of cast changes, number of weeks until the first cast was applied, or family history. However, the risk of recurrence did have a significant relationship with compliance with the bracing protocol after the cast treatment. Patients whose parents were compliant had a five times lower risk of recurrence than did those with noncompliant parents ( $p = 0.009$ , odds ratio = 0.2). Polynesian patients, compared with whites, were found to have a three times lower risk of recurrence, but this comparison had weak significance ( $p = 0.07$ , odds ratio = 0.33).

In Tables II and III, the odds ratios for minor and major recurrences are listed for the variables of interest. With the numbers available after separating the recurrences into subcategories, no significant association was found between minor recurrences and any of the listed variables. However, major recurrences were found to have a significant association with compliance ( $p = 0.05$ , odds ratio = 0.23) and the number of cast changes ( $p = 0.03$ , odds ratio = 0.22) as well as a trend toward an association with ethnicity ( $p = 0.09$ , odds ratio = 0.32). With the numbers studied, no significant association was found between bracing compliance and any of the listed variables (Table IV).

TABLE III Odds Ratios for Major Recurrence

Variable	Recurrence of Deformity		Odds Ratio (95% Confidence Interval)	P Value
	Yes	No		
Pirani score				
Mild	0	3	1.00	
Moderate	0	8	0.38 (0.006, 23.52)	0.64
Severe	12	28	2.57 (0.12, 55.36)	0.55
Cast changes				
1-5	6	32	0.22 (0.05, 0.88)	0.03
>5	6	7	1.00	
Weeks to 1st cast				
<3	8	31	0.52 (0.12, 2.16)	0.36
≥3	4	8	1.00	
Family history				
Yes	5	19	0.75 (0.20, 2.78)	0.67
No	7	20	1.00	
Ethnicity				
Polynesian	5	27	0.32 (0.08, 1.21)	0.09
Other	7	12	1.00	
Brace compliance				
Yes	3	23	0.23 (0.05, 0.99)	0.05
No	9	16	1.00	

### Discussion

The Ponseti method is an effective means of obtaining excellent long-term results of treatment of congenital clubfoot deformity. However, it is important to understand that this method does not obviate the need for surgery in a sub-

stantial number of patients. In Ponseti's own long-term follow-up study, forty-eight (46%) of 104 clubfeet later required a tibialis anterior tendon transfer<sup>8</sup>. Of these forty-eight feet, forty-six required a variety of other procedures in addition to this tendon transfer. These patients then did well functionally

TABLE IV Odds Ratios for Brace Compliance

Variable	Brace Compliance		Odds Ratio (95% Confidence Interval)	P Value
	Yes	No		
Pirani score				
Mild	2	1	1.00	
Moderate	4	4	0.5 (0.03, 7.99)	0.62
Severe	20	20	0.5 (0.04, 5.97)	0.58
Cast changes				
1-5	20	18	1.30 (0.37, 4.58)	0.69
>5	6	7	1.00	
Weeks to 1st cast				
<3	20	19	1.05 (0.29, 3.84)	0.94
≥3	6	6	1.00	
Family history				
Yes	10	14	0.49 (0.16, 1.50)	0.21
No	16	11	1.00	
Ethnicity				
Polynesian	15	17	0.64 (0.20, 2.02)	0.45
Other	11	8	1.00	

for many years. In a thirty-year follow-up study of the same group of patients, who were by then young adults, Cooper and Dietz reported a 78% rate of good and excellent results, with no pain or functional limitation<sup>13</sup>.

In recent years, studies have indicated that the rate of surgery can be reduced by earlier identification of relapses, repeat application of casts, and improved compliance with abduction bracing. In several short-term follow-up studies, including Ponseti's most recent series, early surgical rates were reported to range from 3% to 6%<sup>2,3,6</sup>.

In the current study, we found a 41% rate of early recurrence following use of the Ponseti method. This is one of the highest reported recurrence rates in the literature, and with longer follow-up of these patients we anticipate that the rate will increase. Analysis of several variables with respect to recurrence showed a low rate of compliance with the abduction bracing protocol to be the most glaring reason for recurrence in this series. Only half of the patients' parents were compliant with bracing despite an emphasis on its importance and a clinic system designed to address bracing problems at the family's convenience. Because the compliance rate was based on parental report, the actual compliance rate may, in fact, have been <50%. Authors of previous studies have reported rates of noncompliance with bracing ranging from 10% to 41%<sup>2,3</sup>, and in the study by Dobbs et al.<sup>3</sup>, bracing compliance was found to be a significant predictor of recurrence ( $p < 0.00001$ ).

We had hypothesized that noncompliance with bracing is related to the severity of the clubfoot, which may make bracing intolerable as a result of a poor fit of the feet in the shoes, but this was not borne out by statistical analysis. Compliance with brace wear was also not significantly related to the Pirani score, number of casts, time until the first cast was applied, family history, or ethnicity.

One of the striking findings of this study was that the high rate of early recurrence cannot be attributed to the high proportion of clubfeet seen in patients of Polynesian descent in New Zealand. The Polynesian patients did not have a more severe or resistant deformity. Rather, they were less likely than the white patients to require surgery, a finding that suggests that, despite a higher incidence of clubfoot deformity among Polynesians, it is a less resistant deformity. It was not surprising, then, that the Polynesian babies also had a somewhat lower mean Pirani score (4.6 points) than the white babies (5.0 points). It is important to note a potential selection bias because the families chose between the Ponseti method and an operative pathway as the initial treatment. Pirani scores were not calculated for the patients whose parents chose the operative pathway, making it difficult to ensure that the two groups were similar in terms of clubfoot severity. However, the fraction of Polynesian patients was approximately 60% in both groups, perhaps reducing the risk of selection bias.

On the whole, we have had mixed success with the Ponseti method. Overall, 60% of patients have done well, with no surgical procedures required. Of the twenty-six patients who

completed the requisite course of treatment, defined as compliance with bracing for at least nine months following the completion of cast treatment, twenty-three have avoided a major operation. The results were more disappointing when there was noncompliance with the bracing protocol, with nine of twenty-six patients requiring a complete posterior or posteromedial release.

Future success of the Ponseti method will require improved compliance with the bracing protocol. Our current strategy to enhance compliance involves changes to the protocol. First, the importance of bracing is reinforced at every visit for cast treatment. This ensures that, on five or six occasions, the families hear directly from the orthopaedist that the clubfoot deformity will likely recur without brace use. In fact, the results of this study are used to emphasize the need for compliance with the bracing. Second, we will soon be switching to the Mitchell bracing shoe (MD Orthopaedics, Wayland, Iowa), recently introduced by Ponseti at the University of Iowa, in an effort to more consistently fit and hold the babies' feet without slippage. Third, enhanced surveillance of patients following removal of the last cast and fitting of the shoes and brace has been implemented. Patients are scheduled to return to the clinic on a weekly basis until the clubfoot team is certain that the baby is tolerating a properly fitted brace. In addition to reinforcing the importance of bracing to the families, these additional visits allow earlier identification of mild recurrences, making repeat cast treatment a more feasible, effective intervention. Finally, when a patient who is more than eighteen months of age has an early recurrence following noncompliance with bracing, strong consideration is given to reapplication of casts followed by immediate repeat Achilles tendon lengthening and tibialis anterior tendon transfer. This may help maintain the foot in a corrected position despite the absence of bracing in a noncompliant family. In the end, an early preemptive extra-articular procedure seems to us to be a worthwhile trade-off to avoid a major intra-articular procedure. ■

Geoffrey F. Haft, MD

Sioux Valley Clinic, Van Demark Orthopedic Specialists, 1210 West 18th Street, Suite G-01, Sioux Falls, SD 57104. E-mail address: haftg@mac.com

Cameron G. Walker, PhD

Department of Engineering Science, University of Auckland, Private Bag 92019, Auckland Mail Centre, Auckland 1142, New Zealand. E-mail address: cwalker@math.auckland.ac.nz

Haemish A. Crawford, FRACS

Department of Paediatric Orthopaedics, Starship Children's Hospital, Private Bag 92 024, Park Road, Auckland 5, New Zealand. E-mail address: hcrawford@akldbonesurg.co.nz



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