

# Ponseti treated idiopathic clubfoot - outcome predictive factors in the test of time: analysis of 500 feet followed for five to 20 years

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## Abstract

**Purpose** To investigate a set of risk factors on the outcome of Ponseti treated idiopathic clubfeet (ICF).

**Methods** This study was approved by the institutional review board. A retrospective analysis of prospectively gathered data over a 20-year period, at a single dedicated clubfoot clinic. Records of 333 consecutive infants with 500 ICF were analyzed. Initial Pirani score, number of casts, need for tenotomy, foot abduction brace compliance and functional score had been documented. The need for surgery after initial correction was the outcome measure. All children were followed by the same team throughout the study period. Descriptive statistics, chi-squared and multivariate analysis were performed.

**Results** In total, 82 children (24%) with 119 feet (23.8%) were operated on, with 95.1% of feet being operated up to the age of nine years. There was a significant correlation between the Pirani score at presentation and the number of surgical procedures (chi-squared = 79.32;  $p < 0.001$ ). Achilles tenotomy was done in 94.8% of patients. Pirani score of  $> 4.5$  before casting was strongly associated with increased surgical risk (odds ratio = 1.95). When six to eight cast changes were needed, surgical prospect was 2.9 more, increasing to 11.9 when nine or more casts were needed.

**Conclusion** Foot severity and number of cast changes were the strongest predictors for future surgery. Estimation of the risk of deformity recurrence after initial correction may help in tailoring a cost-effective personal treatment and follow-up

protocol. Personalized focused protocol will help patients and caregivers and will reduce expenses.

**Level of Evidence:** Level II - prognostic study.

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**Keywords:** idiopathic clubfoot; Ponseti; surgery; risk factors

## Introduction

Idiopathic clubfoot (ICF) is one of the most common congenital musculoskeletal deformities. Since the early 1980s, the Ponseti method has been the preferred treatment and gained worldwide popularity due to the high primary correction rate,<sup>1,2</sup> and includes an initial casting protocol +/- Achilles tenotomy followed by a bracing period.<sup>3</sup> The Ponseti method have been shown to be safe and effective, radically lowering the indication for extensive surgery.<sup>4</sup>

There is no consensus regarding the demarcation of correction and the ensuing relapsed foot affecting the rates of surgical procedures.<sup>5</sup> Reported initial correction rates are between 93% to 100%, while the relapse rate is 14% to 48%.<sup>6</sup> In a systematic review of relapse as a primary outcome, using data extracted for 10 500 feet from 84 studies, it has been found that the reported outcome varied significantly. Rate of recurrence ranged from 1.9% to 45%. Tibialis anterior tendon transfer (TATT) rate ranged from 0.6% to 48.8%, while joint invasive procedures rate ranged from 1.4% to 53.3%.<sup>5</sup>

Ponseti and Smoley<sup>7</sup> reported that relapses often occurred shortly after discontinuation of foot abduction brace (FAB). First relapse was noted at a mean age of 2.5 years, the second at 3.0 years while the third at 4.5 years. In a study on their long-term results, Laaveg and Ponseti (1980)<sup>8</sup> found that the mean duration of bracing increased from 20 months to 49.5 months but ages for first and subsequent relapses were similar indicating that the increase bracing time did not affect the relapse.

Both the rate of relapse and surgical intervention increased with length of follow-up.<sup>5,9</sup> Data from papers that reported follow-up less than four years compared

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with those with follow-up of four years or more showed that recurrence rate and surgical intervention was higher in the longer follow-up group.<sup>5</sup> Duration of follow-up was strongly correlated with the relapse rate and has been reported to occur as long as ten years later.<sup>9</sup>

Few studies followed patients for more than five years. Of 62 studies, only 11 (17.7%) reported on more than five years follow-up.<sup>5</sup> Few studies followed patients for at least eight years,<sup>9</sup> and of them, two were reports of Ponseti patients with a mean follow-up of more than eight years.<sup>8,10</sup> Cooper and Dietz<sup>10</sup> followed patients for a mean of 34 years and reported that 50.7% underwent joint sparing surgery.

Our main purpose was to evaluate what patient-related variables influence treatment results in the dimension of time and what subsequent factors may be predictive of the outcome.

The second objective was to determine the age group at which relapse and subsequent surgery commonly occurs. This information will help to better understand the prognosis and improve patient care. This may answer the question regarding the length of time ICF patients should be followed up.

In this study, a database of 333 children with 500 ICF treated with the Ponseti method prospectively collected from 23 July 2000 with a follow-up of five to 20 years, was analyzed. The outcome measure was defined as the need for any surgical intervention after initial correction.

## Material and methods

This is a retrospective evaluation of prospectively collected data of a consecutive series of children with ICF treated with the Ponseti method, followed in our dedicated clinic from 23 July 2000 to 31 May 2020.

All children were treated within the first 106 days of life. The minimum follow-up from the last cast was five years.

The exclusion criteria consisted of ICF children in whom tenotomy was done, in other centres.

At the first visit, the following parameters were recorded: gestational age, sex, birth weight, uni- or bilaterality, family history and age at presentation to our clinic. During treatment and follow-up, the following parameters were recorded: Pirani score at presentation and before each cast change, number of casts, need for tenotomy, compliance with the FAB protocol, functional evaluation and propensity for relapse.

### Outcome measures

Relapse was defined as reappearance of any component of the original deformity requiring treatment.

The primary outcome measure determinate was the need for any surgical treatment after the initial correction.

The surgical procedures included: joint sparing surgery such as tendo-Achilles lengthening, TATT, Steindler plantar fasciotomy and joint invasive surgery such as posterior release (PR) as well as bony procedures.

### Tenotomies

Tenotomies were performed in the outpatient clinic under local anaesthesia. In patients older than three months of age or in patients where a re-do tenotomy was indicated, it was done under general anaesthesia.

### Functional assessment

Functional evaluation was done according to Ezra et al,<sup>11</sup> a modification of the Laaveg and Ponseti method.<sup>8</sup> It was performed by a trained physiotherapist and comprised foot and ankle range of movement, heel position, appearance of forefoot, presence of cavus and/or supination, gait and running pattern, shoe type, pain or lack thereof and overall parent satisfaction. A score of 150 reflects optimal function.

### Bracing schedule and follow-up routine visits

Once correction was achieved, FAB was applied. In order to achieve accurate evaluation of the response to treatment and to enable early detection of non-compliance and/or relapse, patients were scheduled with multiple clinic visits.<sup>12</sup>

During each visit, the general health, developmental milestones as well as propensity for relapse were recorded while monitoring compliance to FAB wear. Following the bracing period, the children were seen in the clinic once in nine to 18 months. The younger children were seen more frequently. At each visit, functional evaluation was part of physical examination.

All the patients who were not seen in our clinic between 31 May 2019 and 31 May 2020 were contacted by the physiotherapist and invited to participate in a parent/guardian phone call survey. Following consent to participate, the following questions were asked and the answers were recorded.

Since your last visit to our clinic:

- |  |     |
|--|-----|
| 1) Did your child continue follow-up in another clinic?  | Y/N |
| 2) Did your child have an operation in another hospital? | Y/N |
| 3) Was the operation on one or both feet?                | 1/2 |

### Statistical analysis

Differences in demographic and health variables were tested for statistical significance with the chi-squared test for categorical variables and Student's *t*-test for continued variables. To find correlation between Pirani scoring, treatment variables (casts number, functional scoring and compliance with the FAB) and surgery, we used Pearson

correlation. The logistic regression model was applied to estimate risk for surgery (odds ratio (OR)) with 95% confidence intervals (CI). For all analysis  $p < 0.05$  was considered statistically significant. The analysis was carried out using SPSS version 25 (SPSS Inc., Chicago, Illinois).

## Results

### *Demographic data (patients and follow-up)*

We studied prospectively collected data of consecutive group of patients with ICF. During the study period, 333 patients were taken care of. Of them, 238 were male (71.5%) and 95 were female (28.5%).

Of 500 clubfeet treated, 166 were with unilateral involvement and 167 with bilateral involvement.

A total of 252 children (75.5%) with 380 club feet (76%) were first seen in our hospital and started the casting protocol at a mean age of eight days (SD 7.6; 0 to 63), while 81 (24.3%) with 120 affected feet (24%) had started casting in another institution and joined our programme thereafter, at a mean age of 27.1 days (SD 22.8; 2 to 106). Casting continued in all but four children (six feet), who started casting in another hospital and underwent percutaneous tenotomy on their first visit.

The oldest child included in the study was born on 23 July 2000 with the youngest being born on 26 March 2015. The last office visit recorded was on 24 May 2020.

While 208 children (62.4%) had attended the club-foot clinic within 12 months before the data collection ended, the others were included in the parent/guardian phone call survey. Of the 125 phone calls made, 117 were answered (93%). We were unable to reach eight patients (6.4%). None of the 117 children had surgery in another hospital. Mean follow-up was 10.7 years (SD 4.2; 5 to 20).

### *Pirani score*

The mean Pirani score at presentation was 4.7 (SD 1.20; 1 to 6) including those patients who start treatment in another institution.

Children with a score below 2.5 (36 feet) had no surgery. Of the children with a score between 2.5 and 4.5 (180 feet), 13.9% were operated on (25 feet) while of those whose Pirani score was  $> 4.5$  (276 feet), 34.1% were operated on (94 feet).

There was a significant correlation between Pirani score at presentation and the number of surgical procedures performed (chi-squared = 36.56;  $p < 0.001$ ).

### *Casting*

The mean number of cast changes before tenotomy was 6.01 (SD 1.91; 0 to 12) including children who started casting in another hospital; 227 feet needed five cast changes

or less (45%), six to eight casts were done on 208 feet (41.6%), while 65 feet (13%) needed nine casts or more to achieve correction.

In 15 children, casting continued following the tenotomy, ranging between one to six casts with a mean of 0.5 changes.

In children requiring five casts or less, 21 feet (10%) were operated on. In the group of six to eight casts, 57 feet (26.9%) were operated on, whilst of those in the group with nine casts and above, 41 feet (63.1%) were operated on.

The number of casts needed to achieve correction strongly correlated with the number of surgical interventions performed (chi-squared = 79.32;  $p < 0.001$ ).

### *Achilles tenotomy*

A child with  $< 10^\circ$  of ankle dorsiflexion or emptiness at the heel pad was offered the Achilles tenotomy. Of 500 feet, 474 (94.8%) underwent tenotomy, while 26 feet (5.2%) did not.

### *FAB compliance*

Mean of recorded FAB compliance reported by parents was 38.4 months (SD 11.69; 3 to 51.5); most of our group reported adherence to the FAB recommendation (Table 1). No correlation was found between compliance with FAB usage and the number of operations.

### *Surgery*

Out of 333 participants, 82 children were operated on (24.6%). Of them, one foot was operated on in 45 children (13.5%) while 37 children underwent bilateral surgery (11.41%). All bilateral procedures were done in one sitting except for one child that had PR at the age of two years on one side and PR + TATT at the age of seven years on the other. Of 500 feet, 119 feet were operated on (23.8%). The mean age at surgery was 5.6 years (SD 2.3; 0.6 to 12.6) while 95.1% of feet were operated on up to the age of nine years, of them, 85.3% were carried out between three and nine years of age (Fig 1). Infrequently, in young patients, preoperative serial casting was performed. There was no statistically significant difference between rate of surgery in unilateral (21% of 166 children) or bilateral affection (25% of 167 children).

The youngest child to undergo a re-do tenotomy was six months old. Joint sparing surgery was done on 31 feet (26.6%) whereas joint invasive procedures were done on 88 feet (73.3%) (Table 2). Bony procedures performed in the older children included lateral column shortening, medial column lengthening and calcaneal osteotomy.

Six children were operated on twice, four had unilateral re-do tenotomy with an additional surgery, PR + TATT, performed later. Two children had PR as their first inter-

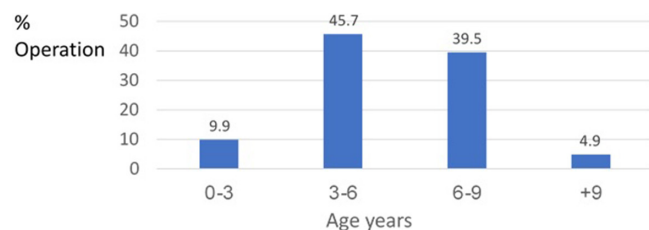
**Table 1** Foot abduction brace compliance and rate of surgery

| Compliance  | Children | Percentage, % | Children operated | Operation, % |
|-------------|----------|---------------|-------------------|--------------|
| First year  | 8        | 2.4           | 2                 | 25           |
| Second year | 20       | 6             | 5                 | 25           |
| Third year  | 93       | 27.9          | 21                | 22.58        |
| Fourth year | 212      | 63.7          | 54                | 25.47        |
| Total       | 333      | 100           | 82                | 24.62        |

**Table 2** Surgical interventions according to type

| Surgery        | Re-do Achilles tenotomy | TATT | PR/PMLR | PR and TATT | TATT +TAL + bony procedure |
|----------------|-------------------------|------|---------|-------------|----------------------------|
| Number of feet | 5                       | 26   | 7       | 75          | 6                          |
| Percentage     | 4.1                     | 21.6 | 5.8     | 62.5        | 5                          |

TATT, tibialis anterior tendon transfer; PR, posterior release; PMLR, posterior medial lateral release; TAL, tendon Achilles lengthening



**Fig. 1** Distribution of operations according to the age of the child

vention with a TATT added at a later stage (one bilateral and one unilateral).

*Functional assessment*

The average functional score of the operated children was 96.1 out of 150 (sD 12.9; 60 to 130). At last evaluation, the mean improved to 130.1 (sD 15.6; 80 to 150). There was a significant improvement of the score following surgery (t = 20.0; p < 0.001). The mean functional score of non-operated children was 136.8 (sD 10.3; 100 to 150).

*Statistical analysis of variables*

Pearson correlation between study variables is summarized in Table 3.

The age of the child at the beginning of treatment did not correlate with rate of surgery or functional score. The initial Pirani score positively correlated with operation rate, number of casts, functional score and FAB compliance (p < 0.05). Number of casts was significantly correlated with rate of surgery, functional score and FAB compliance (p < 0.05). There was no correlation between FAB compliance and rate of surgery or functional score.

The results of multivariate logistic regression analysis are shown in Table 4. ORs along with 95% CIs and p-values were calculated. To estimate the risk for surgery (OR)

the following categories were used: sex, age at first casting, Pirani score (0 to 4.5, > 4.5), number of casts (6 to 8, ≥ 9) and compliance with FAB usage.

Sex, compliance and age of the child were not associated with the increased risk for surgery, whilst a Pirani score of > 4.5 before casting was strongly associated with increased risk surgery (OR = 1.95). Number of casts was a significant factor for recurrence. Children who underwent six to eight cast changes had a 2.9 higher probability of being operated on when compared with those with five casts or less. The probability increased to 11.9 when nine or more casts were needed to achieve correction.

**Discussion**

The main goal of the Ponseti protocol is to regain and maintain a plantigrade pain-free, highly functional foot.

Due to a wide range of reported outcomes,<sup>13</sup> it was decided to use surgery rate as a primary outcome measure enabling us to unequivocally and consistently compare our study with others.

We demonstrated a substantial rate of good results when compared with those reported<sup>5,9</sup> especially for intermediate or long-term studies.<sup>7,8,10</sup> Out of our 333 children, followed for a mean of 10.7 years, 82 children (24.6%), 119 feet (23.8%) were operated on.

Ponseti and Smoley<sup>7</sup> in their five to 12 years follow-up reported a 56% relapse rate and 42% surgery. In a group followed for an average of 18.4 years, Laaveg and Ponseti<sup>8</sup> reported a 47% relapse rate with 46% having had TATT. In their study, relapse rate and surgery rate were quite similar. Recently, Siebert et al<sup>14</sup> reported on 122 of 336 patients (36.3%) who underwent surgery. Between two and five years of age, 79 patients (23%) with 104 feet (20.6%) were operated on, while at age above five years, with 65 feet (16.9%), 53 patients (20.1%) underwent surgical correction. In our study, the mean age of surgery was 5.6 years with 95.1% of feet being operated on up to the age of nine years. It is evident that the reported rate of recurrence increased with follow-up of over four years.<sup>5,9</sup> We would recommend that reports on outcome should have a minimum follow-up of five years. We advise that patients with good clinical outcome be followed until the age of ten years.

While many factors affect the end results, in many studies, different subgroups are too small in numbers which may preclude the ability to analyze them and to recognize the significance of some variables. Overall, the homogeneity, the size of the subgroup and the length of follow-up enabled us to review previously reported risk factors for reoccurrence and surgery. Predicting treatment resistance and eventually the need for surgery is one of the main issues when considering the Ponseti treatment.

**Table 3** Pearson correlation between the study variables

|                  | Age treatment | Pirani score | Cast number | Operation rate | FAB compliance | Functional score |
|------------------|---------------|--------------|-------------|----------------|----------------|------------------|
| Age treatment    | 1             | -0.249*      | -0.284*     | -0.083         | -0.081         | 0.078            |
| Pirani score     | -0.249*       | 1            | 0.507*      | 0.242*         | 0.301*         | -0.276*          |
| Cast number      | -0.284*       | 0.507*       | 1           | 0.353*         | 0.122*         | -0.309*          |
| Operation rate   | -0.083        | 0.242*       | 0.353*      | 1              | 0.026          | -0.842*          |
| FAB compliance   | -0.081        | 0.301*       | 0.122*      | 0.026          | 1              | 0.068            |
| Functional score | 0.078         | -0.276*      | -0.309*     | -0.842*        | 0.068          | 1                |

\*p < 0.05

FAB, foot abduction brace

**Table 4** Multivariate logistic regression analysis

|                                | Odds ratio | 95% confidence interval | p-value  |
|--------------------------------|------------|-------------------------|----------|
| Sex (female = 1)               | 0.76       | 0.45-1.29               | 0.355    |
| Age at first cast              | 0.99       | 0.99-1.01               | 0.904    |
| Pirani (reference ≤ 4.5) > 4.5 | 1.95       | 1.09-3.47               | 0.023*   |
| Cast (reference < 5): 6 to 8   | 2.95       | 1.66-5.24               | < 0.001* |
| Cast (reference < 5): ≥ 9      | 11.96      | 5.67-25.22              | < 0.001* |
| Compliance in mths             | 0.98       | 0.96-1.00               | 0.08     |

\*p < 0.05

Recognition and awareness of risk factors associated with recurrence can direct and provide more attention to individualization of protocol. Patients more likely to need surgery will have a different, stricter protocol. Early and late risk factors that can be used to predict increased risk for surgery have been suggested.<sup>15</sup> Some suggest that female patients were more at risk, while others<sup>16</sup> like us, did not document any sex-related differences. The severity of unilateral and bilateral ICF was discussed by Gray et al.<sup>17</sup> They concluded that bilateral and unilateral clubfeet present with different severity. We found that the difference in the rate of surgery was insignificant.

Severity score before casting, and the duration of casting, were shown to be significant predictors of recurrence.<sup>18-20</sup> In our study, the initial Pirani score positively correlated with operation rate and number of casts needed for correction. Furthermore, the number of casts strongly correlated with the number of surgical procedures performed. Interestingly, foot length at the initiation of Ponseti protocol<sup>21</sup> was significantly correlated both to initial Pirani score and to the number of casts. Severity score, foot length and number of cast changes can be used as early predictors of increased risk for surgery.

Correction of the equinus deformity is of utmost importance to prevent relapse. Residual equinus following tenotomy is associated with high rate of recurrence and need for surgery.<sup>22</sup> In a POSNA (Pediatric Orthopaedic Society of North America) members survey, 81% of patients were estimated to require tenotomy.<sup>2</sup> In a systematic review, the mean tenotomy performed was 75.8%.<sup>13</sup> We strongly believe that the equinus component is the most difficult to correct with casting and requires tenotomy in the majority of patients. Hosseinzadeh et al<sup>22</sup> have

shown the predictive value of residual equinus for future surgery.

The single most important factor associated with recurrence was shown to be noncompliance with FAB usage.<sup>3,15,20</sup> Parent-reported FAB compliance does not accurately reflect the true adequate adherence to FAB use. There was a significant decline in FAB wear once the period was monitored by sensors.<sup>23</sup> An up to ten-times greater relapse rate has been observed in children of non-compliant families.<sup>3</sup> The duration of FAB treatment was suggested to be most influential on the rate of surgery.<sup>12</sup> Our long-term data do not support the idea. It was shown by Laaveg and Ponseti<sup>8</sup> that increased bracing period did not affect the relapse ages. In our study, a similar rate of operation was seen regardless of the duration of FAB usage. We are aware that the majority of our patients reported three to four years of FAB usage and it may affect our conclusions. The heterogeneity in the initial severity score of the different subgroups may add bias to the analysis. In other words, low Pirani will do well after shorter FAB period, while higher Pirani score patients needs a much longer FAB period. Our surgical approach was limited to the correction of any deformity component that recurred either as isolated or in any combination. Our most common combination was TATT and PR (Table 2). Osseous procedures were rare. Most of our patients were operated on up to the age of nine years. This is in accordance with the reports showing that relapses have been reported as late as ten years,<sup>9</sup> and implying that patients should be followed up at least until late childhood.

There are several limitations to our study. Although it is retrospective in nature, the same team has been working together for 20 years. Therefore, the principles of treatment and decision-making were the same. The value of parent-reported FAB compliance is limited.

In conclusion, the efficacy of our protocol can be evaluated by the relatively low rate of operations. The prevalence of recurrence and surgery is dependent on the initial severity score, number of casts and possibly a very high rate of tenotomies performed. These parameters can be used to individualize/personalize the treatment protocol in terms of length of FAB usage and follow-up period needed.

### Conclusion

1. Foot severity (Pirani score) and the number of cast changes were the strongest predictors of future surgery following initial correction of idiopathic clubfeet treated with the Ponseti protocol.
2. 95% of feet were operated up to the age of 9 years, justifying follow-up until late childhood.
3. Estimation of the risk of deformity recurrence after initial correction may help tailoring a personalized focused protocol for the FAB usage and length of follow-up.

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### COMPLIANCE WITH ETHICAL STANDARDS

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

#### OA LICENCE TEXT

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#### ETHICAL STATEMENT

**Ethical approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent:** Informed consent was obtained from all individual participants who were included in the phone interview.

#### ICMJE CONFLICT OF INTEREST STATEMENT

All authors declare that they have no conflict of interest.

#### AUTHOR CONTRIBUTIONS

YH: Designed the study, extracted and analyzed the data, conducted statistical analysis, edited and approved the final manuscript

AY: Collected and assimilated the data, conducted the phone call survey

MK: Collected and assimilated the data

ES: Approved the final manuscript

SW: Conceptualized and designed the study, coordinated the study, interpreted the data, produced and revised the final manuscript

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