ORIGINAL ARTICLE

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Factors affecting adherence with foot abduction orthosis following Ponseti method

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Objective: The Ponseti method is an effective protocol for treatment of congenital idiopathic clubfoot. Foot abduction orthosis (FAO) is sometimes necessary to preserve the correction achieved with the serial casting and tenotomy. Patient and family adherence to brace use is a common problem, as nonadherence is directly related to relapse. The aim of this study was to investigate patient and parent characteristics related to relapse.

Methods: One hundred and fifty-three children who were treated with Ponseti method (mean age: 44.62 months; range: 16–104 months) and their parents were included in the study. Thirty-one patients experienced relapse at an average follow-up of 32 months (range: 6–84 months) since beginning orthosis use. At the time of follow-up visits, parents were questioned about brace use adherence. Satisfaction with Symptoms Scale in the American Academy of Orthopaedic Surgeons (AAOS) Pediatric Outcomes Data Collection Instrument (PODCI) was used.

Results: Difficulties with brace use were encountered in 122 children. Children of parents who were satisfied with the treatment had relapse at an average of 69.13±2.64 months, and those of parents who were not satisfied at 32.83±7.51 months. The most important variable was the child's adaptation to the orthosis treatment without an adverse reaction. Additionally, better compliance was found in children with higher-educated parents.

Conclusion: Non-compliance with periods of intolerance is very common for children during orthosis treatment. Parents' coping strategies are very important to avoid relapses. It is important to develop strategies to guide parents.

Keywords: Adherence; clubfoot; foot abduction orthosis; Ponseti method.

Level of Evidence: Level IV Therapeutic Study

Congenital idiopathic clubfoot is a common and complex deformity. Until recently, it was generally agreed upon that most clubfeet needed extensive surgery in the first year of life, as they were considered resistant to conservative treatment. However, Dr. Ponseti's efforts, along with worldwide reports of success, increased interest in the conservative treatment. Today, most surgeons are in agreement that nonoperative treatment–whether the Ponseti method or the Bensahel method–provides good correction of idiopathic clubfeet.

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The Ponseti method includes gentle manipulations, weekly toe-to-groin casts, and percutaneous Achilles tenotomy when there is persistent equinus. The cavus is reduced by supinating the forefoot in order to achieve normal alignment with the hindfoot. The talus is stabilized, and the foot is abducted in supination under it. In cases where there is residual equinus after the foot is brought to approximately 60–70° of abduction and the heel varus is corrected, a percutaneous Achilles tenotomy is indicated. A final cast is applied for 3 weeks. Excellent rates of correction are reported with this treatment protocol. After the deformity is corrected, a period of bracing is required to maintain the correction and prevent relapse. A brace consisting of open-toe high-top straight-last shoes attached to a bar of shoulder width is used to position the corrected feet in 60–70° of abduction and 10° of dorsiflexion. The brace is used full-time for the first 3 months and at night until the child is 3–4 years old.

Although foot abduction orthosis (FAO) is very effective, adherence to it can be problematic. Adherence is defined as full-time FAO use for 3 months and part-time use thereafter. Considering the duration required, the bracing period can be very demanding. Relapse is reported to occur in more than 80% of cases in nonadherent families, whereas in only 6% of cases in adherent families. Inability to adhere with the orthosis in the first 9 months is defined as nonadherence. Although relapse may be influenced by other factors, adherence has been reported as the most significant factor related to relapse. Other reported factors are parent education of a high school level or less, annual income below $20.000, and ethnic factors.[1,2] Thus, individualization of the treatment method and follow-up protocols were suggested.[3] Additionally, failure to understand the importance of the brace, insufficient instructions, skin problems, transport problems, and lack of communication and support at home lead to nonadherence.[2,4] Dobbs et al. stated that psychosocial factors such as the stigma associated with prolonged use of an orthosis may affect adherence.[1] Morgenstein et al. recently stated that adherence in the first 2 months is directly related to overall adherence.[5]

Alternatives to foot abduction brace, with its theoretical advantage of more comfortable use, are considered unacceptable in the Ponseti method. Family support for adherence in the bracing period and a diligent follow-up bracing program are currently relied upon to avoid relapses. Despite the fact that brace use is very effective, the bracing period is a long and potentially demanding phase of treatment. The authors frequently observed problems with the use of the orthosis, which might have been related to relapse. A PubMed search revealed no studies focusing on the problems encountered by parents during the bracing period.

We hypothesized that some parent and patient characteristics could be related to relapse and that the findings could be used to improve adherence and decrease the rate of relapse in the early period after using the Ponseti method for the treatment of idiopathic clubfeet. It was not the aim of this study to objectively assess the outcome of the Ponseti method. However, objective data was used to define relapses determined clinically by the treating surgeon. Additionally, parent satisfaction with the achieved correction was evaluated.

Patients and methods

The patient population in this study was constituted of 153 children with 226 idiopathic congenital clubfeet treated with the Ponseti method. Mean age at the start of treatment was 2.23 months (range: 3 days to 14 months). There were 121 males and 32 females. Involvement was bilateral in 73 and unilateral in 80 patients. At the time of the study, mean age was 44.62 months (range: 16–104 months). Thirty-one of 153 patients (20%) experienced relapse at an average follow-up of 32 months (range: 6–84 months) after beginning orthosis use. The rate of joint release surgery was 2.6% (4 feet of 4 patients). At the time of follow-up visits, parents were questioned about adherence with bracing. Besides the 2 treating surgeons, the other authors of the present study were available to assist parents when answering the questions. The utmost attention was paid to avoid imposing an answer on the parents, and assistance was limited to helping parents complete the forms.

We used the Satisfaction with Symptoms Scale from the American Academy of Orthopaedic Surgeons (AAOS) Pediatric Outcomes Data Collection Instrument (PODCI) to measure the parents' satisfaction with the current condition of the foot. This scale is intended to measure the parents' long-term acceptance of the condition.

Other questions were designed to evaluate parents' level of trust in the doctor's comments regarding the necessity of the orthosis to help prevent relapse, level of parent information about the treatment, level of parent education, child's tolerance of orthosis, discontinuance of orthosis, and parents' use of coping strategies to accustom the child to the orthosis. Additionally, parents were asked what they felt the reason was in cases where there were problems using the brace. The questions designed for this study are listed in the questionnaire in Table 1.

Table 1. The questionnarie.

Q1	Do you believe that brace use will prevent relapse of your child's foot?	• Definitely • I believe • Not sure • A little bit • I do not believe so
Q2	Do you have any information about the treatment your child is receiving?	• I have researched it in detail • Information received from the treating physician and others • Information from the treating physician only
Q3	What is the level of your education?	• University • High school • Middle school • Primary school • None
Q4	Did your child show any negative reactions to the brace?	• Always • In the beginning • Over time • Sometimes • Never
Q5	Did your child discontinue wearing the brace?	• Completely • In the beginning • Over time • Sometimes • Never
Q6	What did you do when your child was adjusting to the brace?	• Distracted him/her with play • Taught him/her to kick both feet together • I remained committed to use of the brace • Removed the brace when he/she was irritated • Discontinued use of the brace
Q7	If your child had any problems with the brace, what do you feel the reason was?	• The fault of the child • Partly due to the child, partly due to the brace • Completely due to the brace • I do not know • Other (please explain)

The questionnaire included the 7 questions above. The parents were asked to answer the questions as best they could. They were given additional space for any comments they may have. Questions 7 was separately evaluated because it was a dependent question. For statistical analysis, the other answers were converted to numbers, grouping them as shown in the table.

Compliance with the orthosis was defined as full-time brace use for 3 months and during sleep for 9 months or more, as suggested by Haft et al.[6] Relapse was defined as a clubfoot requiring retreatment, as determined by the treating physician's clinical examination. Indications for retreatment were an abduction and extension range that is not compatible with bracing (<60° of abduction and <10–15° of dorsiflexion) during the bracing period of treatment. Thereafter, <15° degrees of dorsiflexion, hindfoot varus, or forefoot adduction not reducible beyond neutral by gentle manipulation were indications for retreatment.

Non-relapsing patients were evaluated for adherence. Variables that have a positive effect on adherence were assessed with logistic regression analysis (Questions 2, 3, 5, 6). Univariate logistic regression analysis was used for assessing patient characteristics and demographic data. Unadjusted odds ratios, (ORs) along with 95% confidence intervals (CIs), and p values were calculated.

For the purpose of statistical analysis, answers to 5 questions were grouped as mentioned in Table 1. Kaplan-Meier survival analysis was performed to relate these parameters to relapse as a measure of objective outcome. Relapse-free survival times were calculated

Table 2. Statistical analysis of cases, relating several characteristics identified by answers to relapses.

	Relapse/n	Relapse-free survival time Mean time±SE (95% CI)	Log-rank test; df p
Total	31/153	67.56±2.64 (62.38; 72.73)	–
Parent satisfaction			
Good	26/141	69.13±2.64 (63.15–74.30)	5.41; 1
Not Good	5/12	32.83±7.51 (18.12–47.54)	=0.02
Belief in necessity of brace			
Yes	24/131	68.93±2.79 (63.47–74.39)	1.99; 1
No	7/22	58.99±7.78 (43.74–74.25)	=0.1579
Level of information about treatment			
High	2/20	64.71±4.78 (55.35–74.08)	1.62; 1
Standard	29/133	66.66±2.85 (61.08–72.24)	=0.2033
Level of education of parents			
University	10/67	61.68±3.02 (55.76–67.60)	1.81; 1
High school or less	21/86	64.64±3.67 (57.45–71.84)	=0.1791
Any intolerance to brace			
Yes	31/122	63.25±3.22 (56.93–69.58)	9.34; 1
No	0/31	N/A (no relapses)	=0.0022
Discontinuance of brace			
Yes	24/76	50.70±3.60 (4.65–57.76)	11.79; 1
No	7/77	76.48±2.72 (71.15–81.81)	=0.0006
Use of coping strategies			
Yes	17/117	71.98±2.70 (66.68–77.28)	10.89; 1
No	14/36	46.12±5.40 (35.54–56.71)	=0.001

n: Total number of cases; SE: Standard error; CI: Confidence interval; df: Degrees of freedom.

as the time from the completion of casting to the final follow-up in patients without relapse. In children who experienced relapse, time from the completion of casting to the diagnosis of relapse was designated as relapse-free survival time. Log-rank test was used for comparing the equality of survival distributions. Statistical Package for the Social Sciences (SPSS) software version 18.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Results

Parents of 141 children (92%) were satisfied with the correction. Difficulties with the brace were encountered in 122 children (80%). Of 93 parents, 29 attributed these difficulties to the child's temper, 28 to the brace, and 36 to both the child and the brace. Fifteen parents reported that they felt the brace restricted the child's movement and hence was not tolerated. Four parents reported that the child's feet easily moved out of the shoes. Three parents reported that the children had sleeping problems with the brace on. Two parents reported that the child struck itself near and on the head with the brace. Statistical analysis of answers to the other questions revealed that difficulties with tolerance, discontinuance, and not using coping strategies were found to have a significant effect on the risk of relapse. However, other parent factors (belief in benefits of brace, level of information about treatment, and level of education) were not related to the risk of relapse.

Children of parents who were satisfied with the treatment experienced relapse at 69.13±2.64 months (range: 63.15–74.30 months), whereas children of parents who were not satisfied experienced relapse at 32.83±7.51 months (range: 18.12–47.54 months) of brace use (Table 2). Clinical consistency was evaluated. Questions 1 (belief), 3 (education), 5 (discontinuing the brace), and 6 (coping strategies) had statistically significant importance on the results. Question 4 was not evaluated, as no parents answered "never," and it had no statistical expression. Significant variables were assessed with logistic regression analysis. At the end of the analysis, the only variable which was still significant was the child's tolerance to the orthosis (p=0.0001 for Question 5). Children who tolerated the orthosis experienced relapse at 76.48±2.72 months (range: 71.15–81.81 months). OR of the child and CI were found to be 18.9 and 5.1–70.2, respectively. The most important variable was the child's

Table 3. Characteristics related to compliance.

	Compliance		Total	p
	Noncompliant	Compliant		
Believes the brace will prevent relapse				
Yes	59	46	105	=0.001
Not sure or No	17	0	17	
Level of information about treatment				
From treating doctor only	70	46	116	=0.051
From additional sources	6	0	6	
Level of education of parents				
University	13	16	29	=0.026
High school or less	63	30	93	
Intolerance to brace				
Always	25	3	28	*
Periods of discontinuance	51	43	94	<0.001
Use of coping strategies				
Yes	44	46	90	<0.0001
No	32	0	32	
Total number of patients	76	46	122	

*Pearson chi-squared test, Asympt. Sig (2-sided). Others: Fisher's exact test (1-sided).

adaptation to the orthosis treatment without an adverse reaction. Non-relapsing patient characteristics related to compliance are listed in Table 3.

Discussion

Although the meticulous method of serial manipulations and cast application as outlined by Ponseti is essential to obtain initial correction of the idiopathic clubfoot deformity, our data demonstrated that noncompliance with the use of the orthosis is the primary risk factor for recurrent deformity. Adherence with bracing is a major factor required for successful treatment with this method, as indicated by our nonadherence rate of 41%.[1]

The successful use of the Ponseti technique to correct clubfoot deformity has been demonstrated in several centers worldwide,[1,2,4,7–11] and satisfactory long-term function of feet corrected using this technique has been demonstrated.[7] Although initial correction of the deformity can be reliably achieved, the greater challenge in the successful use of the Ponseti method is the prevention of relapse. The key to maintaining initial correction of the foot is educating and encouraging parents in the proper use of the post-corrective brace.[3] Our data demonstrated that nonadherent patients had a significantly higher recurrence rate of 32% (24/76), compared to adherent patients with a recurrence rate of 9% (7/77) (Table 2). Adherence with bracing is a major factor required for successful treatment with this method. Level of education of parents, belief in necessity of the brace, and level of information about treatment have a direct effect on compliance; therefore, these variables have an indirect effect on incidence of relapse (Tables 2 and 3). Furthermore, our data reveal that parent satisfaction, intolerance to brace, and use of coping strategies have a direct effect on relapse.

Brace compliance is the most important factor to avoid recurrence following Ponseti treatment for pes equinovarus (PEV).[1,2,6,10,12] Parent education at the high-school level or above, and instructing parents about the time commitment required and importance of compliance are significantly important to prevent recurrence.[1] In addition, we concluded that children with higher-educated parents have better compliance. The positive effect of education is possibly related to better communication and comprehension skills of the parents. Morin et al. suggested that improving the manner in which doctors communicate with parents is directly related to recurrence rate.[13]

Several factors may play a role in influencing family acceptance of brace treatment. Parents frequently report that bracing makes their child irritable and limits his or her movements.[2] In our study, 15 parents reported that they felt the brace restricted the child's movement and hence was not tolerated. Often, when an infant cries, the parents remove the brace. It is difficult to distinguish between a cry of pain and one of annoyance, and many parents assume the former. Frequent removal of the brace can promote relapse of the deformity, which may make it more difficult to properly apply the brace, which in turn

may lead to increased discomfort and further protest from the infant, thereby creating a cycle which results in recurrence.

Success of the Ponseti method is dependent on the parents' ability to consistently and properly apply the post-corrective brace.[3] Thus, it is important to develop strategies to ensure their cooperation. It is crucial to obtain full correction of the deformity before placing the infant in the FAO.

The brace should be inspected for signs of appropriate wear. Noonan observed that a slight narrowing of the ankle represents the "hallmark of a compliant family."[14] Dobbs reasoned that noncompliance may reflect other intrinsic factors related to recurrence, such as an already recurring foot which cannot be accommodated adequately or comfortably in the brace.[1] In our study, 4 parents reported that child's feet moved easily out of the shoes, resulting in an early recurrence of the deformity.

One of the more common reasons cited by parents for brace removal is sporadic crying of the infant. We recommend that the parents apply the brace whenever the child is placed in the crib or bed to sleep, so that wearing the brace becomes an invariable part of the routine of going to bed. This consistency seems to improve acceptance of the brace by both the patient and the parents. In this study, difficulties with the brace were encountered in 122 children (80%). Of 93 parents, 29 attributed difficulties to the child's temper, 28 to the brace, and 36 to both the child and the brace. Three parents reported that the child had sleeping problems with the brace on. Engaging the infant in play while she or he is in the brace is often helpful in alleviating crying. A strategy that is useful with orthoses with quick-release shoe attachments involves applying the shoe portion of the braces before the child falls asleep and attaching the bar once the child is sleeping. However, if the child continues to cry and cannot be easily consoled, the parents should be instructed to remove the brace to inspect the skin.

No objective monitoring of brace use, such as with sensors, was employed in any of these studies. There are no objective measures to assess adherence, forcing us to rely on parent statements. Nonadherence may be related to inability to fit the orthosis to the recurring foot; in such cases, nonadherence is not the cause of relapse, but vice versa.

Our results showed that noncompliance with periods of intolerance or discontinuance of the orthosis was very frequent with the use of FOA. The relation between coping strategies and rate of relapse suggests that parent education and monitoring compliance are very important in order to prevent relapse. Success of the Ponseti method is dependent on the parents' ability to consistently and properly apply the post-corrective brace. Thus, it is important to develop strategies to enlist parents' cooperation.

Conflics of Interest: No conflicts declared.

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