

## Improved bracing compliance in children with clubfeet using a dynamic orthosis

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### Abstract

**Purpose** Non-compliance with foot abduction bracing in children with clubfeet treated with the Ponseti method is the leading risk factor for deformity recurrence. A dynamic foot abduction orthosis is believed to result in improved compliance, fewer skin complications, and fewer recurrences. A case–control trial was conducted to test this hypothesis.

**Methods** A prospective cohort of children with idiopathic clubfoot using a dynamic brace was compared to a historical control group treated with a standard orthosis. Compliance, skin complications, recurrence, and the need for surgical soft tissue release were compared between groups at equivalent follow-up.

**Results** The dynamic and standard brace groups are equivalent in age at the start of treatment (1.9 vs. 2.9 months), number of affected feet (97 vs. 92), and severity (average of four casts required for correction in each group). Fifty-seven children were followed in each group for an average of 2 years. All were corrected initially with the Ponseti method. Compliance is higher using the dynamic brace (47/57, 81%) compared to the standard brace (21/57, 47%) ( $P < 0.001$ ). The recurrence rate is lower using the dynamic brace (11/57, 19%) compared to the standard brace (22/57, 39%) ( $P < 0.02$ ). Skin complications are fewer in the dynamic brace (2/57, 3%) compared to the standard brace (11/57, 19%) ( $P < 0.008$ ).

Most importantly, five children using the standard brace underwent posteromedial release within 2 years of treatment, compared to none in the dynamic brace group.

**Conclusion** The dynamic foot abduction brace results in improved compliance, fewer recurrences, fewer skin complications, and reduced rates of surgery in idiopathic clubfoot than the traditional brace after non-operative correction with the Ponseti method.

**Keywords** Clubfoot · Ponseti

### Introduction

Talipes equinovarus, commonly referred to as clubfoot, is a complex foot and ankle deformity involving forefoot adduction, hindfoot varus, cavus, and equinus caused by soft tissue contracture and bony malalignment. Initial treatment for this deformity is predominantly non-operative with serial manipulation and casting [1]. Several methods of manipulation have been used historically; however, Ponseti's method has resulted in the highest success rates and has been reproduced at several institutions [2–10]. Further, long-term studies have shown excellent functional and structural results with long-term follow-up greater than 30 years [11, 12]. Ponseti's treatment method is well-described in his text on the subject and in the recent literature [4, 6, 7, 13].

One often cited criticism of the Ponseti method is its relatively high rate of adjunct surgery, most frequently tibialis anterior transfer to the middle cuneiform [8]. An integral part of Ponseti treatment is adherence to strict postcorrection foot abduction. This has traditionally been maintained using straight last shoes connected to a Denis Brown bar (Fig. 1). Non-compliance with abduction

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**Fig. 1** Traditionally used foot abduction brace composed of shoes connected to a Denis Brown bar

bracing has been identified by multiple surgeons as a major risk factor for the recurrence of deformity [3, 4, 7–9, 14, 15]. Recurrence of deformity entails significant time and cost in additional treatment. This can range from repeat manipulation and casting, repeat Achilles tenotomy, tibialis anterior transfer, and soft tissue releases about the foot and ankle. Although soft tissue release for the treatment of idiopathic clubfoot was once thought not only to be relatively benign, but rather a preferred treatment for this condition, several long-term follow-up studies have shown unsatisfactory results from surgery as a result of stiffness, pain, and persistent deformity (either over- or under-correction) [16–21].

A dynamic foot abduction orthosis was developed in response to parents' criticisms and frustrations with the standard brace (<http://www.dobbsbrace.com>) (Figs. 2 and 3). The most notable feature is a dynamic bar connecting the feet that allows motion of each foot in the sagittal plane while maintaining abduction. At our institution, a custom molded solid ankle foot orthosis made of thin copolymer thermoplastic is combined with a molded inner boot made



**Fig. 2** Dynamic foot abduction orthosis with custom foot piece and articulating bar allowing for independent foot motion. This was the device used during the study period



**Fig. 3** Currently used model of the dynamic foot abduction orthosis. The foot piece is identical to the study brace. The dynamic bar has been modified in its weight and dimensions but has the same range and mobility as the dynamic bar used in the study group

from Duraflex with a dorsum pringle pad. Traditionally in clubfoot orthoses, straight last shoes have been attached to the bar. While our preference is to use the custom solid AFO, the dynamic bar can also be attached to Markell straight last shoes (<http://www.markellshoe.com>) or Mitchell clubfoot sandals (<http://www.mdorthopaedics.com>), as utilized by Ponseti in Iowa.

The increased freedom of motion given by the dynamic bar is believed to be more tolerable for the infant. We hypothesized that usage of the new brace would improve compliance and reduce recurrence and subsequent surgical procedures. The purpose of this study was to test this hypothesis using a case-control method at a single institution with a single treating physician.

## Methods

After institutional review board approval, infants with idiopathic clubfoot were enrolled into the experimental study group. Inclusion criteria included infants with idiopathic clubfoot not treated surgically elsewhere. Children with prior manipulation and casting were included since the practice covers a large region of the US and many infants are referred to our clubfoot center following initial casting as newborns near their homes. Children were excluded from the study if they had any neuromuscular disorders, genetic syndromes, arthrogyrosis, or previous surgery for clubfoot (including previous Achilles tenotomy). The treatment of clubfoot was done by a single Ponseti-trained orthopedic surgeon, according to a previously published protocol [4]. The only deviation from this protocol involved the Achilles tenotomy. Achilles tenotomy is now routinely performed in a procedure room in the clinic under local anesthesia rather than in the operating room.

Prior to the initiation of treatment, demographic data was collected. Clubfoot severity was determined after treatment by the number of casts required to achieve correction. Infants were followed prospectively through treatment, and all had successful correction of their deformity using the Ponseti method. At the time of Achilles tenotomy, infants were measured for their foot abduction brace. After coming out of their casts following tenotomy, the infants went into the dynamic foot abduction brace full-time (23 of 24 h) for 3 months. Infants came out of their brace only for stretching and bathing. After this period of full-time use, the children proceeded to nap and night-time brace wear. Ideally, this continues through to the age of 4 years; however, in reality, compliance generally diminishes with advancing age.

To remain consistent with prior bracing studies in the literature, compliance was defined as family-reported brace wear as instructed for 12 months following the correction of deformity. While this is far from a perfect method of evaluating compliance, it is the most widely used method described in the clubfoot literature. The use of more advanced technology such as heat or pressure sensors implanted in the brace was cost-prohibitive during this study period, but may be considered in the future.

Recurrence of deformity was diagnosed based on clinical evaluation. Almost universally, initial recurrence was treated with repeat manipulation and casting. Some infants required repeat Achilles tenotomy, and those failing these measures progressed to surgical treatment of recurrent deformity either with tibialis anterior transfer or soft tissue release.

Sixty-five children were initially enrolled in the study group, with an average age of 2.7 months at the start of treatment. There were 14 females and 44 males. The average follow-up was 21.1 months (range 12.2–32 months). Eight children were lost to follow-up, leaving 57 children (14 female, 43 male) with 97 affected feet as the study group. A historical control group was identified using clubfoot center treatment records immediately preceding initiation of the dynamic brace. Inclusion and exclusion criteria were identical to the experimental group. These patients were treated according to the same clinical protocol as the experimental group. The only difference was their foot abduction braces, which were the standard straight last shoes attached to a Denis Brown bar. The control group is comprised of 57 children with 92 affected feet. The group is comprised of 21 females and 36 males, with an average age of 1.9 months at the start of treatment. The average follow-up was 29.0 months (range 10.1–72.1 months).

The severity of clubfoot was classified using the number of casts required for correction of the deformity. This is the method utilized by all reports from Ponseti's group at the

University of Iowa. In the study group, an average of 4.1 (standard deviation [SD] 1.1) casts was required for correction compared to 3.8 (SD 1.1) in the control group. Furthermore, an equivalent number of feet (7%) in each group were considered to be severely affected (defined as feet requiring greater than five casts for correction). There was no significant difference in the need for Achilles tenotomy in the two groups, with 93 of 97 feet in the study group and 89 of 92 feet in the control group undergoing Achilles tenotomy. A skin complication was defined as any skin condition of the lower limb developing during the course of bracing requiring a cessation of bracing to allow for skin healing.

Clinical records for the historical group were reviewed retrospectively, as well as followed prospectively once the study was initiated. The data points collected were identical as to the experimental group. The same definition for compliance was used and treatment for recurrence was according to the same criteria as the experimental group.

## Statistical methods

Clinical data were analyzed using SAS statistical software (SAS Institute Inc., Cary, NC, USA). The mean (SD) of continuous variables or percentage (frequency) of categorical variables was reported for patients. Non-parametric tests (Wilcoxon rank-sum tests) were used to test group differences for continuous variables because of the non-normal distribution of the data. In general, Chi-square tests were used for between-group comparisons of categorical variables. However, when cell sample sizes in the contingency table were small, Fisher's exact test was used instead. A *P*-value of less than 0.05 was considered to indicate statistical significance.

## Results

As we hypothesized, the rate of compliance with foot abduction bracing was significantly higher in the dynamic abduction brace group as compared to standard bracing. Forty-seven of the 58 children (81%) in the dynamic bracing group were compliant with bracing. In contrast, only 21 of the 57 children (47%) in the control group were compliant with bracing ( $P < 0.001$ ).

In terms of recurrence, in the experimental group, 11 children had recurrent deformity (19%). All were subsequently corrected with repeat manipulation and casting; one child required repeat Achilles tenotomy. Four of these children had been compliant with bracing, seven had not been. Thus, seven of 11 non-compliant children suffered recurrence of deformity as compared to only four of 47

who were compliant. No child required surgical treatment for recurrence.

Recurrence rates were significantly higher in the control group. Twenty-two children (39%) in the control group suffered a recurrence. This was a significantly greater number than in the experimental group ( $P < 0.002$ ). Many were able to be corrected non-operatively after recurrence; however, five children had further surgery to correct their deformity via a posteromedial soft tissue release. Three of the 36 children who were non-compliant with bracing proceeded to undergo posteromedial soft tissue release. Of those in the control group who were compliant with bracing, two went on to have posteromedial soft tissue release. Despite our recommendations, the patient's parents elected for posteromedial release without attempting repeat manipulation and casting. They were not interested in the time investment required for successful non-operative management of their child's recurrence. In contrast, no child using the dynamic brace went on to have posteromedial soft tissue release ( $P < 0.03$ ).

The severity of the clubfoot at initial presentation did not have any effect on the rates of recurrence between the two groups. Four children in each group were considered to have severe clubfeet (>5 casts required for correction). These included a total of six feet in each group, with two of six severe clubfeet in the control group and three of six severe clubfeet in the study group developing recurrence. In both groups, two of the four children with severe clubfeet were non-compliant with abduction bracing. In the control group, both non-compliant patients developed a recurrence. In the study group, one of the non-compliant patients developed a recurrence and one of the compliant patients developed a recurrence.

There was also a significant difference in skin complications between the two groups. Two patients (3%) in the dynamic brace group and 11 patients (19%) in the control group had at least a temporary cessation of bracing as a result of skin ulceration or blistering.

## Discussion

The data in this case-control study show a dramatic improvement in the rates of compliance with abduction bracing using a dynamic brace. Although there was some loss to follow-up in our prospective experimental cohort, this finding remains significant, even assuming that all eight children lost to follow-up in the experimental group were non-compliant ( $P < 0.004$ ). This is not an unreasonable assumption, as families who are motivated to follow with the Ponseti method of clubfoot treatment are generally quite reliable and regular in their follow-up.

A drawback to the use of historic controls in this study is our improving education and support process with brace wear. A dedicated registered nurse for the clubfoot center works closely with families during the treatment and bracing period. She speaks with families via telephone at least once a week for the first month while brace wear is being initiated to assist with any difficulties that parents are having as their child adapts to the new brace. She also contacts patients the day after the initiation of clubfoot casting and the day after Achilles tenotomy. Although the same registered nurse was part of the treatment team during the time when the control group was treated, the regular, frequent telephone contact was not part of the treatment protocol. In the past, most families having problems with compliance called us with difficulties, in which case we could support them and given them ways to improve their child's tolerance of the brace. In some cases though, we did not realize families were having trouble with brace compliance until they came in for their appointments and relayed them to us. With our current system of regular phone contact through treatment and as brace wear is initiated, problems are identified early and can often be solved by our team. This change in the surveillance of bracing compliance is an important confounding factor in our results. Clearly, improved communication between the treating surgeon and family can only benefit the patient and improve the rates of treatment compliance. Determining the magnitude of this benefit in relation to the benefit from the dynamic brace cannot be assessed with this study design.

As expected, higher bracing compliance rates in the experimental group also led to decreased rates of deformity recurrence. This strong finding is in line with many previously published reports. Although this difference does not remain statistically significant if we assume that all eight children lost to follow-up had a recurrence, there remains a trend towards a significant difference ( $P < 0.07$ ). Furthermore, in this instance, as opposed to with brace compliance, it is unlikely that patients with recurrent deformity would stop following up. A parent is unlikely to leave their child with a recurrent deformity and not seek orthopedic attention. Our institution is the primary center for clubfoot treatment in the region and we are often referred patients from other orthopedists who have failed to correct the deformity or whose patients have developed recurrent deformity. It is unlikely that any other physician in the region would treat a recurrent clubfoot, especially one who they did not treat initially.

Clubfoot severity is another potential confounding factor for compliance rates. A hypothesis can be made that a child with a more rigid and severe clubfoot will have more difficulty with abduction bracing and, therefore, have higher rates of non-compliance. Only four children in each

group were considered to have severe clubfeet, of which half were non-compliant with bracing in both the control and study groups. Due to the small numbers, we cannot exclude the severity of clubfoot as a confounding factor in brace compliance. Nevertheless, more severe clubfeet usually have a syndromic or neuromuscular basis and were excluded from this study of idiopathic clubfoot. Few idiopathic clubfeet are so severe that they require more than five casts for correction. This is reflected in our patient characteristics for the time period of research collection in this study. We feel that the results generated from this study can be appropriately applied to the idiopathic population but cannot be extended to the neuromuscular or syndromic clubfoot.

Assessing skin complications is difficult to do objectively; therefore, the decision was made to consider a patient as having a skin complication if it resulted in a discontinuation of bracing to allow for healing. Although this definition also subjects the study to bias, it was felt to be the best solution when dealing with a historical control group in which skin condition was only appreciated through clinical notes rather than examination. An independent examiner evaluating a prospective cohort would have been ideal for the assessment of skin condition and will be utilized for future studies.

Although the study was not designed to evaluate the mechanics of the brace and skin-brace interface, we believe that most skin problems occur as a result of shear motion between the child's skin and the brace shoe or foot piece. The higher incidence in the control group is thought to be due to children attempting to move or kick out of their shoes, resulting in this shear force. The mobile brace allows the foot and foot piece to move as one and this was hypothesized as the reason for fewer skin issues in the experimental group. This cannot be proven, however, without a more detailed biomechanical study that is beyond the scope of this project.

Furthermore, beyond just the difference between the Denis Brown bar and the dynamic bar, the brace system studied also differed from the control group in the foot piece. Feet in the control group were held in a straight last shoe, while feet in the study group were held in a custom solid ankle foot orthosis with a Duraflex liner. This custom foot piece likely controls the foot and prevents slippage better than a straight last shoe. We cannot determine from this study how much of the improved compliance rates are due to the foot piece versus the dynamic bar.

Finally, rates of surgical treatment of resistant clubfoot were examined. In Ponseti's original literature, a tibialis anterior transfer is not considered as a failure of treatment, but, rather, as a tool to treat dynamic forefoot supination during ambulation [8, 13, 22]. In our series, tibialis anterior transfers were all done in a delayed fashion, greater than

4 years after the treatment was begun. It is difficult to argue that the lack of bracing compliance led to subsequent transfer—and none of the children in the experimental group have greater than 4 years of follow-up at the current time. Thus, it is improper to compare rates of tendon transfer between the two groups.

Although many debate whether tibialis anterior transfer is a surgical treatment for failed conservative treatment of clubfoot, extensive soft tissue release is clearly treatment for failed conservative management. In our series, five patients underwent posteromedial release. Of these, three had tried and failed repeat manipulation, casting, and Achilles tenotomy. Two may have been able to be corrected non-operatively, but were adamant about desiring operative correction. While it may seem that requiring surgical correction with posteromedial release in only five of 92 feet (5%) is a low figure, several studies have shown that success rates of non-operative treatment up to 100% can be achieved [4, 6, 7]. All patients in the dynamic bracing group currently have stable, plantigrade feet, without evidence of recurrence.

As a case-control series with a historical cohort and unblinded examiners, this study has obvious limitations. Clearly, the standard brace with straight last shoes and a Denis Brown bar is poorly tolerated, as many researchers have shown. Several physicians have developed alternative braces, with varying rates of success and varied scientific methodology in reporting their results [23, 24]. We believe our brace to be better tolerated by infants and, therefore, more likely to be used in the strict fashion (full-time for 3 months, nights and naptime thereafter to the age of 4 years) that Ponseti advocates. Based on our experience, we no longer offer the standard brace except in the very rare case where an infant does not tolerate the dynamic brace.

Another drawback to the study is applicability to developing nations. At our institution, the cost of the Denis Brown bar is 24 USD, while the cost of the dynamic bar is 110 USD. Straight last shoes as used traditionally costs 45 USD, while the custom solid AFO and foot insert costs 257 USD. In the US, almost all children have their health care paid for by either private insurance or government health care programs. Most private insurance carriers will pay anywhere between 80 and 100% of the cost of the abduction brace, while government programs pay for the full cost of the abduction brace. Until the dynamic abduction system can be produced more cheaply, there will still be an important role for simple hand-made bars and shoes in the developing world. When used properly, simple devices to maintain foot abduction can, in most cases, provide excellent clinical results.

Despite the positive findings in this study, the rate of compliance with the dynamic brace remains less than ideal. Assuming that all patients lost to follow-up were

non-compliant, we are left with a compliance rate of only 71%. While this is much higher than the rate of compliance in the previous reports in the literature and in our control group, 100% compliance should be the goal for all physicians treating patients with clubfoot. To this end, we have continued to evolve our method of brace wear surveillance. Our treatment group already includes a registered nurse who has a close relationship with all clubfoot families as described. We are hoping to add a team member who can also carry out home visits to give parents more hands-on help in assuring brace compliance. We are also constantly looking at ways to improve the brace, especially in improving the comfort of the foot piece for our patients.

Well over 90% of infants with idiopathic clubfoot can be treated successfully without extensive surgery using Ponseti's technique. This study, along with previously reported studies, clearly demonstrates that the recurrence of deformity due to brace wear non-compliance is a preventable problem. Reducing the rate of recurrence will result in less work days lost by parents due to the need for repeated manipulations, less skin irritation of infants due to repeated manipulation and casting, and, most importantly, decreased rates of extensive soft tissue surgery for patients with clubfoot, thereby, preventing the pain, stiffness, and disability associated with clubfoot surgery.

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