

Early Experience with the C-PRO ADM Brace in Clubfoot

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Abstract

Background: Successful treatment of clubfoot by the Ponseti method involves prolonged bracing with The Foot Abduction Bar and Brace (FABB). Compliance with this bracing program can be difficult for some patients. A new brace made by C-PRO called the ADM (abduction dorsiflexion mechanism) is a dynamic unilateral brace that can be used in the treatment of clubfoot. The purpose of this study is to review and present the early descriptive experience with this brace.

Methods: Outpatient records were queried for patients with clubfoot who were prescribed the ADM brace. Data was collected and analyzed, including age of patient, diagnoses, changes in brace plan, brace failure and compliance.

Results: 38 patients with clubfoot were prescribed the ADM brace and included in the study. Mean age at ADM brace initiation was 5.1 years. Patients had used the brace for an average of 22 months, and still utilized in 87%. 45% of patients were unable to wear the brace as initially prescribed but most were able to continue with the brace after modification of the prescribed use recommendations.

Conclusions: FABB remains the gold standard for bracing after successful correction in the Ponseti method. However, in some patients, particularly older patients, who find the FABB intolerable and ongoing bracing is recommended, the C-PRO ADM brace may be a useful alternative. Because of the dynamic nature of the brace, about half of the patients find it difficult to tolerate all night long, but can be used during the evening and screen-time.

Keywords: Therapeutic Studies, Retrospective Case Series, Level IV

Introduction

Ponseti treatment of idiopathic congenital clubfoot is now standard [1], and after achieving initial correction of the deformity, prolonged use of the foot abduction bar and brace is a critical component to maintaining the correction and optimizing the result [2]. Various braces have been described and utilized in the United States, including the Denis Browne Bar [2], Dobbs brace [3], Mitchell brace [4,5] and a dynamic abduction bar [4]. While simple ankle foot orthoses have shown increase the risk of recurrence [6], most foot abduction bar and bracing, if worn correctly, can achieve the critical function of maintaining foot abduction and ankle dorsiflexion in the brace [7,8]. Compliance with the bracing program has been shown to decrease recurrence of the deformity in many studies [9-13]. Some authors [14-16] have recommended that bracing extend beyond the typical four years of age to decrease chance for recurrence in these children with particularly tight feet. However, compliance with the foot abduction bar and

bracing regime can be difficult for some patients and families [17]. Some children may protest the bar and the tether of their feet during sleeping. Families of older children may have difficulty with the lack of independent ambulation in the abduction bar and brace. Other difficulties with the standard FABB brace may also occur. With decreased use of the foot abduction bar and brace, the risk of recurrence of the clubfoot deformity increases, potentially necessitating further procedures or interventions. Furthermore, there are some children with clubfoot who may benefit from foot abduction bar and bracing beyond the age of 4 years, but who are unwilling to cooperate with the restricted mobility caused by the bar.

A newer clubfoot brace has recently been introduced by C-PRO DIRECT (7A Enterprise Way, Edenbridge, Kent, TN8 6HF UK), called the ADM (abduction dorsiflexion mechanism) brace, See Figures 1,2. This dynamic spring-loaded brace provides an active dorsiflexion and abduction moment on the foot, without a bar; it can be utilized on one foot (only) or on both as necessary, See Figures 3,4. As a newer product, it remains unproven in treating clubfoot. For patients and families who can no longer

tolerate the foot abduction bar and brace, however, it has emerged as a useful bracing option. The C-PRO ADM brace has been used by the primary author for over two years for clubfoot patients who have failed the standard foot abduction bar and brace (typically Mitchell) or who are determined to need ongoing bracing because of a persistently tight foot but not felt severe enough (or parents have chosen to hold off) for tibialis anterior transfer after age four years old. Patients and families were told that this brace was still experimental but may be useful to try. Additionally, as it is well tolerated, some patients with clubfoot who are beyond age of traditional bracing can utilize this brace as a dynamic dorsiflexion stretching brace. As such, many patients have utilized the brace successfully. The purpose of this study is to retrospectively review and present the early descriptive experience with the C-PRO ADM brace for treatment of idiopathic clubfoot.



Figure 1: C-PRO ADM (Abduction Dorsiflexion Mechanism) brace. View from the medial side of the brace.



Figure 2: C-PRO ADM (Abduction Dorsiflexion Mechanism) brace. View from the back of the brace.



Figure 3: C-PRO ADM (Abduction Dorsiflexion Mechanism) brace on a child's foot. View from the lateral side of the brace.



Figure 4: C-PRO ADM (Abduction Dorsiflexion Mechanism) brace on a child's foot. View from the front of the brace.

Materials and Methods

Institutional Review Board approval was obtained prior to the initiation of this study. Outpatient records were queried from March 2016 through March 2017 during the first year of availability of this brace. Patients who were prescribed the brace were identified by the query for ADM or c-pro. Inclusion criteria

included any patient with clubfoot who was prescribed the ADM brace, filled the prescription and tried using the brace. Clinical data was collected on clubfoot patients who were prescribed the brace, including age at initial ADM brace prescription, gender, diagnosis and any follow-up issues or modifications to the prescription and recommendation. Follow up of patients and brace use through July 2018 was done. Data was collected including continuous (age), dichotomous (gender), categorical (physician, patient diagnosis) and descriptive (initial brace use plan and recommendations). Date of initiation of ADM use was noted, as was length of time until records review and whether the brace was still being utilized. Any change of brace plan and reasons for the change were recorded. Recurrence while using the brace was noted, even if recurrence was related to non-compliance. Brace failure was defined as inability to continue using the ADM brace, either due to recurrence or complete intolerance.

Simple descriptive statistics were used to assess gender, diagnosis, laterality, initial brace prescription and any change in prescription. We additionally assessed age of patient at time of brace initiation (mean and standard deviation) and length of time since brace initially prescribed (mean and standard deviation).

Results

A total of 38 patients with clubfoot were prescribed the ADM brace and included in the study. Three different pediatric orthopedic surgeons utilized the brace for their patients, with the majority from the lead author (STM). The mean age at ADM initiation was 5.1 years (standard deviation 2.0, range 1.0 - 9.2 years). Sixty-three percent were boys (24/38). ADM brace was initiated bilaterally in 29% (11/38), left only 32% (12/38) and right only in 39% (15/38). Initial brace plan was nighttime only 89% (34/38); other patients were told to use it in the evening for few hours, for screen-time or daytime in addition to nighttime. In 71% of the children in whom the ADM brace was used (27/38) the diagnosis was clubfoot over the age of 4 years, where ongoing bracing was felt to be beneficial to the maintenance of the clubfoot correction and the Mitchell brace considered unlikely to be tolerated. It was also used only rarely for clubfoot under the age of four years, and only when other more standard brace types had proven intolerable.

At the time of data collection, the ADM brace had been used an average of 22 months (standard deviation 4.2 months), and the brace was still used by the patient in 87% (33/38) of cases. Follow-up since the brace was prescribed was available in 87% (33/38). Of those with follow-up, 29 were initially prescribed nighttime use of the brace. No modification of the initial brace plan was needed in 55% (16/29) of patients and they were able to continue with nighttime use of the ADM brace. In the remaining 45% (13/29) of patients, modification of the initial prescription of nighttime only use of the ADM brace was needed. Because the brace was in some cases poorly tolerated at night during sleep, screen-time or additional daytime use was added in 10 patients. There were two brace failures: one patient returned to casting due to recurrence, one patient switched back to the Mitchell brace by preference; additionally, one patient was weaned off the brace. The patient

who returned to casting due to relapse occurred because a new larger ADM brace was not approved by their insurance company when it became too small and the patient stopped using the brace, thus suffering relapse.

Discussion

The Foot Abduction Brace and Bar (FABB) remains the gold standard for brace treatment when utilizing the Ponseti method for treatment of clubfoot. However, there are situations where the FABB becomes intolerable to the patient or family for a variety of reasons. This can be because of inconsolability of the child, simple non-compliance of the family, or difficulties with independence as the child is older but ongoing bracing is felt to be needed to avoid more invasive surgery. While there are several braces available for treatment of clubfoot [2-4,6], successful bracing has been shown to require an abduction bar; the only study assessing ankle foot orthoses (AFO) to abduction bar (with the Denis Browne Bar) found a significantly higher recurrence rate using AFO. We present the early results of a new brace, the c-pro ADM brace, which is a single limb brace with a dynamic spring loaded mechanism that pushes the foot into dorsiflexion and abduction. This dynamic nature is distinct from clubfoot braces previously available, and has the benefit of making a bar unnecessary. This leads to the beneficial situation of the feet not being tethered together, and in the situation of unilateral condition, one can treat just the involved foot. Furthermore, patients may walk short distances in the brace without significant safety risk. It is also well tolerated in older patients who benefit from a dynamic dorsiflexion stretching brace for persistently tight Achilles. In our patient population, we have used this brace mostly in the setting of clubfoot as it was initially designed. We still consider the Mitchell foot abduction brace and bar the gold standard of treatment, and typically only utilize the ADM brace for recalcitrant cases or older children for whom ongoing bracing is felt to be necessary.

The spring-loaded mechanism of the brace stretches and presses on the foot similar to dynamic braces currently used for joint contractures, which has theoretic benefit over a static brace in maintenance of foot position. Generally, we would not recommend use of this brace in the setting of deformity, but after correction of deformity to maintain correction. Unfortunately, the dynamic stretch component may impact compliance, as it can be difficult for children to tolerate at night while sleeping. We found that in about half (45%) of the patients, their initial nighttime prescription was modified for use in the evening, during screen-time and (in some cases) shorter nighttime use. With modified protocols, the brace was found to be well tolerated by most and effective. In this study we had one patient return to the Mitchell brace by choice. We had only one patient who returned to casting after treatment of the ADM brace, and this was because of insurance issues that failed to approve a larger brace when she outgrew the old one. There are limitations to this study, including its retrospective nature, lack of rigorous follow-up and evaluation, and descriptive nature of the report. However, we felt it beneficial to share our initial experience with this new dynamic clubfoot brace.

In conclusion, the c-pro ADM brace is a useful adjunct to brace treatment for clubfoot, and may be useful in other diagnoses as well. Because of the dynamic nature of the brace, about half of the patients find it difficult to tolerate all night long, but can be used for evening and screen-time to increase the hours in the brace.

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