CASE REPORT

Unilateral Abduction Dorsiflexion Mechanism Brace as an Attractive Alternative of Congenital Talipes Equino-Varus Treatment – a Preliminary Report

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Abstract

Ponseti method of CTEV treatment includes use of a foot orthosis, compliance with this can be a challenge. A new brace- Abduction Dorsiflexion Mechanism brace (ADM, C-Prodirect) was introduced to address this. The aim of the study was to assess whether the new ADM brace improves compliance and prevents relapse in children with corrected clubfoot. Eight children with unilateral CTEV who did not tolerate the standard brace were included in the study. All children had been previously treated with Ponseti casting, Achilles tenotomy and Ponseti AFO Abduction Brace (C-Prodirect®). The mean age of children included was 27 months. Parents' satisfaction with the brace was assessed using Client Satisfaction with Device (CSD) questionnaire. Parents reported better tolerance of the brace by the child in six out of eight cases. ADM brace is viable alternative in maintaining correction of unilateral idiopathic CTEV when compliance to standard AFO abduction brace is poorly tolerated.

Level of evidence: IV

Keywords: Abduction dorsiflexion mechanism brace, Clubfoot, Compliance, Congenital talipes equino-varus, Ponseti

Introduction

Congenital talipes equino-varus (CTEV) is a congenital deformity requiring early treatment. The Ponseti method of treatment gives excellent results and is currently regarded as a "gold standard". Widespread popularity of the Ponseti method of treatment improved long term results and reduced the need for extensive operative interventions.[1,2] Treatment includes correction of the deformity with manipulations, serial casting and frequently Achilles tenotomy then the child is placed in an abduction brace.[3] The aim of bracing is to maintain correction and reduce the risk of relapse.[4] The most common cause of relapse is failure to adhere to the prescribed bracing regime.[5] Use of the brace decreases with time.[6] The median brace use recorded by the sensors was 62% of that recommended by the physician. Relapse patients wore splints significantly less than relapse-free patients.[7] new, more user-friendly braces have been introduced in the hope of improving the rate of compliance.[5]

An attempt to improve compliance resulted in the introduction of a new Abduction Dorsiflexion Mechanism brace (ADM, C-Prodirect) [Figure 1]. It was registered and introduced into clinical practice in 2014. The brace is applied only on the affected leg. It maintains the desired position of the foot by means of a shoe and a stirrup connected by a system of springs leaving the contralateral leg free and avoids the use of the bar. Preliminary results suggested that this brace is safe and well tolerated by children.[8]

Figure 1. Abduction Dorsiflexion Mechanism brace (ADM, C-prodirect): A.Medial side; B.Lateral side; C.Applied on foot

The aim of the study was to assess whether a new ADM brace is safe, improves compliance and can be used as an alternative to the standard brace, when the original one is

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not tolerated by a child.

Case Presentation

Eight children with unilateral idiopathic talipes equino-varus have been prospectively enrolled into the study. All children have been treated with manipulations and corrective casts according to Ponseti protocol, percutaneous Achilles tenotomy and Ponseti AFO Standard Sandals with Abduction Brace (C-Prodirect®). The mean age at the beginning of treatment was 13 days (range: five - 20 days). The mean number of casts required to achieve correction was seven (from three to 12). Ponseti abduction brace treatment was commenced after removal of the cast for 23 hours/day for three months followed by nighttime and day nap only. Relapse requiring repeated casting was seen in three children. No child in the study required further operations. The study was conducted in adherence to the Declaration of Helsinki and was approved by approved by the local NHS Research Ethic Board (REB).

Inclusion criteria for a study were:

- Unilateral, idiopathic, non-syndromic, corrected talipes equino-varus deformity
- Difficulties in maintaining the brace reported by parents/carers
- Willingness to participate in a study and inform consent given by parents/carers.

Foot correction and relapse was assessed using a Pirani score.[9] It assesses six elements: morphology (curvature of the lateral border, medial and posterior creases and emptiness of the heel) and passive correction of the foot: coverage of the talar head and ankle dorsiflexion. Each component gets 0; 0.5 or one point (the higher the score the more deformed foot; maximum six points). This system proved to be a reliable and reproducible scoring system for the assessment of the severity of clubfoot deformity.[10] Foot dorsiflexion was measured by a hand-held goniometer. Pirani score, skin status and compliance with the brace was recorded on each visit. Parents' satisfaction with usage of the brace has been assessed with the Client Satisfaction with Device (CSD) questionnaire [Table 1]. This is a widely used validated questionnaire for the assessment of patient's satisfaction with the orthosis.[11,12] Its revised form consists of eight questions regarding various aspects of user's satisfaction with the device: the presence of skin pressure sores, comfort, pain-free to wear, difficulties in applying the orthosis, its durability and weight.[13] Answers are rated on a four-level Likert scale: Strongly Agree (one point); Agree (two points); Disagree (three points); Strongly Disagree (four points) with higher scores indicating poor satisfaction.

Table 1. The Client Satisfaction with Device module of the Orthotics and Prosthetic Users' Survey (CSD-OPUS) (modified)

	Strongly Agree (one point)	Agree (two points)	Disagree (three points)	Strongly Disagree (four points)
Child's skin is free of abrasions and irritation				
Device is comfortable throughout the night				
Device looks good				
Device is pain free to wear				
Device is durable				
Device fits well				
It is easy to put on child's leg				
The weight of the device is manageable				

All children enrolled into the study had a corrected foot (below 1.5 according to Pirani score) with passive dorsiflexion above neutral at the beginning of new brace treatment. The mean age of children when enrolled into the study was 27 months (range: 22 to 31 months). All children were monitored every six weeks for the first three months and every three – four months afterwards. The mean duration of AMD bracing was 19 months (range: 13-25 months) when brace treatment was discontinued as per Ponseti management protocol or stopped due to the relapse of the deformity.

The brace was well tolerated by six of eight children. In two children we observed redness of the skin caused by the brace. Parents were very satisfied with the new brace and reported better tolerance of the brace by the child. This reflected in a better score on the CSD questionnaire [Table 2]. The mean CSD score with the standard brace was 20.25 (range: from 16 to 26). The mean CSD score with the new ADM brace improved to 15.6 (range: from 11 to 23). In comparison to the standard brace, parents appreciated better tolerance of the brace at night and its lower weight. In one case (patient number three – table two) there was a need

to replace a brace to the one with a weaker spring at the beginning of the treatment, which improved comfort and tolerance of the brace reported by the parents. In the other case (patient number seven) the parents have changed the time when the brace was on from nighttime to daytime and for walking with a good effect. In two children the change of the brace to the ADM one did not improve compliance. In both cases the brace was not used regularly resulting in relapsing of the deformity.

Pirani score for both cases increased to 2 (from 0.5) and 2.5 (from 1) respectively. Further manipulations and casting were required in both cases. There was no need to perform Achilles tenotomy or surgical correction in these cases. After casting and correction of the relapsed deformity parents opted to continue with ADM treatment. Results of the management in ADM brace are summarized in [Table 2].

Table 2. Patients characteristic and results of treatment with ADM brace

Patient number	Age at the beginning of study (months)	Gender	Side	Duration of ADM brace treatment (months)	Pirani score at ADM fitting	Pirani score at the last follow-up	CSD score (standard brace)	CSD score (ADM brace)	Outcome
1	25	M	L	22	0	0	16	11	satisfactory
2	22	M	L	14	0.5	2	23	21	relapse
3	29	M	R	20	0.5	0.5	22	15	satisfactory
4	24	M	L	25	0.5	0	20	14	satisfactory
5	28	F	R	20	0.5	0.5	16	13	satisfactory
6	31	M	L	13	1	2.5	26	23	relapse
7	27	M	R	23	0	0	21	16	satisfactory
8	30	M	L	17	1	0.5	18	12	satisfactory

Discussion/Conclusion

New ADM brace proved to be a safe and effective device in maintaining correction of clubfoot. Improved compliance in children who do not tolerate standard abduction braces was shown. This observation echoed findings of McCartney *et al.*[8] They tried ADM braces in ten children with unilateral clubfoot for 12 weeks. The authors observed good compliance with maintenance of correction. The authors did not observe increased incidence of skin problems associated with the use of the new brace. Our findings were similar, with parents' satisfaction being high.

Better results with ADM brace observed in our study are most likely achieved due to the novel, dynamic and "child friendly" design of the device. It uses springs that apply pressure on the foot in a controlled, continuous manner that can be modified by the position of the child's foot.

Leaving the other leg free of a brace and lower weight of the brace may be also contributing factors for better compliance and high satisfaction rate with the new brace. This was confirmed with a decrease in CSD score. Similar findings were observed in the pilot study of McCartney *et al.*[8] Also, Mahan *et al*. in their pilot study of 38 children treated with ADM brace showed good compliance and a brace was utilized in 87% of children for the average of 22 months.[14]

There are certainly deficiencies in our study given the small sample size with no control group. As a proof of concept, we have shown improved compliance in a patient group that would otherwise have a higher recurrence rate. Our study was designed to assess the compliance of the new device in a selected, very hemogenic group of children. All children in the study group had a corrected foot, their compliance with the standard brace was poor and they were treated with the same protocol. Two cases in the study group relapsed. In the study of Sangiorgio *et al.* the authors concluded that the overall probability of a relapsed deformity may reach 52% at age six years, and this probability is significantly reduced by adherence with bracing.[15] Our selected study group was at a very high risk of recurrence and overall result and compliance rate should be regarded as satisfactory.

Good compliance, high caregivers' satisfaction and low recurrence rate observed during the treatment with ADM brace strongly support its usefulness and safety. New Abduction Dorsiflexion Mechanism is an attractive alternative in maintaining correction when the compliance with the standard brace is poor. It has proven to be safe and well tolerated. Its usage may improve compliance particularly in unilateral cases when the standard brace is poorly tolerated, and the compliance is unsatisfactory. Our study should be regarded as a pilot study and appropriately powered randomized control study is required before its widespread use.

Patient consent: Informed consent was obtained from the parents / guardians.

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