Original Article

The DUTh Abduction Brace: A New Orthosis Design for Maintaining Foot Correction in Idiopathic Clubfoot

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Objective: To evaluate the effectiveness of the "DUTh" device in achieving static maintenance of desirable characteristics of the foot after clubfoot correction over a period of one year.

Materials and Methods: A prospective study was conducted of idiopathic clubfoot patients treated following the Ponseti protocol during the period 2014 through 2016. Dimeglio and Pirani scores were recorded before attaching the DUTh brace and at 3, 6, 9, and 12-month follow-up visits, including level of compliance and any complications with the brace.

Results: The DUTh brace was applied to 47 feet of 30 patients. At initial brace application, there was no change in the Dimeglio or Pirani scores ($p>0.05$). The average daily period in the brace was 16, 12, 9.5, and 9.5 hours for months 1 to 3, 4 to 6, 7 to 9, and 9 to 12 months, respectively.

Conclusion: The DUTh brace is appropriate alternative foot abduction brace for post-correction maintenance of clubfoot correction. Advantages of the brace include greater comfort due to the brace being custom-made, light weight, easily adjustable for length and angle by parents, provision of easy heel accessibility, efficacy in static maintenance of the desirable foot position, and low incidence of complications.

Keywords: Idiopathic clubfoot, Foot abduction orthosis

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Idiopathic clubfoot is the most common congenital foot deformity, with an incidence of 1.03 per 1,000 newborns[1]. The objective of treatment is a plantigrade foot and walking without pain. Currently, the Ponseti protocol is used worldwide to treat clubfoot and has had a success rate of up to 89%. The Ponseti protocol involves manipulation and weekly casting, either with or without Achilles tenotomy[2,3], followed by bracing to maintain the correction[4,5]. Previous studies have found that cases of failure of the Ponseti method are directly related to noncompliance with the brace protocol, i.e., not wearing the brace regularly as directed, leading to recurrence of the deformity in up to 50% of cases[3,6-11].

The brace itself consists of two footplates or shoes which are attached to a metal bar. The plate can be turned 70 degrees externally for the affected foot and 10 to 15 degrees of dorsiflexion. Parents were instructed to use the brace nearly full-time, i.e., 23 hours per day, for the first 3 months, then just at nighttime and naptime. Due to parent's failure to comply with the bracing regimen, some physicians tried to design a new orthosis, but some disadvantages persisted[12-15].

The authors created a new, inexpensive, and less complicated orthotic device, the DUTh abduction brace, as a means of increasing parents' compliance with the bracing regimen and improving maintenance of the child's foot after clubfoot correction. The objective of the present study was to evaluate the efficacy of the DUTh device in terms of its ability to preserve the desirable characteristics of the child's foot.

Materials and Methods

This prospective study was conducted during the period April 2014 through March 2016. Inclusion criteria included newborn patients who were diagnosed with idiopathic clubfoot. Exclusion criteria included cases of recurrent clubfoot and receipt of previous treatment for clubfoot. All patients had had their feet manipulated weekly using the Ponseti technique until forefoot adduction and hindfoot varus were corrected, after which all patients underwent an Achilles tendon tenotomy leading to full correction and prevention of congenital vertical talus or "rocker-bottom foot".

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After the surgery and three weeks in a long leg cast, the DUTh device was applied.

The DUTh abduction brace consists two custom-made footplates made of thermoplastic, a material that becomes moldable when heated. The plates are designed to include a "heel hole" which makes it possible to check if the heel is on the bottom of the orthosis (Figure 1). In addition, the medial edge of the plate is higher than the lateral edge to prevent medial rotation (Figure 2). The footplates are placed on an adjustable length metal bar. The distance between the medial edges is set to equal the patient's shoulder width. The plates are set at 70 degrees of external rotation on the affected foot and 40 degrees on the non-affected foot, with 10 degrees of dorsiflexion (Figure 3, 4). Parents were informed about the need for full-time use of the orthosis (23 hours per day) for the first 3 months followed by part-time use at nighttime and naptime.

The efficacy of the DUTh brace in static maintenance of desirable foot form was evaluated using Dimeglio and Pirani scores before using brace and at 3, 6, 9, and 12 months after application of the brace. Measurements included degrees of passive dorsiflexion, forefoot abduction relative to hindfoot, horizontal plane of derotation of the calcaneopedal block and valgus heel. Information was also obtained on parents' compliance with recommended hours of

Figure 1. Front view of the right footplate of a DUTh brace showing the "heel hole" used to determine if heel is on the bottom of the orthosis.

Figure 2. Lateral view of the right footplate showing that the medial edge is higher than the lateral edge to prevent medial rotation.

Figure 3. View of the DUTh brace from below. The footplates are place on connected to an adjustable metal bar. The distance between the medial edges is equal to the patient's shoulder width.

Figure 4. Footplates are set as 70 degrees of external rotation on the affected foot (right foot) with 10 degrees of dorsiflexion and 40 degrees of external rotation on the non-affected foot (left foot).

brace use during the first 3 months and after 6, 9, and 12 months. All patients were evaluated by two orthopedic surgeons and the data were tested for inter-rater reliability using Cohen's Kappa statistic. Repeated analysis of variance [ANOVA] was used to compare the means of all degree measurements and Dimeglio and Pirani scores during the one year follow-up. Categorical variables were tested using the Chi-squared test and continuous variables were tested using the paired t-test. Statistical analysis was done using Stata 11 (Stata Corp., College Station, TX, USA) statistical software. The *p*-values <0.05 were considered statistically significant. The required sample size was calculated to be 43 feet based on the assumption that the success rate with the current standard abduction brace was 60% and using a 5% significance level to achieve 80% power.

The present study was approved by the Ethics Committee of Khon Kaen Hospital Institute Review Board in Human Research. Parents of the children included in the study signed an informed consent statement prior to participation.

Results

A total of 19 males and 11 females were included in the present day. Thirteen of the children had unilateral clubfoot and 17 had bilateral clubfoot. All the patients were treated using the Ponseti method and followed by an Achilles tenotomy. After the final cast was removed, the DUTh device was applied. Demographic data prior to using the DUTh brace are shown in Table 1.

The F-test comparing baseline, 3, 6, 9, and 12 months found a significant difference in degrees of passive dorsiflexion (*p*-value 0.001), forefoot abduction relative to hindfoot (*p*-value 0.042), valgus heel (*p*-value <0.001), Dimeglio score (*p*-value 0.008), and Pirani score (*p*-value 0.024), but the difference in the horizontal plane of derotation of the calcaneopedal block was not statistically signficant (*p*-value 0.164).

During the first 3 months of DUTh brace application, the degree of passive motion increased by 0.95 degree (<1 degree). Even though the change was statistically significant, it represented no real clinical change. The 6 months follow-up revealed no significant change in degrees of dorsiflexion or heel valgus, but did find significant improvement in other components. At 9 months, the degree of dorsiflexion and heel valgus had become significantly lower, and the rest were significantly better and the other measured factors were significantly improved as well. At the 12 months follow-up, there was significant reduction in dorsiflexion, horizontal plane of derotation of the calcaneopedal block, and the degree of heel valgus. In the other hand, there was also a significant improvement in the degree of forefoot abduction relative to the hindfoot; however, as was the case at 3 months, the small degree of change at 6, 9, 12 months had no clinical significance.

Table 1. Demographic data prior to using DUTh brace

	Mean ± SD
Age at presentation (weeks)	2.3±0.7
Dimeglio score at initial presentation	15.3±1.27
Pirani score at initial presentation	5.6±0.38
Number of casts needed to correct foot	9.1±1.8
Age at Achilles tendon tenotomy (weeks)	16.8±3.0
Age at initial bracing (months)	5.7±0.7

At one year, there was no significant change in the Dimeglio or Pirani scores compared with the values at initial brace application. The average time of brace use was 16 hours per day in first 3 months, 12 hours per day from 3 to 6 months, 9.5 hours per day from 6 to 9 months and from 9 to 12 months (Table 2).

A complication occurred in only one patient, a skin breakdown in the first metatarsophalangeal joint area. The condition was cured with antibiotic ointment only, with no interruption or discontinuation of bracing.

Discussion

One of the most common congenital foot deformities is idiopathic clubfoot or idiopathic talipes equinovarus[1]. Presently, the Ponseti protocol is widely utilized in which the deformity is corrected sequentially by talar head counteraction followed by application of a long leg cast which is changed weekly[16]. When forefoot adduction and heel varus is corrected, an Achilles tenotomy is done to correct the equinus then a final long leg cast and brace are applied for 3 weeks. This system has achieved a success rate of 89%[2,3]. However, a long-term follow-up study by Ramirez et al[10] of 73 idiopathic clubfeet previously treated using the Ponseti technique found a recurrence rate of 33%, and a study by Haft et al[8] reported that 41% of 51 patients had a recurrence. The concordant conclusions of both studies was that the level of failure of compliance with abduction bracing recommendations was consistently negatively correlated with recurrence rate. Those studies also reported that there was no correlation between recurrence rate and any patient demographic data, time

Table 2. Degree/score at initial application and changes at 3, 6, 9, and 12 months follow-up

Degree/scoring system	Initial application	3 months follow-up	Change* (*p*-value)	6 months follow-up	Change* (*p*-value)	9 months follow-up	Change* (*p*-value)	12 months follow-up	Change* (*p*-value)	*p*-value (F-test)
Dorsiflexion	13.08 (±6.72)	14.04 (±5.77)	0.95** (<0.001)	13.40 (±6.35)	0.32 (0.12)	10.95 (±7.49)	-2.12** (<0.001)	10.95 (±7.49)	-2.12** (<0.001)	0.001
Forefoot abduction relative to hindfoot	46.38 (±10.91)	50.21 (±7.58)	3.82** (<0.001)	49.57 (±7.43)	3.19** (<0.001)	47.23 (±12.80)	0.85** (<0.001)	47.23 (±12.80)	0.85** (<0.001)	0.042
Horizontal plane of derotation of the calcaneopedal block	28.93 (±6.75)	30.95 (±6.56)	2.02** (<0.001)	29.57 (±4.64)	0.63** (0.002)	29.57 (±6.90)	0.63** (0.002)	28.29 (±7.01)	-0.63** (0.002)	0.164
Heel valgus	22.02 (±4.62)	24.25 (±5.31)	2.23** (<0.001)	21.70 (±4.80)	-0.32 (0.12)	20.10 (±6.12)	-1.91** (<0.001)	19.25 (±6.42)	-2.76** (<0.001)	<0.001
Dimeglio score	4.1 (±0.31)	4.04 (±0.20)	-0.06 (0.76)	4.08 (±0.28)	-0.02 (0.91)	4.21 (±0.41)	0.10 (0.61)	4.21 (±0.41)	0.10 (0.61)	0.008
Pirani score	0.07 (±0.17)	0.04 (±0.14)	-0.03 (0.88)	0.04 (±0.14)	-0.03 (0.88)	0.1 (±0.20)	0.03 (0.88)	0.1 (±0.20)	0.03 (0.88)	0.024

* Change = degree/score at follow-up less value at initial application , ** Statistically significant (*p*-value <0.05)

Data are presented as mean (± SD)

and age or severity at presentation, number of casts, or parent's education level[8,10]. Contrarywise, a study of the duration of brace wearing by Eamsobhana et al. in 79 children at Siriraj Hospital reported no significant association between bracing time less than 20 to 23 hours per day during the first 3 months and risk of recurrence[17].

There are many types of foot abduction braces designed for maintenance of foot position after clubfoot correction such as the Mitchell-Ponseti brace, the Steenbeek brace, the Dobbs brace, and a brace from the Xin-Hua Hospital, China. The Steenbeek brace is less expensive than the others, but neither the length of the bar nor the abduction angle of the foot can be adjusted. The brace from Xin-Hua Hospital, China is also not adjustable for length or angle, but it is lighter in weight. The Mitchell-Ponseti brace is adjustable for length and angle, but is more expensive than the others and has been found to provide no increase in level of parental compliance with bracing recommendations. The Dobbs brace is a dynamic foot abduction orthosis that has achieved a higher level of parental compliance with bracing with a low incidence of complications, but it is very expensive, costing around 1,200 USD[12-15].

The ergonomic function principle of the DUTh brace is different from other foot abduction braces. The DUTh brace is more comfortable as it is custom-made, is light weight (200 grams), is easy adjustable by parents for length and angle, and provides easy heel accessibility. Efficacy of the DUTh brace in static maintenance of the position of the foot was demonstrated in the present study by the absence of significant change in the Dimeglio or Pirani scores during the entire 12 month follow-up period. The DUTh brace is also relatively inexpensive (about 33 USD). In Thailand, the brace is provided free under the universal health care system in Thailand.

There is no consensus about a definition of noncompliance with the recommended period of daily use of an orthosis. Dobbs et al[6] and Abdelgawad et al[18] suggested using complete discontinuance of the orthosis, while Morcuende et al[19] suggested that noncompliance should be defined as use of the brace for less than 10 hours per day. In the present day, noncompliance was considered to be use of the brace for less than 15 hours per day. Noncompliance using the DUTh brace was 33% (10 of 30 patients) compared with 41% noncompliance by patients with a traditional foot abduction brace, in both cases using the 15 hours per day definition of noncompliance. With the custom-made fit and the light weight of the orthosis, compliance with the DUTh brace was increased, but it did not reach the noncompliance level of 7.1% with the Dobbs brace[14]. Most parents reported sleeping problems of the child wearing the brace was the reason for noncompliance. Although the present study found an average of 16 hours brace use per day during the first 3 months, a rate not similar to the Ponseti protocol, a recent study of duration of brace wearing found that a duration of less than 23 hours did not adversely affect the ability to maintain the foot correct foot position[17].

The DUTh brace provides greater efficacy in maintenance of the corrected foot position, even with shorter periods of brace use during the first 3 months. Another advantage of the DUTh brace is the low incidence of complications, with only one incident of a skin problem (3%) compared with a complication rate of 23.5% using a traditional foot abduction brace

and 7% using the Dobbs brace[14].

One limitation of the present day is that only the position and flexibility of the feet was recorded, but not the patient's function and acceptance of wearing the brace. Another limitation is that the efficacy of the brace was calculated without regard to brace wearing time, something which could potentially obscure the actual efficacy of the brace. Finally, the present study did not collect data on recurrence or on reoperative treatment. These data could be included in a future prospective randomized controlled trial for the purpose of evaluating newly developed types of abduction brace for maintenance of correction in idiopathic clubfoot patients.

Conclusion

The DUTh brace is a suitable alternative foot abduction brace for maintenance of foot position after clubfoot correction because of its advantages, e.g., being more comfortable as it is custom made, being light weight, being easily adjustable for length and angle by parents, affording easy heel accessibility, the efficacy in static maintenance of the desired child's foot position, and the low incidence of complications.

What is already known on this topic?

According to failure of bracing compliance, some physician tried to design new orthosis but some disadvantages were persist such as Mitchell-Ponseti brace, Steenbeek brace, Dobbs brace, brace from Xin-Hua Hospital, China. The Steenbeek brace has lower cost but unable to adjust the length of the bar and the abduction angle of the foot. The brace from Xin-Hua Hospital, China was also unadjustable for length and angle but light weight. The Mitchell-Ponseti brace could adjust for length and angle but it was more expensive than the others and still not provide better result according to failure of bracing compliance. The Dobbs brace was a dynamic foot abduction orthosis that give more compliance and low complication but very expensive, costing around 1,200 USD.

What this study adds?

The workgroup created new orthosis named "DUTh" abduction brace. The principle of ergonomic function of DUTh brace is different from the other foot abduction brace. DUTh brace are more comfortable by custom-made, light weight with only 200 grams, easy adjustable for length and angle by parents, easy heel accessibility, the efficacy in static maintenance of desirable child's foot as the present study showed no significant change in Dimeglio and Pirani score at all 12 months follow-up, inexpensive with cost about 33 USD.

Potential conflicts of interest

The authors declare no conflict of interest.

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