Original Clinical Article

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Inferior results with unilateral compared with bilateral brace in Ponseti-treated clubfeet

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Abstract

Purpose The Ponseti method for treating clubfoot was introduced in Norway in 2003, and a cohort of children has been followed for 8 to 11 years. In a previous study, we found good results after follow-up of two to five years, with 3% rate of extensive surgery (posterior release or posteromedial release). During 8 to 11 years of follow-up, the rate of extensive surgery increased to 11%. The children had been treated with a bilateral brace or a unilateral brace. In this multicentre study we aimed to compare these two post-corrective treatment methods.

Methods In all, 94 children (133 feet) were initially treated according to the Ponseti method, and had post-corrective treatment with either a bilateral foot abduction brace or a unilateral above-the-knee brace. The children were examined at a mean age of 9.3 years (8 to 11) regarding flexibility and deformity of the foot and ankle. Information including type of brace, brace compliance and surgical procedures was obtained from the patient records. The parents answered questionnaires and radiographs were taken of the feet.

Results Feet treated with a bilateral brace had better dorsal flexion ($p = 0.008$), plantar flexion ($p = 0.02$), external rotation ($p = 0.001$) and less forefoot adduction ($p = 0.04$) than feet treated with a unilateral brace. Children using a bilateral brace had a better Functional Rating System score ($p = 0.005$) and Disease Specific Instrument score ($p = 0.02$).

Conclusion Children treated with a bilateral brace had better parent-reported outcomes and more flexible feet than children treated with a unilateral brace. Our results do not support the use of a unilateral foot abduction brace in clubfoot treatment.

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Introduction

Clubfoot is a common congenital deformity with an incidence of about 1.4 per 1000 in the Scandinavian population.[1] During the last 10 to 20 years the treatment has shifted towards non-operative Ponseti treatment,[2-7] and this method is efficient also in non-idiopathic clubfeet.[8-10] The primary treatment goal is to correct the deformity with serial casting, followed by a percutaneous tenotomy of the Achilles tendon if necessary to achieve satisfactory range of motion in the ankle. Second, the purpose of the treatment is to prevent recurrences, and post-corrective brace treatment is recommended until the age of four years. Ponseti's recommendation was to use a bilateral foot abduction brace,[11] but unilateral braces have also been used following Ponseti casting treatment.[12,13] In a previous multicentre study we found good results at two to five years of follow-up, and only five feet (3%) were treated with extensive surgery (posterior release or posteromedial release) due to relapse.[14] Approximately two-thirds of patients had used a bilateral foot abduction brace and approximately one-third had used a unilateral dynamic foot abduction brace. We were not able to detect differences in outcome between the two braces. Follow-up of the patients at 8 to 11 years revealed that the rate of extensive surgery had increased from 3% to 11%.[15] Poor compliance with the brace is a common problem in the treatment of clubfeet[4,16,17] and prolonged use of the brace improves the results.[18] Both brace compliance and type of brace might explain the increased rate of surgery over time in our patient cohort, and the aim of the present study was to search for potential differences between children treated with a bilateral foot abduction brace and children treated with a unilateral brace at follow-up of 8 to 11 years of age.

Methods

All children born between 2004 and 2006 with congenital, idiopathic clubfoot treated at eight hospitals in Norway were prospectively registered and eligible for the study.

During the last part of 2014, one of the authors visited all eight hospitals and performed a standardised examination of the children registered. The children are from the same cohort previously reported with short-term results after introducing the Ponseti method in Norway[14] and a study comparing Ponseti treatment to traditional treatment.[15] Of the children examined in 2014, 115 were confirmed to have idiopathic clubfoot and had been treated with the Ponseti casting technique. Approximately two-thirds of the children had used a standard bilateral foot abduction brace to prevent recurrence, but mainly two hospitals prescribed a unilateral brace. A majority of the children using the bilateral foot abduction brace used the Markell boots and bar (Fig. 1), but eight children used the Alfa-Flex brace. Fourteen children switched from the Markell brace to another model of bilateral foot abduction brace, 11 children switched to the Alfa-Flex brace and three children switched to the Mitchell brace. The unilateral brace is custom-made, dynamic and above-the-knee, and has a rubber band on the lateral side of the ankle joint which enables the brace to both dorsiflex and partially to externally rotate the foot (Fig. 2).[14] Information about type of brace, compliance and any changes in type of brace used was prospectively registered in the patient records at each visit, and was collected from the records at the follow-up in 2014. It was recommended to use the brace night and day for the first three months, and thereafter every night until the age of four years. Brace compliance was graded: 'Poor' = brace used less than two years or less than six hours every night; 'Fair' = brace used more than two years and more than six hours every night, but terminated before the age of four years; and 'Good' = brace used minimum ten hours every night until the age of four years.

To find potential differences in the results after using the two types of braces, we compared children treated only with a bilateral brace (62 children, 88 feet) with children treated only with a unilateral brace (32 children, 45 feet). Children changing type of brace during treatment were excluded from this study (Fig. 3). The sample size of Children using the bilateral brace was twice as big, had a lower rate of initial tenotomy of the Achilles tendon and were treated with fewer casts. Otherwise, the two groups were equal (Table 1).

Information about operations due to recurrence was collected from the patient records. Relapse surgery in the two brace groups consisted of re-tenotomy (6/132 feet, 4.5%), open Achilles tendon lengthening (2/132 feet, 1.5%), tibialis anterior tendon transfer (19/132 feet, 14%) or Posterior release or posteromedial release operation (13/132 feet, 10%). The posteromedial release was performed as described by Turco with the navicular bone stabilised to talus with a K-wire transfixion.[19] The posterior release was performed also as described by Turco, without extending the dissection distally on the medial border of the foot.

Achilles tendon tenotomy, Achilles lengthening and tibialis anterior tendon transfer were defined as minor surgery. Soft-tissue release operations were defined as extensive surgery.

Outcome measures

Flexibility and deformity

A hand-held goniometer was used to measure dorsal flexion and plantar flexion in the ankle, external rotation of the foot and ankle, and forefoot adduction.

Parent-reported outcome

We used two different clubfoot-specific questionnaires regarding the child's level of pain, function and satisfaction. Laaveg and Ponseti's Functional Rating System for clubfoot consists of three specific questions regarding the child's satisfaction, function and pain.[3] In addition, the

Fig. 1 Bilateral foot abduction brace, Markell type.

Fig. 2 Unilateral brace, left side. Front and lateral view.

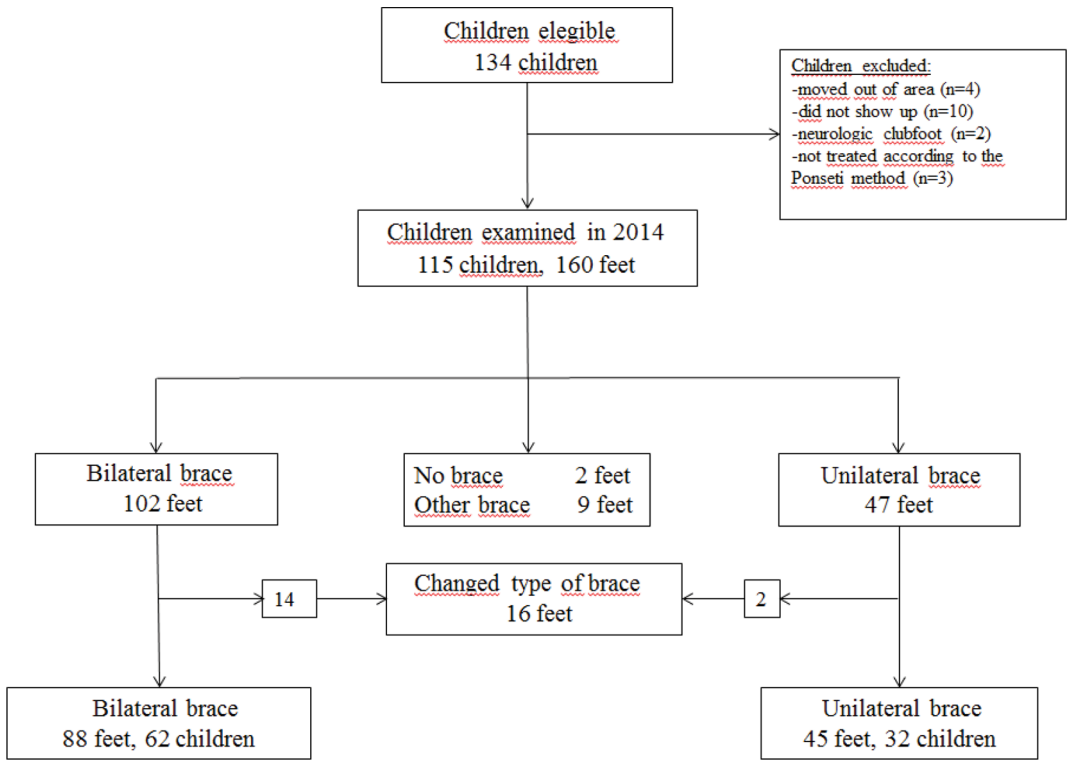

Fig. 3 Flow chart of children included in the study and type of brace used.

Table 1. Patient demographics, initial treatment and brace compliance.

	Bilateral brace	Unilateral brace	p-value
Children (n)	62	32	
Gender (% boys)	75	64	0.2
Clubfeet (n)	88	45	
Bilateral	59%	56%	0.7
Age (yrs) at follow-up (range)	9.3 (8.0 to 10.6)	9.1 (7.7 to 10.6)	0.2
Pirani score at birth	4.9	4.9	0.9
Number of casts	6.5	7.9	<0.05
Initial tenotomy (n, %)	68 (77)	42 (93)	0.02
Compliance (n, %)			
Good	31/62 (50)	26/32 (81)	0.01
Fair	16/62 (26)	2/32 (6)	
Poor/Non-compliant	15/62 (24)	4/32 (13)	

score system consists of a physical examination/evaluation of the heel while standing, flexibility of the foot and ankle, and evaluation of gait pattern. The maximum (best) score is 100 points. Roye's Disease-Specific Instrument for clubfoot consists of ten questions regarding satisfaction and function, including pain.[20] All items are scaled from 1 (best) to 4 (worst) and a linearly transformation is used to transform each response to a 0 (worst) to 100 (best) scale, so 1 = 0, 2 = 33.3, 3 = 66.7 and 4 = 100. The total scores on the responses are added up and then divided on the number of items (ten items). This transformation of the Disease-Specific Instrument to a scale of 0 to 100 [21] was made for ease of interpretation, and is well described by Dietz et al.[22] The answers on the Disease-Specific Instrument scheme refer to the worst foot in bilateral cases. The parents completed both questionnaires.

Radiographic outcome

Standard anteroposterior and lateral radiographs were taken of both feet. The presence of flat top talus was assessed on the lateral view, and graded from 0 (normal concentric curve) to 3 (gross flattening).[23,24] A consultant paediatric orthopaedic surgeon and a consultant paediatric radiologist reviewed and graded all the radiographs together. Fourteen feet (11%) were not radiographed, and in seven feet (5%) a radiographic assessment could not be performed due to inaccurate lateral view images.

Looking for a correlation between talar flattening and both flexibility of the feet and functional score, we grouped talar flattening into two groups: normal/mild or moderate/severe.

Statistical methods

IBM SPSS version 22.0 was used for statistical analyses. To account for bilateral observations, we analysed the

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Table 2. Flexibility and forefoot adduction of the feet.

	Bilateral brace (88 feet)	Unilateral brace (45 feet)	p-value
Dorsal flexion (°)			
≥ 15	83% (73/88)	62% (28/45)	0.008
< 15	17% (15/88)	38% (17/45)	
Plantar flexion (°)			
≥ 35	16% (14/88)	7% (3/45)	0.02
25-35	68% (60/88)	58% (26/45)	
< 25	16% (14/88)	36% (16/45)	
External rotation (°)			
≥ 40	58% (51/88)	27% (12/45)	0.001
< 40	42% (37/88)	73% (33/45)	
Forefoot adduction (°)			
0	69% (61/88)	51% (23/88)	0.04
5	11% (10/88)	9% (4/45)	
≥ 10	19% (17/88)	40% (18/45)	

Table 3. Parent-/patient-reported functional outcome and number of operations due to relapse.

	Bilateral brace (62 children, 88 feet)	Unilateral brace (32 children, 45 feet)	p-value
Functional Rating Score	87 points	78 points	0.005*
Disease Specific Instrument score	82 points	74 points	0.02
Relapse surgery	21 (24%)	19 (42%)	0.03*
Minor surgery†	12 (14%)	15 (33%)	0.006
Major surgery‡	9 (10%)	4 (9%)	0.8

*To account for bilateral observations, generalised estimations equations (GEE) was used

†Minor surgery: re-tenotomy of Achilles, Achilles lengthening and tibialis anterior tendon transfer

‡Major surgery: posterior release and posteromedial release

Functional Rating System (continuous data) and the data regarding relapse operations (categorically data) using generalised estimations equations (GEE). All other categorical data were analysed using Chi-square test. Regarding the Disease-Specific Instrument, there is only one score per patient and these data were analysed using t-test. p-values < 0.05 were considered to be statistically significant.

Ethics

The study was approved by the Regional Ethics Committee of western Norway (191.03).

Results

Compared with the unilateral brace, use of a standard bilateral foot abduction brace gave significantly better flexibility (dorsal flexion, plantar flexion and external rotation) and less forefoot adduction (Table 2). Children treated with a bilateral brace also had higher parent reported functional outcome based on the Functional Rating System and the Disease-Specific Instrument (Table 3). Feet treated with a unilateral brace had higher risk of surgery due to recurrence (Table 3). A higher prevalence of talar flattening was seen in feet treated with the unilateral brace, and all five feet with severe talar flattening were treated with this brace (Table 4). Feet assessed to have moderate or severe talar flattening had reduced dorsal flexion ($p < 0.001$), reduced plantar flexion ($p = 0.002$), increased forefoot adduction ($p < 0.001$) and low Functional Rating System score ($p < 0.001$) compared with feet assessed to have normal or mild talar flattening. Overall, brace compliance was good in 61%, fair in 19% and poor in 20% of the children, with best compliance among children using the unilateral brace ($p = 0.001$; Table 1). Poor brace compliance did not result in reduced flexibility, deformity or inferior functional outcome and we found no correlation between compliance and relapse operations. Additionally, we did not find a correlation between brace compliance and results when doing stratified analysis on bilateral brace only and unilateral brace only.

Table 4. Talar flattening on radiographs.

	Bilateral brace (69 feet)*	Unilateral brace (43 feet)*	p-value
Normal	12 (17%)	3 (7%)	0.006
Mild	44 (64%)	22 (51%)	
Moderate	13 (19%)	13 (30%)	
Severe	0	5 (12%)	

*Fourteen feet were not radiographed, and seven feet were excluded from this analysis due to poor quality of radiograph

Discussion

Children treated with a standard bilateral foot abduction brace had better flexibility and functional outcome, less forefoot adduction and less talar flattening than children treated with a unilateral, dynamic, above-the-knee brace. The need for surgery due to recurrence was lower in the bilateral brace group even five years after termination of the brace. It was easier for the family and child to comply with the unilateral brace, and most of the children who changed brace were initially treated with the bilateral brace (not included in the study, see Fig. 1).

Using a unilateral brace is not in accordance with the protocol for Ponseti treatment, but some authors have tried unilateral braces due to compliance problems associated with the strict bracing protocol. Data regarding outcome after the use of alternative braces is limited, but in general the results of unilateral braces have been found inferior to the standard bilateral brace.[12,13] In our two- to five-year

follow-up study from 2012, we were not able to demonstrate any differences between the standard bilateral foot abduction brace and a custom-made unilateral dynamic foot abduction brace.[14] In that study, the analyses were performed based on the intention to treat principle. In the present study, however, only children who did not change type of brace were included in the analyses, to avoid misinterpretation of patients changing brace type during treatment. Our results indicate that the bilateral brace has better effect in children followed until the ages of 8 to 11 years, compared with the unilateral brace. The unilateral brace used by children in our study was custom-made and above the knee, enabling the brace to hold the foot in an external rotated position, unlike a plain ankle foot orthosis. Together with a hinged ankle joint with a rubber band on the lateral side of the joint and a flexed knee, this orthosis exerts both dorsal flexion- and abduction forces on the foot. Even so, the unilateral brace in our study could not match the results of the bilateral brace.

Most authors find a relation between recurrences and brace compliance.[16,18,25] Even if Ponseti recommended using the brace for four years, the definition of compliance/ non-compliance varies greatly. Some report non-compliance as complete discontinuation of the use of the brace,[25,26] while others have defined good compliance as night time bracing until 12 months of age, and poor compliance as termination before that.[16,27,28] Defining non-compliance as use of brace less than ten hours per day before four years of age is a more strict definition.[4,29] It is our experience that children often partly comply with the brace and that is why we differentiated brace compliance. Overall brace compliance in our study was rather good as 61% of the children used the brace as prescribed for four years, and 20% were defined as poor or non-compliant. However, the exclusion of children who changed type of brace prior to the analyses, bias the results slightly toward better compliance. This might explain why we did not find a correlation between poor compliance and flexibility, deformity, functional outcome or risk of relapse operations. Another possible explanation for not finding this correlation might be that mild feet end up with a good result despite poor compliance. Information concerning brace compliance was parent-reported, and even though this information was prospectively recorded in the patient records on each visit, one can assume that parents overestimate the hours their child use the brace, as documented by Sangiorgio et al.[30]

The patients and their parents are maybe the best to judge the result after clubfoot treatment. That is why we used patient/ parent reported assessment tools. As the children were only 8 to 11 years of age, we let the parents complete the Functional Rating System questionnaire, and we used the originally parent-based version of the Disease Specific Instrument for clubfoot.[20]

Different radiological measures have been used when evaluating clubfoot treatment.[31,32] It is reasonable to assume that dorsal- and plantar flexion movement is influenced by the shape of the dome of the talus. Dunn and Samuelson introduced the radiographic classification of flat top talus in adults,[23] and the classification was later used in children and adults by Hutchins et al.[24] The prevalence of flat top talus in our patient cohort was higher than that of Hutchins et al. and lower than what Dunn and Samuelson reported. The prevalence of moderate and severe talar flattening was higher when using a unilateral brace. We found a strong correlation between talar flattening and reduced flexibility, more forefoot adduction and low Functional Rating System score. We believe talar flattening is at least to some degree an iatrogenic injury caused by pressure forces on the talar dome during treatment. A higher prevalence of moderate and severe flat top talus in traditional surgical treatment compared with Ponseti treatment may support this.[15] In a study of 11 idiopathic clubfeet investigated with MRI scan at the age of 2.5 to 3 months, no signs of flat top talus was found, indicating that this deformity occurs later.[33] The unilateral brace used in this present study is a dynamic brace with a rubber band over the joints, placing constant dorsal flexion forces over the ankle joint. This might explain the higher prevalence of moderate and severe flat top talus after using this unilateral brace.

A weakness of this study is that the patients were not randomly allocated to the two different treatment groups, but the unilateral brace was mainly used in two of the eight hospitals. There was also a difference in the rate of tenotomy and number of casts between the two groups, which could theoretically indicate a selection bias with more difficult cases in the unilateral brace group. There were no differences between the two groups regarding gender, age, bilateralism and Pirani score at birth. We believe the difference in number of casts and rate of initial tenotomies between the two groups expresses difference in treatment approach at the different hospitals, rather than differences in severity of the deformity between the two groups. A tenotomy rate of 77% in the bilateral brace group is higher than that reported by Ponseti,[11] indicating that feet in the bilateral brace group are not particularly easy cases.

A fairly high number of patients included in the study and few patients lost to follow-up, strengthen this study.

In conclusion, after 8 to 11 years of follow-up there are significant differences in the results between clubfeet treated with a bilateral foot abduction brace and those treated with a unilateral, dynamic, above-the-knee brace. Children who used the bilateral brace to prevent relapse had better flexibility, less deformity, better patient- and parent-reported outcomes, and less talar flattening deformity on radiographs. Despite better compliance with the unilateral brace, our study does not support the use of unilateral braces to prevent relapse in clubfoot treatment.

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COMPLIANCE WITH ETHICAL STANDARDS

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ETHICAL STATEMENT

All authors planned the study and participated in the interpretation of the results. CS examined all children and evaluated all radiographs. CS wrote the draft manuscript, but all authors contributed to improvement of the manuscript.

The study was approved by the Regional Ethics Committee of western Norway (191.03).

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