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FOOT ABDUCTION BRACE NONCOMPLIANCE IN CHILDREN WITH IDIOPATHIC CLUBFOOT: HOW THE DEEP SQUATTING POSTURE MIGHT HELP

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Background. Compliance with the foot abduction brace (FAB) is essential for idiopathic clubfoot (ICF) managed by the Ponseti method. The deep squatting posture (DSP) was correlated with favorable outcomes in ICF.
Aim. The aims of the study were to identify the noncompliance rate with the FAB, and assess how the routine practice of ankle stretching and Asian-style DSP affected the ICF correction during the Ponseti method.
Materials and methods. Of 42 children with ICF, 63 ICF underwent the Ponseti method at an average age of 8.7 ± 12.6 weeks using an average of 5.4 ± 1.7 casts followed by FAB wear. The children practiced the DSP exercise as an adjunct to the FAB protocol. Children noncompliant with the FAB protocol but compliant with the DSP exercise (group A) were compared with children noncompliant with both FAB protocol and DSP exercise (group B).
Results. At an average follow-up of 3.5 ± 1.4 years, 8 of 42 children compliant with the FAB protocol. The FAB protocol deviation was documented at an average of 10.3 ± 4.8 months. Children who did not adhere to the practice of the DSP exercise had a higher recurrent rate of any ICF deformity (OR 7.82, 95% CI 1.35–53.79, $p = 0.003$). Of the 34 children (48 feet) noncompliant with FAB, the children in group A (39 feet) had lower recurrence rate ($p = 0.02$), a better Dimeglio grade ($p = 0.005$), and a better Pirani score ($p < 0.001$) at the most recent evaluation than children in group B (nine feet). However, recurrent metatarsus adductus was more prevalent in group A.
Conclusion. The DSP exercise should be advocated as a supplemental modality but cannot substitute the regular use of FAB.

Keywords: clubfoot; foot orthotic device; muscle stretching exercise; patient compliance; recurrence.

НЕСОБЛЮДЕНИЕ РЕЖИМА НОШЕНИЯ БРЕЙСОВ У ДЕТЕЙ С ИДИОПАТИЧЕСКОЙ КОСОЛАПОСТЬЮ: КАК МОЖЕТ ПОМОЧЬ ПОЛОЖЕНИЕ ГЛУБОКОГО ПРИСЕДАНИЯ

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Обоснование. При лечении идиопатической косолапости по методу Понсети важную роль играет соблюдение режима ношения брейсов. Применение позиции глубокого приседания было связано с хорошими результатами лечения идиопатической косолапости.

Цель — определение частоты несоблюдения режима ношения брейсов и оценка влияния рутинного растяжения голеностопного сустава и азиатской позы глубокого приседания на коррекцию идиопатической косолапости при лечении по методу Понсети.

Материалы и методы. Коррекция 63 стоп по методу Понсети в среднем в течение 8,7 ± 12,6 нед. проведена 42 детям с идиопатической косолапостью, наложены 5,4 ± 1,7 гипсовые повязки с последующим ношением брейсов. В дополнение к брейсам дети выполняли упражнения с глубоким приседанием. Детей, нарушавших режим ношения брейсов, но выполнявших упражнения с глубоким приседанием (группа А), сравнивали с детьми, которые нарушали режим ношения брейсов и не выполняли упражнений с глубоким приседанием (группа В).

Результаты. Средняя продолжительность наблюдения составила 3,5 ± 1,4 года. Из 42 детей режим ношения брейсов соблюдали восемь. Несоблюдение режима ношения брейсов регистрировали в сроки 10,3 ± 4,8 мес. У детей, не выполнявших упражнения с глубоким приседанием, частота рецидива идиопатической косолапости была выше при любой деформации (относительный риск — 7,82; 95 % доверительный интервал — 1,35–53,79; $p = 0{,}003$). Из 34 детей (48 стоп), не соблюдавших режим ношения брейсов, при последнем осмотре в группе А (39 стоп) частота рецидива была ниже ($p = 0{,}02$), чем в группе В (9 стоп), степень по Димеглио ($p = 0{,}005$) и Пирани ($p < 0{,}001$) меньше. Однако рецидив приведения переднего отдела стопы чаще встречался в группе А.

Заключение. Выполнение глубокого приседания следует рекомендовать в качестве вспомогательной методики, но она не может заменить регулярного ношения брейсов.

Ключевые слова: косолапость; ортезы для стопы; упражнение на растяжение мышц; приверженность пациента лечению; рецидив.

Idiopathic clubfoot (ICF) is effectively managed by the Ponseti method [1–3]. The method starts with gentle manipulation and weekly serial casting. Before the final casting, percutaneous tendoachilles tenotomy (pTAL) is performed to ensure that the deformity is completely corrected. To maintain the correction after casting, a foot abduction brace (FAB) with a transverse bar is prescribed according to the protocol recommended by Ponseti until the age of four years [1, 4].

Compliance with the FAB protocol is the most crucial part of the Ponseti method to achieve a successful outcome [3, 5, 6]. It is a challenging process and requires immense commitments of the caregivers. The relapse risks of the deformity are increased in children who are FAB noncompliant [1, 7]. Several strategies have been recommended to improve children's and caregivers' compliance. Nonetheless, the noncompliance rates as high as 42–60% have been reported [2, 8]. In addition to FAB wear, an ankle-stretching exercise is encouraged during the off-brace time to maintain a range of ankle dorsiflexion [1, 7].

The deep squatting posture (DSP) is commonly practiced among different ethnicities and cultures across Asia [9, 10]. The position is regularly performed in the Asian lifestyle, e.g. during praying or using the toilet. A recent study demonstrated that the ability to perform the squatting position was associated with several favorable parameters of clubfoot after the Ponseti method [11]. The DSP could be recommended as a supplemental exercise to preserve the range of ankle dorsiflexion and to maintain the correction of ICF deformity throughout the maintenance phase of the Ponseti method.

The aims of the study were to identify the noncompliance rate with the FAB, and assess how the routine practice of ankle stretching and Asian-style DSP affected the ICF correction during the Ponseti method.

Materials and methods

Research design

During the 2011–2016 study period, medical records of children with ICF undergone the Ponseti method at a university-affiliated tertiary care hospital were retrospectively reviewed. We excluded clubfoot with neuromuscular system involvement or known syndromes associated with limb deformities. One of the authors (NL) was responsible for performing the Ponseti method, and pre-treatment and follow-up evaluations. Demographic data and compliance with the FAB protocol and the DSP exercise were retrieved. Clubfoot severity was classified according to the Dimeglio grading system and rated by the Pirani score at the initial presentation and at the most recent follow-up visits.

The Ponseti FAB protocol was instructed to all families after the final casting was completed and the ICF was fully corrected, determined

clinically by forefoot abduction more than 70° and ankle dorsiflexion more than 15° [1]. The type of FAB (fixed vs. articulated) was chosen based on the caregivers' discretion. The FAB protocol after the cast was divided into three phases as initial (the first three months after the final cast), weaning (the following 6-month period) and maintenance (until four years of age) phases. The recommended FAB wear during each phase was 23, 14–22, and 12–14 hours, respectively [4]. The number of hours of wearing FAB was recorded according to the caregivers' report. All children were followed every 3 months after the initiation of the FAB protocol. Noncompliance was defined as any deviation from the recommended FAB protocol. The duration when the recommended FAB protocol starting to deviate after initiation of the FAB protocol was noted.

During the weaning and maintenance phases of FAB, caregivers were instructed to perform an ankle stretching exercise during the off-brace period, and the children were trained in the DSP exercise after they could walk independently. The ankle stretching exercise was performed by holding the foot, moving the ankle through a range of maximum dorsiflexion and plantar flexion following the recommendation by Dobbs et al. (Fig. 1) [1].

The DSP exercise, a squatting position defined as sitting with both feet flat on the floor, dorsiflexion of the ankles, full flexion of the knee and hip joints, and the ischial tuberosity just above the ground (Fig. 2*a* and *b*), was practiced for at least 15 minutes twice daily [9, 10]. DSP should be included in the child's daily activities, such as playing with toys. Fig. 2*c* shows an improper positioning of the feet during the DSP exercise. Compliance with ankle stretching and DSP exercises was documented during each clinic visit.

a *b*

Fig. 1. Stretching exercise of the ankle. (*a*) plantar flexion position; (*b*) dorsiflexion position

Research findings

Children with ICF who were noncompliant with the FAB protocol were divided into two groups. Group A were children who adhered to the stretching and DSP exercises, and group B were those who did not. Recurrence of ICF deformity was defined as the recurrences of any deformity including ankle equinus, heel varus or metatarsus adductus (MTA) [3]. Outcome parameters including type of recurrence, degree of ankle dorsiflexion, Dimeglio grade, and Pirani score were compared between groups A and B.

a *b* *c*

Fig. 2. The deep squatting posture. (*a*) frontal view, both feet should be flat on the floor and close together (arrows); (*b*) lateral view; (*c*) an improper position, both feet separated apart (arrowheads)

Table 1

A number of idiopathic clubfoot classified by the Dimeglio grade and the Pirani score during the treatment by the Ponseti method

N = 63 feet		Initial	The most recent follow-up	*P*
Dimeglio grade	I	7 (11%)	60 (95%)	<0.001
	II	7 (11%)	3 (5%)	
	III	9 (14%)	0	
	IV	40 (64%)	0	
Pirani score		5 (4.5–5)	0 (0–0.5)	<0.001

Note. Data were presented as number (percent) or median (interquartile range). *P*-values were calculated by χ^2-test or Mann-Whitney *U* test, as appropriate.

Statistical analysis

Statistical analysis was performed using Stata 13 (StataCorp LP, College Station, TX, USA.). Data were reported using number, percent, mean ± standard deviation (SD), range, and median (interquartile range) as appropriate. Mann-Whitney *U* test was used to compare continuous data and Chi-square (χ^2) or Fisher's exact test was used to compare categorical data, respectively. The noncompliance rate with the FAB protocol was calculated by the Kaplan-Meier analysis. The odds ratio was calculated for the chance of recurrence of the deformities and practice of the stretching and DSP exercises. *P*-values of less than 0.05 were considered statistically significant.

Results

Research sample (participants/respondents)

During the study period, 42 children with 63 ICF underwent the Ponseti method. There were 25 males (60%) and 17 females (40%), 21 unilateral ICF (50%) and 21 bilateral ICF (50%) cases, and 30 right ICF (48%) and 33 left ICF (52%).

The casting was initiated at our institution in 32 children (76%), 10 children (24%) had the initial cast elsewhere and were referred to our clinic for further management. The mean age at the first cast was 8.7 ± 12.6 weeks (range, 0.1–58.1). The average number of casts required before ICF attained a complete correction was 5.4 ± 1.7 casts (range, 3–12). Percutaneous tendoachilles tenotomy was performed in 58 feet (92%).

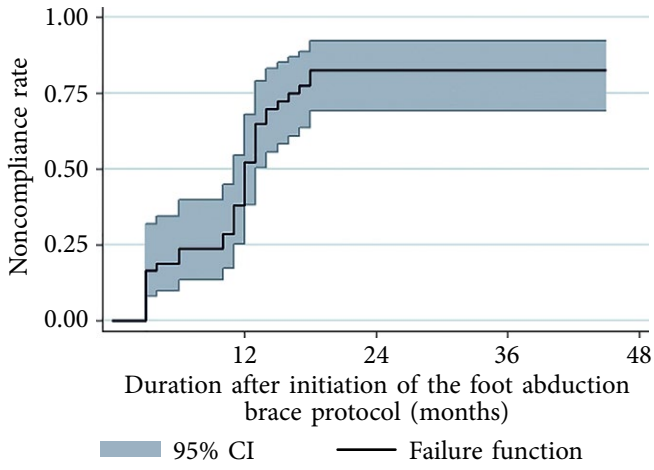

Fig. 3. A Kaplan-Meier estimate of the noncompliance with the foot abduction brace protocol

Primary findings

At the most recent evaluation, the average age of the children was 3.8 ± 1.4 years (range, 1.5–7.2) with the average duration after the final cast of 3.5 ± 1.4 years (range, 1.1–6.9). The average degree of ankle dorsiflexion was 24.6° ± 9.2° (range, 0–40°). Table 1 summarizes the number of ICF classified by the Dimeglio grading system and severity rated by the Pirani score before the initiation of the Ponseti method and at the most recent evaluation.

During the maintenance of the ICF correction by FAB, 25 children (60%) used the traditional Denis Browne type of FAB while 17 children (40%) used the articulated type (Dobbs bar). As reported by the caregivers, full compliance with FAB was noted in eight of 42 children. The deviation from the FAB protocol started at an average of 10.3 ± 4.8 months (range, 3–18) after the initiation of the FAB protocol. The noncompliance rate during the maintenance phase of the FAB was 0.82 (95% CI 0.69–0.92) after 18 months since the initiation of the FAB protocol as demonstrated by the Kaplan-Meier analysis in Fig. 3.

The type of bar utilized was not associated with the compliance with FAB ($p = 0.65$) or the recurrence

of the deformities ($p = 0.25$). The stretching and DSP exercises were regularly practiced in 36 of 42 children (54 feet, 86%). The correction was maintained in 46 of 63 feet (73%). Children who did not perform the stretching and DSP exercises demonstrated a significantly higher risk of recurrence of the ICF deformities (odds ratio 7.82, 95% CI 1.35–53.79, $p = 0.003$).

Table 2 summarizes the parameters of children with ICF based on compliance with the FAB protocol. A group of 34 children with 48 ICF that was not compliant with the FAB protocol was analyzed. Children who were noncompliant with FAB but performed regular exercise (group A) demonstrated a significantly higher number of feet that maintained correction, a significantly higher degree of ankle dorsiflexion, and a significant improvement of the Dimeglio grade and the Pirani score when compared with group B. However, recurrent MTA was still prevalent.

Undesirable phenomena

The five feet with recurrent ankle equinus underwent a soft tissue release "a la carte" procedure after failed reapplication of Ponseti casting [12], while recurrent MTA was flexible and a watchful observation was chosen.

Discussion

Summary of the primary research results

In the current study, the effectiveness of the Ponseti method for the initial correction of ICF was confirmed; however, a high rate of noncompliance with FAB wear was encountered early during the treatment course. MTA was the predominant recurrence deformity. We supplemented the stretching exercise and the practice of the Asian-style DSP to the Ponseti method. The study demonstrated that these additions could help to maintain the range of ankle dorsiflexion during the follow-up period. Although the stretching and DSP exercises were related to a lower risk of ICF recurrence, it must be emphasized that the stretching and DSP exercises could be, at best, a supplemental modality and are not intended to be a FAB substitute.

Discussion of the primary research results

Compliance with FAB is the most important contributing factor to the success of ICF treatment [1]. Strict compliance with the protocol decreases the recurrence rate and unplanned surgical intervention [2]. A wide range of noncompliance rates has been reported. Recurrence could be due to retraction of the posteromedial soft tissue of the ankle joint thus the use of FAB

Table 2

The parameters of children with ICF based on compliance with the FAB protocol

Parameters		Children noncompliant with the FAB protocol			Children compliant with the FAB protocol
		Group A	Group B	*P*	
Number of patients		28	6		8
Number of feet		39	9		15
Recurrence of deformities	no	28	3	0.02	15
	ankle equinus	2	3		0
	metatarsus adductus	9	3		0
Degrees of ankle dorsiflexion		20° (15°–25°)	10° (0°–20°)	0.03	30° (30°–35°)
Dimeglio grade at follow-up	1	39	6	0.005	15
	2	0	3		0
Pirani score at follow-up		0.5 (0–0.5)	1 (0.5–2.5)	0.02	0

Note. FAB; foot abduction brace. Data are presented as number or median (interquartile range). *P*-values were calculated by χ^2-test, Fisher's exact or Mann-Whitney *U* test between the data in groups A and B. Group A: Children noncompliant with the foot abduction brace protocol who adhere to the stretching and deep squatting posture exercises. Group B: Children noncompliant with the foot abduction brace protocol who do not adhere to the stretching and deep squatting posture exercises.

maintains the position and the flexibility of the corrected foot while the soft tissue becomes mature [3, 13]. Compliance with the FAB protocol should be emphasized to the caregivers at every clinic visit. Leg hourglass and orthotic wear signs are a simple clinical sign to confirm the compliance with FAB and should be observed [13]. The definitions of noncompliance with FAB vary widely and the calculated time is based on different resources, mainly caregivers' reporting [2, 3, 8]. Nonetheless, we found a high rate of noncompliance with FAB. Families deviated from the recommended protocol as early as within the first 3-month. Furthermore, full compliance with FAB was low at one year after the initiation of the FAB consistent with the findings in recent reports [6–8]. Noncompliance with FAB in different ethnicity and cultural background is a subject of debate [14]. This study was a cohort of Asians in a Thai cultural setting. Our 82% noncompliance rate was higher than those previously reported in other Asian countries, for example, Bangladesh (60%) [8], China (43%) [3], and Iran (23.3%) [7].

To improve FAB compliance rates, different approaches should be encouraged. Modifications of boots design with softer and durable materials or adding a dynamic component to the original Denis Browne bar have been introduced [15, 16]. Hemo et al. compared clinical outcomes of ICF and found no difference between the silicone type orthosis with detachable shoes and the Denis Browne bar [16]. Chen et al. confirmed that a new design of bar with single-plane movement joints was effective in improving the compliance rate and maintained ICF correction [15]. In the current study, we utilized both Denis Browne bar and Dobbs bar but could not demonstrate any difference in compliance and recurrence.

The range of ankle dorsiflexion after treatment is the major factor associated with functional outcome. Our findings emphasized the necessity of pTAL, an important part of the Ponseti method [2, 17, 18]. A low threshold of performing pTAL before the final casting should be applied, as this might facilitate the stretching and DSP exercises performed by the children and caregivers during the follow-up period. The pTAL did not disturb calf muscle development [17]. As the child becomes an adult, decreased ankle flexibility was associated with limited functional capabilities in daily activities in adulthood [9, 10]. In contrast, tendoachilles tenotomy performed as a part of the soft tissue release procedure for ICF was associated with calf muscle weakness [12].

The noncompliance rate found in our cohort highlighted the urgent need for other additional treatment to prevent a recurrence. A routine practice of stretching exercises by the caregivers prevented recurrences and improved the Dimeglio grade during follow-up [7]. Current recommendations include stretching exercise of the ankle during the off-brace period to maintain the range of ankle dorsiflexion [1]. The DSP is a common sitting position practiced in many cultures across Asian [9]. We postulated that the ankle dorsiflexion position during squatting would maintain the elongation of the soft tissue after casting. This was supported by the finding of structural adaptation at the myotendinous junction after dynamic exercise and an increase of ankle range of motion and tendoachilles length after static stretching [19]. Stretching may increase the passive range of motion, and decrease stiffness and resistive torque at the muscle-tendon unit [20]. The ability to perform squatting has been used as a clinical assessment during follow-up and correlated with favorable outcomes [11]. We advocate routine daily exercise for every child as it could maintain a high range of ankle dorsiflexion.

In contrast, children who suffered from recurrent MTA were prevalent. The DSP might not result in an adequate abduction of the feet when compared with the 70-degree abduction position acquired during the FAB wear. All recurrent MTA in our study were flexible; however, the consequences of an imbalanced muscle need to be elucidated. An abductor hallucis tenotomy could be a viable option for recurrent MTA to correct the forefoot abduction during casting. A more rigid MTA in recurrent ICF cases could lead to dynamic supination of the foot and might need a tibialis anterior tendon transfer (TAT). We anticipate that the recurrent MTA could be increased during the long-term follow-up of our cohort. We recommended that the FAB is still the mainstay treatment to prevent the recurrence of ICF. The physician should promote the FAB wear since the recommended exercise could maintain only the range of ankle motion but could not prevent the recurrence of MTA, which is a part of the ICF deformity. Caregivers should

be made aware of the possibility of an additional tendon transfer procedure or a soft tissue release procedure during the follow-up period if they do not comply with the FAB protocol [5, 12].

Research limitations

There were limitations to the study. Due to the nature of the retrospective study, the compliance with the FAB protocol and the DSP exercise was based on caregivers' self-report and was subject to recall bias. Therefore, the number of children noncompliant with the FAB protocol could be significantly higher. The FAB wearing-period in some of the children with ICF was shorter than the recommended 4-year period [4]. Nevertheless, the optimal duration of the FAB protocol is a subject of ongoing research [5]. Longer follow-up might also demonstrate even lower compliance rates. The usefulness of the stretching and DSP exercise needs to be confirmed in a prospective study with a control group.

Conclusion

In conclusion, our findings confirmed that FAB wearing during the Ponseti method was challenging and the noncompliance rate was high. Physicians treating the children with ICF should regularly educate their children's families, and prepare to explore the reasons behind noncompliance and solve the problem as soon as it is identified. The routine practice of the stretching exercise by caregivers and the DSP exercise by children might maintain the range of ankle dorsiflexion in the short-term, although it might not prevent recurrent MTA.

Additional information

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Conflict of interests. Authors declare no explicit and potential conflicts of interests associated with the publication of this article.

Ethical statement. This study was approved by the ethical review board of the Faculty of Medicine, Chulalongkorn University (COA 939/2017), and complied with the declaration of Helsinki and its later amendments. Formal inform consent was exempted for this type of study.

Author contributions

P. Sailohit — methodology, validation, formal analysis, investigation, data curation, writing — original draft.

N. Limpaphayom — conceptualization, methodology, validation, formal analysis, investigation, data curation, writing — review & editing, visualization.

All authors made a significant contribution to the research and preparation of the article, as well as read and approved the final version before its publication.

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