Original Clinical Article

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A modification of the Ponseti method for clubfoot management: a prospective comparative study

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Abstract

Purpose We aimed to compare our parent-based exercise programem's efficacy with the foot abduction brace (FAB) Ponseti manipulation as a retention programme.

Methods We conducted this prospective multicentre cohort study between August 2009 and November 2019. The included children were allocated into one of two groups according to the retention protocol. The Pirani and Laaveg-Ponseti scores were used to assess the feet clinically and functionally. Radiological assessment was performed using standing anteroposterior and lateral radiographs of the feet. We assessed the parents' satisfaction and adherence to the retention method. SPSS version 25 was used for the statistical analysis.

Results A total of 1265 feet in 973 children were included. Group A included 637 feet managed with FAB, while group B included 628 feet managed with our retention programme. All patients were followed up to the age of four years. At the final follow-up, Pirani scores in group A participants were excellent, good and poor in 515, 90, and 32 feet, respectivel, while in group B the scores were excellent, good and poor in 471, 110 and 44 feet, respectively. The mean total score of Laaveg-Ponseti was 87.81 (sd 19.82) in group A and 90.55 (sd 20.71) in group B (p = 0.02). Group B participants showed higher satisfaction with the treatment method (p = 0.011) and more adherence to the treatment (p = 0.013).

Conclusion The deformity's recurrence related to the brace's non-compliance in the Ponseti method might be reduced by substituting the brace with our home-based daily stretching exercises.

Level of Evidence: II

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Keywords: idiopathic clubfoot; modified Ponseti method; Pirani score; stretching programme; daily exercise programme; Dennis Brown splint; reoccurrence; talipes equinovarus; idiopathic congenital talipes equinovarus

Introduction

The Ponseti method, a manipulative technique to correct congenital clubfoot with no need for invasive surgeries, has become widely accepted as the strandard management for clubfoot.[1] This method involves serial manipulations, casting of the clubfoot, tenotomy in most cases and long-term bracing using a foot abduction brace (FAB) as a retention programme to prevent the recurrence of deformity.[2-4] Although using the foot abduction brace is an essential part of the treatment, it does not dramatically improve the foot's appearance or function.[2,4] The use of FAB could be challenging to the child, family and healthcare team with variable compliance rates.[5,6] Non-adherence and non-compliance to FAB use is the most common cause of deformity recurrence.[6-10] The parental non-adherence to FAB use can affect 34% to 61% of children, resulting in five- to 17-fold higher odds of relapse.[2,9,11] A suggested alternative to the FAB is using a specific manipulation programme that may be as effective as the FAB with a higher compliance rate.[9] This study assessed our parent-based exercise programme's efficacy compared with the FAB Ponseti manipulation as a retention programme.

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Materials and methods

The study was performed in compliance with the recommendations of the declaration of Helsinki.[12] We followed the Strengthening the Reporting of Observational Studies in Epidemiology guidelines while reporting the results of our study.[13] We conducted this prospective multicentrd cohort study within the period from 15 August 2009 to 22 November 2019. Multiple certified Ponseti-trained surgeons participated in the management of the patients. The surgeons treated, casted and assessed the included children during the follow-up period.

The children meeting the following criteria were included in our study: 1) patients with genuine idiopathic typical clubfoot presented in the first month of life; 2) patients whose parents or caregivers agreed to participate in the study and signed informed consent.

All cases with genetic, neurological pathology, atypical clubfeet or previous treatment history were excluded from the study.

A total of 1320 clubfeet in 1018 children (code Q66.0, International Classification of Diseases, World Health Organization) were identified.[9,11] In total, 55 feet in 45 children were excluded because they did not meet our inclusion criteria or due to the incomplete follow-up data. A total of 1265 feet in 973 children were included in our study and completed the final follow-up (supplementary material). At baseline, each patient underwent a detailed orthopaedic and paediatric examination. According to the Pirani score, the feet were given a score between 0 and 6.[1,14,15] The results were excellent for scores between 0 and 1, good for scores between 1.5 and 2.5 and poor for scores > 3. The feet were given a score out of 100 points according to the Laaveg-Ponseti functional scoring system.[8-11] A score of 90 to 100 points was rated excellent; 80 to 89 points were good, 70 to 79 points were fair and < 70 points were rated as poor.[11,16,17] The radiological examination was performed at the final follow-up visit by obtaining the standard standing anteroposterior (AP) and lateral radiographs of the foot. The following angles were used: AP and lateral talocalcaneal angles (TCA). Both were used to calculate the talocalcaneal index (TCI).[18-20] The normal feet of the patients with unilateral clubfoot served as controls.[21-23] The feet were manipulated and casted weekly according to the Ponseti method. Percutaneous tendon Achilles tenotomy was done if ankle dorsiflexion was < 15°. The tenotomy cast was continued for three weeks.

At the time of removal of the final cast, the patient was categorized into one of two groups of retention programmes: 1) group A (standard Ponseti method): the parents were instructed to use FAB for 23 hours per day for three months. After that, for a minimum of ten hours at night time up to the age of four; 2) group B (modified Ponseti group): the parents were instructed for a home-based exercise programme up to the age of four years without using any braces. The exercise programme consisted of dorsiflexion and foot abduction maneuvers, 50 times for each maneuver to be repeated five times a day during the first two years of life and then three times a day up to the age of four[9] (Fig. 1 and supplementary material). A full explanation of the nature of deformity, stages of correction, the possibility of tendoachillis tenotomy and the importance of adherence to brace or exercise was given to parents or caregivers.

All feet were assessed at regular follow-up (every month for the first six months, then every three months in the first three years and every six months until the latest follow-up). During follow-up visits, the physicians assessed the feet clinically using the Pirani score and functionally using the Laaveg-Ponseti score[11] (supplementary material). During each follow-up visit, the physicians assessed the parent's adherence to the retention programme. The parents' compliance and adherence to the retention programme were assessed via the questioner, asking the parents in each visit about their satisfaction with the treatment method (either brace or exercises). Also, they were asked about the adherence to the programme and whether they would recommend their retention programme to others or not (supplementary material). In group A, non-adherence to bracing was defined as caregivers reporting more than two hours less than prescribed daily wear. For group B, non-adherence was defined as caregivers reporting sessions less than three times/day. Relapse was defined as the reappearance of any component of the clubfoot deformity, necessitating further treatment.

Feet with recurrent deformity were managed according to the timing of recurrence and severity. In most cases, the correction of the deformity was achieved with manipulation and multiple cast applications. For feet with a fair outcome, subsequent surgical intervention such as a limited posterior release (PR) was indicated when residual ankle equinus remained despite a previous percutaneous Achilles tenotomy. For feet with resistant equinus and varus deformities, a complete posteromedial release (PMR) was required to allow full correction of all the clubfeet deformities.

Statistical analysis

The collected data were computerized and statistically analyzed using the SPSS programme version 25 (IBM, Inc, Chicago, IL). Patients were analyzed per foot, and in the case of bilateral involvement, both feet were allocated in the same group and received the same treatment method. The unaffected feet in unilateral patients were considered the data for the normal limbs. Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as mean and SD or as median

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and range. The McNemar, paired Wilcoxon, and Spearman correlation co-efficiency tests were used according to the data type. The hypothesis of the difference between the two groups was checked using the chi-square test for discrete variables. A p-value of < 0.05 was considered statistically significant.

Results

A total of 973 children (1265 feet) were included in our study. Of them, 602 were boys (61.87%) and 292 children had bilateral involvement (30.01%). The patients were divided into two groups. Group A included 488 children (637 feet), while group B included 485 children (628 feet).

The mean age of all patients at the first consultation was 14.67 days (SD 3.61; 3 to 31) and it was 92.58 months (SD 29.04; 72 to 150) during the final follow-up examination. The demographic characteristics of the included patients are shown in Table 1.

The mean initial Pirani score was 4.73 (SD 1.8; 3 to 6) among group A patients, and it was 4.59 (SD 2; 2.5 to 6) among group B children, with no statistically significant difference (p = 0.07) (Table 2). Achilles tenotomy was required for 572 feet (89.8%) in group A patients and 551 feet (87.7%) in group B patients. The median number of casts was six (5 to 9) in group A and five (4 to 8) in group B. There was no statistically significant difference between both groups in terms of Achilles tenotomy or the number of casts (p= 0.53 and p = 0.16) (supplementary material). Gender and bilaterality were not significantly correlated with the number of casts. High collinearity of the Pirani score and the number of casts was observed, i.e. there was a positive correlation between the initial Pirani score and the total number of casts (r = 0.44; p < 0.001), as shown in Figure 2. At the final follow-up, the Pirani score ranged from 0 to 2.5, with a mean score of 0.82 (SD 0.81) in group A. While it ranged from 0 to 3 in group B, with a mean score of 0.86 (SD 0.83). We detected excellent, good and poor results in 515, 90 and 32 among group A children and 471, 110 and 44 among group B children. There was no statistically significant difference between the studied groups (Table 2). The functional outcome was assessed using the Laaveg-Ponseti score. The mean of the total score of the Laaveg-Ponseti score was 87.81 (SD 19.82) in group A children, and it was 90.55 (SD 20.71) in group B children, with a statistically significant difference between both group (p = 0.02). In group A, the scores were excellent, good, moderate and poor in 347 (54.5%), 207 (32.5%), 68 (10.7%) and 15 (2.3%) feet, respectively. While in group B, the scores were excellent in 327 (52%), good in 214 (34.1%), moderate in 79 (12.6%) and poor in 8 (1.3%) feet (Table 3). Regarding the Laaveg-Ponseti score's satisfaction item, 78.81% of group A were very satisfied, 12.24 % were satisfied and 8.95% reported being

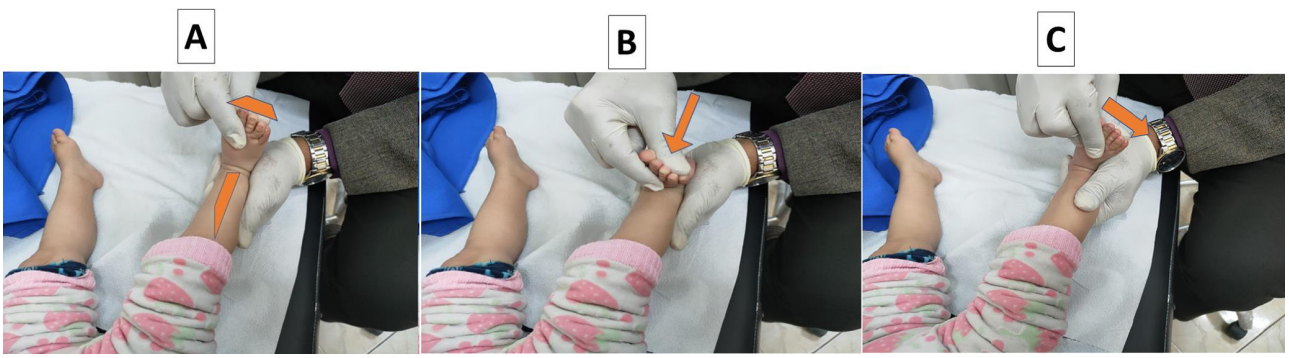

Fig. 1 a) Each parent was trained to do exercises, starting by making the toes perpendicular to the long axis of the tibia; b) then repeating the gentle maximum dorsiflexion for each foot, maintaining it for one second each time for 50 times; c) then gentle maximum abduction for each foot, maintaining it for one second each time for 50 times.

Table 1 General characteristics of the included patients

Demographics		Group A (n = 488 children, 637 feet)	Group B (n = 485 children, 628 feet)	p-value
Sex, frequency (%)*	Female	200 (*46.7*)	171 (*35.3*)	0.07 NS
	Male	288 (*53.3*)	314 (*64.7*)	
Side, frequency (%)*	Right	245 (*50.2*)	253 (*52.2*)	0.83 NS
	Left	94 (*19.3*)	89 (*18.4*)	
	Bilateral	149 (*30.5*)	143 (*29.4*)	
Mean age at first consultation, days(SD; range)†		14.41 (3.53; 3 to 28)	14.76 (3.12; 4 to 31)	0.10 NS
Mean follow-up period, months (SD; range)†		93.10 (29.51; 81 to 150)	92.08 (27.53; 70 to 151)	0.57 NS

*chi-squared test
†Independent *t*-test
Group A, standard Ponseti; Group B, modified Ponseti; NS, not significant (p > 0.05)

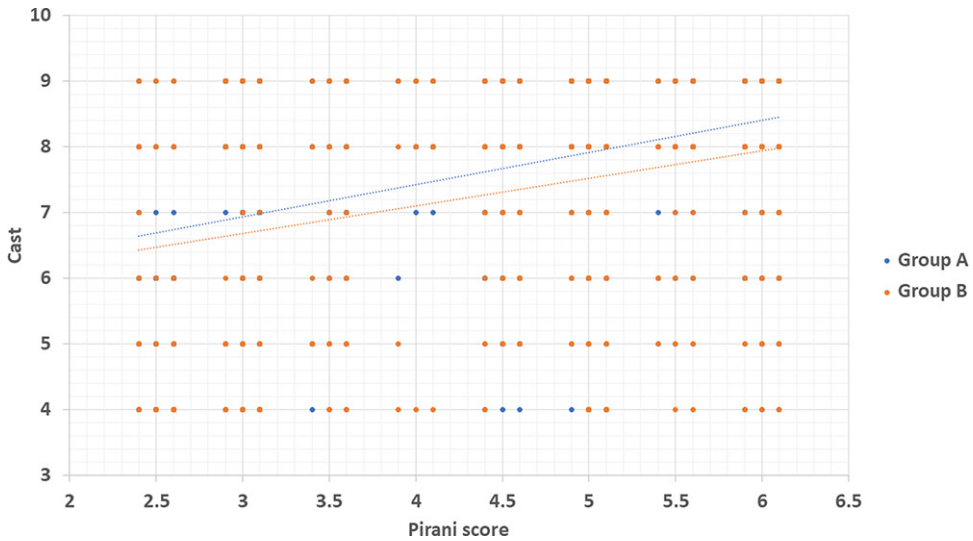

Fig. 2 Displays a high collinearity between the Pirani score and the number of casts required to achieve proper correction.

Table 2 Detailed Pirani score

Pirani score		Group A (n = 637 feet)		Group B (n = 628 feet)		P1	P2
		Initial visit	Final follow-up	Initial visit	Final follow-up		
Excellent (scores between 0 and 1)	n (%)	0 (*0*)	515 (*80.85*)	0 (*0*)	474 (*75.48*)	0.32* NS	0.06* NS
Good (scores between 1.5 and 2.5)	n (%)	48 (*7.54*)	90 (*14.13*)	*57* (*9.08*)	110 (*17.52*)		
Poor (scores ≥ 3)	n (%)	589 (*92.46*)	32 (*5.02*)	*571* (*90.9*)	44 (*7.0*)		
Mean (sd)		4.73 (1.8)	0.82 (0.81)	4.59 (2)	0.86 (0.83)	0.07†NS	0.42† NS
Median (range)		5 (3 to 6)	1 (0 to 2.5)	4.6 (2.5 to 6)	1 (0 to 3)		
P3	McNemar test	< 0.001‡††		< 0.001‡††			
	Paired Wilcoxon test	< 0.001**††		< 0.001**††			

*chi-squared test
†Mann Whitney
‡McNemar test
**Paired Wilcoxon
††highly significant (p < 0.01)
NS, not significant (p > 0.05); P1, initial score in group A *versus* group B; P2, final score in group A *versus* group; P3, initial *versus* final score in each group

Table 3 Results of the functional assessment

The Laaveg-Ponseti score	Group A (n = 637 feet)			Group B (n = 628 feet)			
Part A	**n**	**%**	**Mean (SD)**	**n**	**%**	**Mean (SD)**	**p-value**
Excellent (90 to 100)	347	*54.5*	94.46 (4.98)	327	*52*	96.35 (4.86)	0.31* NS
Good (80 to 89)	207	*32.5*	84.33 (4.75)	214	*34.10*	84.36 (4.81)	
Moderate (70 to 79)	68	*10.7*	74.82 (4.93)	79	*12.60*	74.33 (4.87)	
Poor (< 70)	15	*2.3*	46.8 (18.41)	8	*1.30*	45 (18.49)	
Total	637	*100*	87.81 (19.82)	628	*100*	90.55 (20.71)	0.02*†‡
Part B			**n**	**%**	**n**	**%**	
Satisfaction	Very satisfied	-	502	*78.81*	512	*81.53*	0.02*‡
	Satisfied	-	78	*12.24*	105	*16.72*	
	Neither satisfied nor dissatisfied	-	*57*	*8.95*	11	*1.75*	
The function of daily life	Did not limit their activity	-	562	*88.30*	540	*86*	< 0.001* **
	Occasionally limited their strenuous activities	-	*25*	*3.90*	*73*	*11.6*	
	Usually limited their strenuous activities	-	50	*7.80*	15	*2.4*	
Passive movement	Mean (SD)	-	8 (2.67)		8.4 (2.8)		0.01†‡
	Range	-	3 to 10		4 to 10		

*chi-squared test
†Independent t-test
‡significant (p < 0.05)
**highly significant (p < 0.01)
NS, not significant (p > 0.05)

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neither satisfied nor dissatisfied. While in group B, 81.53% were very satisfied, 16.72% were satisfied and 1.75% were neither satisfied nor dissatisfied (p = 0.02). In terms of the passive range of the ankle movement (a part of the Laaveg-Ponseti score), there was a statistically significant difference, with a higher range of movement in group B children (p = 0.01) (Table 3). The two groups' radiological assessment showed a significant difference between the normal feet and the affected side. The mean AP and lateral TCA angles were 13.98° (SD 5.16 °) and 32.78° (SD 7.32°) in group A, while they were 16.02° (SD 5.26°) and 35.83° (SD 7.54°) in group B. Both measurements were smaller than normal in both groups (all p < 0.05), indicating mild residual heel varus (Fig. 3, Table 4). The radiological assessments of the TCA in AP and lateral views, as well as the TCA in TCI measures hind-foot varus, are shown in the supplementary material. The mean TCI was 35.28° (SD 8.76°) in group A, and it was 36.47° (SD 8.03°) in group B. This difference was statistically significant between the two groups (p = 0.02). However, both values were less than the mean value of the control feet, as shown in Table 4. This may be attributed to the good alignment of the lateral TCA in both groups, compensating for residual varus in an anteroposterior view. The first recurrence was reported in 210 feet (33%) in group A patients (cavus only in 102 feet, cavus and adduction deformity in 55 feet, equinus in 42 feet and recurrence of the whole deformity in 11 feet). The first recurrence was recorded in group B patients in 202 feet (32.2%) (cavus only in 93 feet, cavus and adduction deformity in 47 feet, equinus in 44 feet, recurrence of the whole deformity in 18 feet) as shown in Table 5. There was no statistically significant difference between the two groups regarding the recurrence rate (p = 0.76). The leading cause of this early

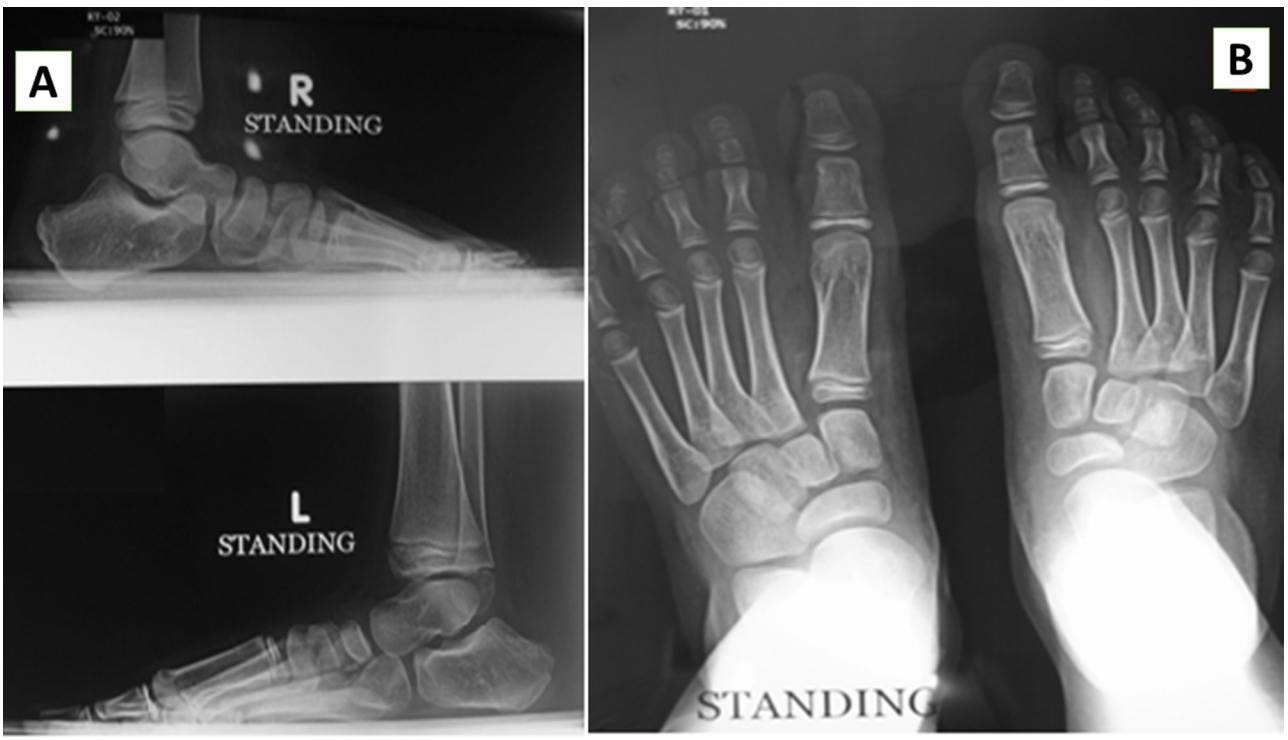

Fig. 3 The radiograph of right unilateral talipes equinovarus of an eight-year-old child showing mild right-side residual varus compared with the left side. Weight-bearing lateral view (a) and anteroposterior view (b).

Table 4 Final interpretation of the radiological assessment

Variable, mean (sd)	Group A	Group B	Normal	P1	P2	P3
	n = 255 feet	n = 251 feet	681 feet in both groups			
The talocalcaneal angle in anteroposterior view	13.98° (5.16°)	16.02° (5.26°)	29.05° (7.3°)	0.01†	< 0.001*	< 0.001*
The talocalcaneal angle in lateral view	32.78° (7.32°)	35.83° (7.54°)	41.26° (10.31°)	0.03†	0.01†	0.008*
The talocalcaneal index	35.28° (8.76°)	36.47° (8.03°)	58.65° (14.12°)	0.02†	< 0.001*	< 0.001*

Independent t-test used
*highly significant (p < 0.01)
†significant (P<0.05)
P1, group A *versus* group B; P2, group A *versus* normal; P3, group B *versus* normal

Table 5 Epidemiology of the recurrent cases

	Variables	Group A (n = 637 feet and 488 children)		Group B (n = 628 feet and 485 children)		p-value
		n	%	n	%	
First recurrence	No	427	*67*	426	*67.8*	0.76 NS
	Yes	210	*33*	202	*32.2*	
	Recurrence cavus alone	102	*48.6*	93	*46*	
	Recurrence cavus and adduction	55	*26.2*	47	*23.3*	
	Recurrence of equinus	42	*20*	44	*21.8*	
	Recurrence whole deformity	11	*5.2*	18	*8.9*	
		Group A (n = 11 feet)		**Group B (n = 9 feet)**		
Second recurrence (assessed at the age of four)	A limited posterior release	3	-	2	-	0.45 NS
	A complete posteromedial release	2	-	1	-	
	Tibialis anterior tendon transfer	5	-	4	-	
	Ring fixator applications and gradual correction	1	-	2	-	

Group A, standard Ponseti; Group B, modified Ponseti; NS, not significant (p > 0.05)

recurrence in each group was non-adherence to the retention method (98.7%). All recurrent cases were managed by repeated Ponseti technique with revision tenotomy when required. All the cases were enrolled again in their group of retention programmes. By the age of four years, the final recurrence rate was reported in 11 feet (1.73%) in group A (three feet managed by a limited PR, two feet managed by a complete PMR, five feet managed by tibialis anterior transfer and one foot managed by ring fixator applications and gradual correction. While in group B, the final recurrence was documented for nine feet (1.43%) managed as following; two feet by PR and one foot by PMR, four feet by tibialis anterior transfer and two feet by ring fixator applications and gradual correction (Table 5). At the final follow-up visit, the questioner assessed the parents/caregivers' compliance with the treatment and adherence of both management options and whether they would recommend this treatment method to others. The families were satisfied with treatment in 76.9% and 82.64% for group A and group B. There was a statistically significant difference between both groups (p = 0.011). The adherence to treatment was reported in 81% in group A and 86.15% in group B, with a significant difference (p = 0.013) (Table 6). In terms of recommending the treatment method to others, 78% and 83.12% of group A and group B participants would recommend their retention method of treatment, with a statistically significant difference (p = 0.022) (Table 6).

Discussion

The idiopathic clubfoot is one of the most common musculoskeletal abnormalities in childhood, which affect the lower limb and can be challenging to treat. Although the Ponseti method is the standard treatment method, non-compliance to bracing was closely associated with deformity recurrence.[7,11,15,19,21-24]

We aimed to compare the efficacy of our parent-based exercise programme and the FAB Ponseti manipulation as a retention programme. The assessment of our cases was done using a combination of three items for global and comprehensive evaluation; clinical (Pirani score), functional (Laaveg-Ponseti score) and radiographic evaluations. Moreover, we introduced a questionnaire at the final follow-up visit to assess the parents' compliance and adherence to the retention programme.

In terms of the Pirani score, group A achieved comparable results with previous studies. Lampasi et al[17] managed 79 idiopathic clubfeet with the standard Ponseti method in 47 patients. The mean initial Pirani score was 4.8 (2 to 6) and the mean number of casts was 4.4 (2 to 7). Both groups A and B were matched and could be compared with each other. Both groups had high mean Pirani scores (4.73 in group A and 4.59 in group B), indicating that most cases were moderate to severe.[25-28] Achilles tenotomy was performed in 84.8% of the clubfeet. The mean Pirani score at the final follow-up was 0.41 (0 to 1.5). The study of Elgohary and Abulsaad[19] used the traditional Ponseti method to treat 20 children (34 feet) showed that the Pirani score was initially 5.17 (SD 0.62; 4 to 6) and tenotomy was performed in 91.2% (31 feet of 34). At the final follow-up visit, the Pirani score was 0.49 (SD 0.42; 0 to 1). The authors documented a recurrence rate of 14.7%.

At the final follow-up, the Pirani score showed that group A had more 'excellent' results, while group B had more 'good' results, with no statistically significant difference between both groups. The tenotomy was done in 89.8% and 88% in group A and B patients, respectively. This is in line with the current literature; the range is between 80% and 92%.[9,13,20,26,29,30,31] However, our cut-off (Pirani score < 2.5) for tenotomy was lower than the ones suggested by other authors such as Scher et al[26] (Pirani score ≥ 5.0), Goriainov et al[20] (Pirani score ≥ 4.0) and Aydin et al[29] (Pirani score > 5.0 points).

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Table 6 Questionnaire to assess patients' compliance with treatment and adherence to the retention method

	Group A (n = 637 feet)	Group B (n = 628 feet)	p-value
Satisfaction with the method of treatment, n (%)			
Yes	490 (*76.9*)	519 (*82.64*)	0.011*‡
No	147 (*23.1*)	109 (*17.36*)	
Adherence to the treatment, n (%)			
Yes	516 (*81*)	541 (*86.15*)	0.013*‡
No	121 (*19*)	87 (*13.85*)	
Whether they will recommend this method of treatment to others or not?			
Yes	497 (*78*)	522 (*83.12*)	0.022*‡
No	140 (*22*)	106 (*16.88*)	

*chi-squared test
‡significant (p < 0.05)
Non-adherence was defined as caregivers reporting brace wear of more than two hours less than that prescribed daily wear; non-adherence was defined as caregivers reporting less than three times/day exercises

The collinear relation between the Pirani score and the number of casts was similar to the findings of Lampasi et al[17,21] and Awang et al.[18] The Laaveg-Ponseti score was used for the functional assessment. In our study, group A showed a mean total score of 87.81. In all, 54.5% of cases showed excellent scores, 32.5% showed good scores, 10.7% showed moderate scores and 2.3% showed poor scores.

Cooper and Dietz[16] studied 71 clubfeet in 45 patients treated with the standard Ponseti method and showed that 78% of the patients had an excellent/good outcome. The same percentage was reported in Ippolito et al,[15] who conducted their study on 32 patients (49 feet), with a mean Laaveg-Ponseti score of 85.4. Laaveg and Ponseti[11] included 70 patients (104 feet) and showed that the mean Laaveg-Ponseti score was 87.5; 74% of the cases had excellent/good results. In 2012, Wallander et al[23] managed 60 children with idiopathic clubfoot by the standard Ponseti method. They reported that the mean Laaveg-Ponseti score was 74 (SD 20). In total, 13 patients (22%) had an excellent outcome, 17 patients (28%) had a good outcome, eight patients (13%) had a fair outcome and 22 patients (37%) had a poor outcome. Our results in group A using standard bracing protocol were comparable with the literature using either the Pirani score and/or the Laaveg-Ponseti functional score.

According to the Laaveg-Ponseti score, the percentage of excellent results was 54.5% in group A, while group B showed a higher incidence of good feet (35.3%). However, the combined percentage of good and excellent cases was equal (87%) for both groups.

However, the mean total score of Laaveg-Ponseti scoring was higher in group B (90.55 SD 20.71) than in group A (87.81 SD 19.82), and this difference was statistically significant (p = 0.02). Regarding the parents' satisfaction, 78.81% in group A and 81.53% in group B were very satisfied. This difference was significant (p = 0.02). The clinical and functional outcomes of both groups were almost the same, but group B showed better satisfaction and compliance with the retention programme.

We used the AP and lateral TCA as well as the TCI for the radiological assessment of the feet. These are the most widely used and accepted parameters, as they reflect the anatomical relationship between the talus and the calcaneus.[4,6,7,30,31] The children in group A had a mean AP, lateral TCA and TCI of 13.98°, 32.78° and 35.28°, respectively, in the diseased feet. However, the measurements were 29.05°, 41.26° and 58.65° in the normal feet. This is in agreement with several previous studies.[4,7,32-35] Segev et al[33] compared their unaffected value with the standard Ponseti method and showed that the TCA on the AP view ranged from 30° to 531° (mean 41.4°) for the unaffected side and from 17° to 451° (mean 31.4°) for the affected side. The TCA on the lateral view ranged from 37° to 501° (mean 44.9°) for the unaffected side and from 12° to 351° (mean 24.5°) for the affected side. The TCI ranged from 70° to 951° (mean 86.3°) for the unaffected side and from 32° to 771° (mean 55.9°) for the affected side. Our results agree with the published results of Brand et al[25] and those published in 1981 by Ponseti et al.[1,5,6,11] The radiological parameters were significantly smaller on the affected side compared with the unaffected side. These observations were also supported by Pirani et al,[36] who used a 3D MRI study to confirm the radiological parameters in the corrected club foot. As our group A results are comparable with the published data, we could use it as a control group to assess our modified Ponseti technique's efficiency using a home-based exercise programme instead of bracing.

Comparing the radiographic assessments of both groups, the mean AP, lateral TCA angles and TCI were 13.98°, 32.78° and 35.28° in group A, and 16.02°, 35.83° and 36.47° in group B, respectively. All radiological parameters were significantly higher in the group B children than in group A children; however, previous literature has reported controversy regarding the connection between radiological findings and functional outcomes.[15,19,25]

Our study recorded the first recurrence for 33% and 32.2% of group A and B patients, with a non-significant difference. This is in line with the literature.[1,5,8,10,15,20,24,30,34,37,38] The main cause of the first recurrence was the non-adherence and non-compliance to the retention programme in 98.7% of the recurrent cases, while it was idiopathic in 1.3%, with no obvious cause for recurrence.

Non- or poor compliance with the Ponseti brace protocol was identified as the leading cause of relapse, and it directly affects the success of treatment.[4,5,7,9,25,26,28,33] Other factors, such as the low educational level of parents and low annual family income, were associated with poor compliance with bracing and recurrences.[14,19,32,33,36,39] Some parents wrongly think that once the feet are corrected, it can never recur.[19,21] Thus, they consider using the brace as cumbersome, especially in unilateral cases.[11,17,28]

Simultaneously, some parents find it difficult to apply the brace, especially in older children. Technical factors such as keeping proper angles of the brace and correcting them in case of loosening add to the difficulty of using the FAB.[7,17,20] Financial issues are important factors for keeping an appropriately sized and maintained brace, especially in low-income countries.[11,27,29,30,37] In some communities, using the FAB may be psychologically disappointing to the mothers and children. Some parents refuse to use the brace once they get the foot corrected.[9,15,19] Besides, there is no consensus on the minimal number of hours of use of the FAB per day to prevent recurrence.[9,27,30,31,34]

The recurrence of the deformity and subsequent surgical interventions were associated with long-term deformity and disability.[7,9,15,29,32,35,39,40] Since most of the recurrences and failures of the Ponseti method are secondary to the lack of compliance and adherence to the FAB use, we are introducing the use of a parent-based exercises programme, replacing the use of FAB, assuming better compliance of the family or caregiver with subsequent low recurrence rate.[9] We conducted this study on a large group of patients in a prospective multicentre study to compare the results of using FAB and our new home-based exercise programme.

Our exercise programme is different from the 'French' functional method. The French functional method was based on daily physiotherapy with immobilization by adhesive bandages and pads to correct the deformity, as well as long-term bracing to maintain correction.[14,24] It is time-consuming and expensive for many patients because they have to travel to find a trained physiotherapist.[21,22] In addition to the associated rate of surgical release, the results were poor in the long-term follow-up.[8,10,19,22,38,39] Our new exercise programme is a retention programme that could replace FAB use after achieving correction with standard Ponseti casting and tenotomy. Although many new FAB designs are being proposed and developed, evidence regarding biomechanical effects, clinical outcomes, functionality and patient adherence is limited.[2,19,24,41] This modification of the Ponseti technique aims to increase parent compliance with the retention programme provided that it could achieve comparable results with the classic Ponseti method with the use of FAB.[9] However, after correcting the first recurrent deformity using serial casting with or without tenotomy, we observed that the parents became more adherent to the treatment as mentioned by the parents, with no true percentage of improvements. This could explain the lower incidence of recurrence/relapse at the final follow-up visit, which has been reported in only 11 feet in group A and nine feet in group B; in these cases, surgical intervention was performed. These cases were managed by anterior tibial tendon transfer to the third cuneiform in four feet in group A and six feet in group B with an excellent outcome. The PMR was required in five relapsed feet in group A and three feet in group B.

The final follow-up questionnaire showed that the parents were compliant and adherent to the exercise protocol with more satisfaction and less recurrence in group B compared with group A. Our study's main limitation was that the Laaveg-Ponseti outcome measure is not a validated outcome measure and categorical determinations of good *versus* poor scores are arbitrarily set. Our study is prospective and, in many cases, comparing two homogenous groups but with mid-term follow-up. We think that further evidence with long-term follow-up is required to know exactly the minimum number and effective frequency of exercises.

In conclusion, the deformity's recurrence related to the brace's non-compliance in the Ponseti method might be reduced by substituting the brace with our stretching home-based daily exercises. This alternative retention protocol may be used by parents who are not comfortable using the FAB or find it very difficult to apply to children, especially when they get older. Nevertheless, we have to keep in mind that some parents may prefer the FAB if their work and daily life do not allow them to do the exercises.

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Informed consent: Informed consent was obtained from all individual participants included in the study.

ICMJE CONFLICT OF INTEREST STATEMENT

All authors confirm and declare no conflict of interest or any foundation source in any form related to this work.

AUTHOR CONTRIBUTIONS

RAS: Principal author, Study design, Main surgeon, Performed measurements, Manuscript preparation, Revised and approved the final version to be submitted.

ME: Study design, Surgeon, Performed measurements, Manuscript preparation, Revised and approved the final version to be submitted.

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SUPPLEMENTAL MATERIAL

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