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Plantar Pressure Distribution of Right and Left Foot in Bilateral Clubfoot Treated by Ponseti Method: A Correlation Analysis

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Data Interpretation D
Manuscript Preparation E
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Background: Congenital clubfoot is a common pediatric orthopedic deformity that can be corrected by Ponseti method, and pedobarographic analysis has been used to assess the outcomes. However, the relationship between the plantar pressure distribution of the right and left foot in children with bilateral clubfoot has not been studied. In this study, the pedobarographic data of patients with bilateral clubfoot who were treated by the Ponseti method were reviewed, and a correlation analysis was conducted to clarify the relationship between the right and left foot.

Material/Methods: A retrospective cross-sectional study of children with bilateral clubfoot who were treated by the Ponseti method in infancy was performed, in which all the patients were available for clinical evaluation, and pedobarographic analysis was conducted on each patient after treatment. The Pearson's correlation coefficient (r) were calculated for all the measurements of the left and right foot.

Results: A total of 20 children (mean age 6.9±1.07 years, range 4–8 years) with bilateral clubfoot who were treated by the Ponseti method were included. The Dimeglio and Pirani scores before and after treatment between the right and left foot were significantly correlated. All the pedobarographic measurements between the left and right foot were correlated, indicating different degrees of positive correlation.

Conclusions: The plantar pressure measurements between the 2 feet in patients with bilateral clubfoot were highly correlated before treatment, and a correlation was also observed after those patients were treated by the Ponseti method. We should take these correlations into consideration during study design and analysis of clubfoot cases.

MeSH Keywords: **Clubfoot • Dermatoglyphics • Statistics as Topic**

Abbreviations: **ANOVA** – analysis of variance; **BMI** – body mass index; **CA** – contact area; **CT** – contact time; **FPA** – foot progression angle; **LH** – lateral heel; **M1** – first metatarsal; **M2** – second metatarsal; **M3** – third metatarsal; **M4** – fourth metatarsal; **M5** – fifth metatarsal; **MF** – midfoot; **MaF** – maximum force; **MH** – medial heel; **PP** – peak pressure; **PTI** – pressure-time integral; **SD** – standard deviation; **T1** – hallux; **T2–5** – toes 2–5

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3155 3 2 32

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Background

Congenital clubfoot is one of the most common deformities in pediatric orthopedics and is bilateral in 50% of cases [1]; it can be treated by the Ponseti method [2] and excellent long-term function has been widely reported [3]. However, it is noteworthy that even clinically asymptomatic children who were successfully treated by the Ponseti method can show significant foot loading deviations [4]. Pedobarographic analysis has been used to study foot loading in children with bilateral clubfoot in order to better address foot function [5], which provides detailed information about the whole foot contact and loading in various foot regions during stance phase, and also can be used to analyze the force across a defined surface, whereas force describes the interaction between 2 bodies [6,7]. Moreover, it provides an objective method for determining how the foot functions in addition to relying on patient reports or questionnaires [8].

Previous studies using pedobarographic analysis reported a number of differences between the Ponseti method of treatment and surgical treatment of clubfoot [8–11]. However, the majority of these studies did not distinguish unilateral clubfoot from bilateral clubfoot when collecting cases. In clubfoot-based studies, interventions are commonly assigned to a patient, while the efficiency of treatment is separately assessed in each foot. Pedobarographic measurements are commonly gathered from each foot of a patient with bilateral clubfoot and analyzed along with data obtained from a patient with unilateral clubfoot [9–11]. It has been shown that in the right and left foot of each bilateral clubfoot patient, the baseline severity and response of initial treatment by the Ponseti method were highly correlated [12,13]. In pedobarographic analysis of bilateral clubfoot treated by the Ponseti method, it is still unclear whether the plantar pressure distributions in the left foot are related to the right foot. Therefore, it is not rigorous to consider the pedobarographic data of each foot as an independent observation, which may affect the accuracy of statistical results due to the potential correlation between the 2 feet.

To the best of our knowledge, there are no studies based on pedobarography that focused on the relationship between the right and left foot in patients with bilateral clubfoot who were treated by the Ponseti method. As pedobarography sensitively detects changes in residual deformities after treatment [8–11], we hypothesized that distributions of foot loading between the right and left foot of each patient with bilateral clubfoot who were treated by the Ponseti method were correlated, and the measurements of each foot should not be treated as independent data for research purposes. To test this hypothesis, the present study reviewed the pedobarographic data of children with bilateral clubfoot who were treated by the Ponseti method, and a correlation analysis was conducted to assess the relationship between the right and left foot.

Material and Methods

Subjects

Medical records were retrospectively reviewed to identify children with bilateral clubfoot who were initially treated by the Ponseti method in infancy at our institution. The patients had been strictly treated according to the Ponseti method [14] of casting correction and tenotomy surgery by a single physician. Pedobarographic analysis was routinely conducted for each treated patient with clubfoot at least 1 year after removal of the foot abduction orthosis. Exclusion criteria were: incomplete data for clinical evaluation and pedobarographic analysis, patients with additional neurological or orthopedic conditions, or those who required orthotics to walk or undergo further surgery, those who have relapsed feet or under-corrected feet, or those who were initially treated by other institutes or other methods. The study was approved by the Ethics Committee of our institution and conducted in accordance with the 1964 Declaration of Helsinki. Informed consent was obtained from all patients' parents prior to beginning the study.

Clinical and functional examinations

We routinely conducted clinical evaluation for each patient with bilateral clubfoot who was admitted to our institute for treatment, which included the severity of deformity as determined by the Dimeglio scoring system [15] and Pirani scoring system [16], and the foot length and width were measured according to the minimum circumscribed rectangle of the static footprint. All the evaluations were conducted prior to undergoing Ponseti treatment and the last follow-up. All patients' data were stored in computer-based patients' records. The Dimeglio and Pirani scoring system was implemented by the first author, and was rechecked by the second author. All the manipulations and casts, as well as tenotomy under local anesthesia, were performed by an experienced orthopedic physician.

Instrumentation and pedobarographic analysis

The pedobarographic analysis was conducted for patients at least 1 year after the braces were released in order to avoid the effects of braces on walking patterns. All plantar pressure measurements were performed using the Footscan® 3D pressure system (RSscan International, Paal, Belgium). The platform was located at the center of 2 carpets with the same external dimension to provide a "complete platform" that was 4 m in length [5]. Before each measurement, the plantar pressure plate was calibrated to the child's weight. Patients were instructed to walk barefoot and at a self-selected speed, and care was taken that the starting point was at a distance of 2 m to the platform, ensuring that at least 3 steps were taken before data collection. Only data obtained from an unaided,

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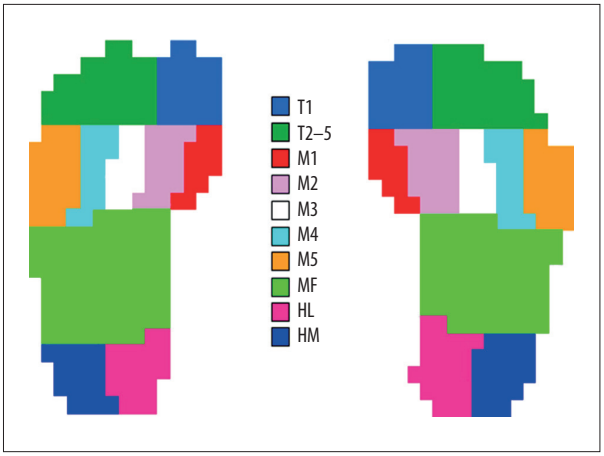

Figure 1. The foot shape and the subdivided zones for the left and right foot of a representative subject. T1 – hallux; T2–5 – toes 2–5; M1 – first metatarsal; M2 – second metatarsal; M3 – third metatarsal; M4 – fourth metatarsal; M5 – fifth metatarsal; MF – midfoot; MH – medial heel; LH – lateral heel.

fluid gait were considered significant for analysis. We identified 3 representative and reliable trials and recorded them in our database.

The collected data were processed using Scientific Footscan® software (RSscan International, Paal, Belgium), which automatically divided the foot into 10 mask zones on the basis of anatomical landmarks (Figure 1): hallux (T1), toes 2–5 (T2–5), first to fifth metatarsals (M1, M2, M3, M4, and M5), midfoot (MF), medial heel (MH), and lateral heel (LH). The contact time of each foot was determined using a force-time plot (Figure 2). After each measurement, a visual assessment was undertaken to ensure that the anatomical landmarks fitted with the automatically generated masked zones. If the software could not identify the foot in some cases, a static image of the plantar surface of the participant's foot was used as reference to carry out manual corrections by the first author.

The foot progression angle (FPA) was calculated as the angle between the gait direction and the line located between the medial and lateral parts of the heel and between the second and third metatarsal heads[17]. A positive angle indicated an

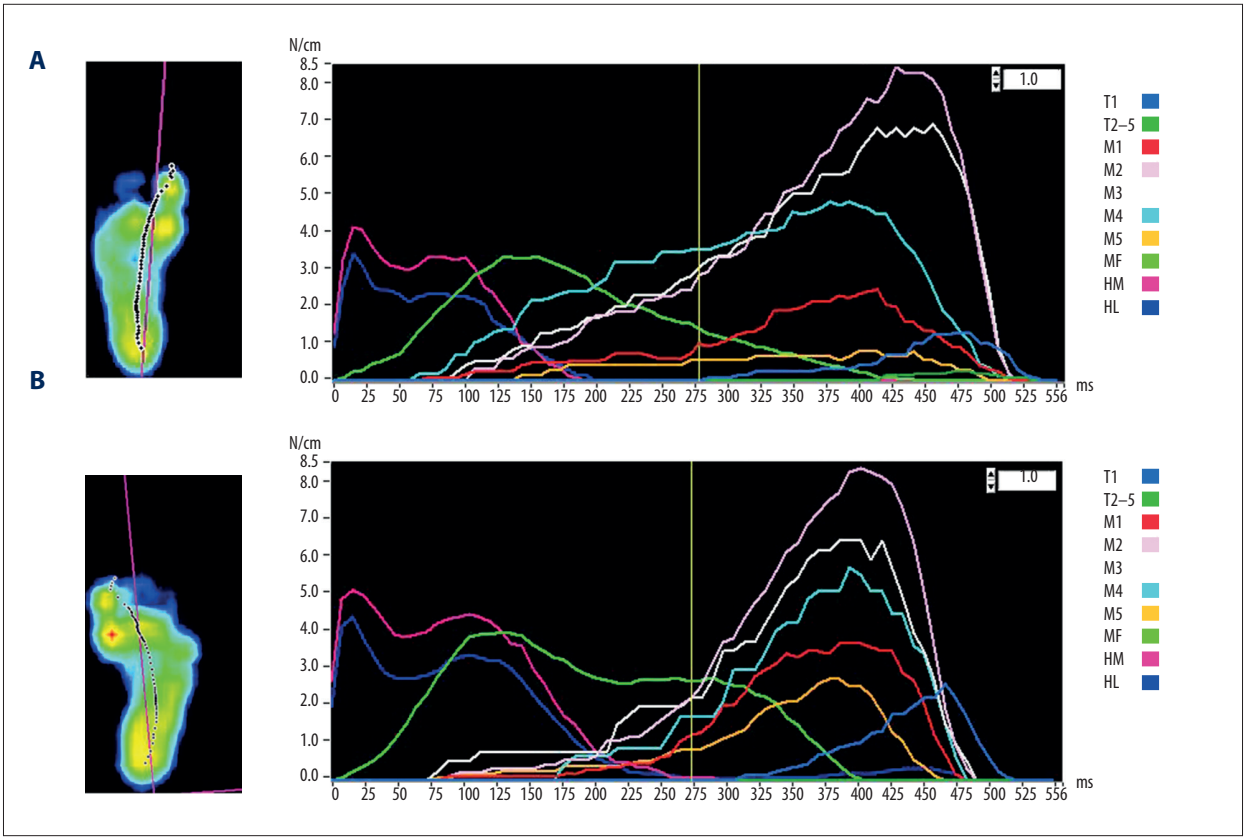

Figure 2. The curves of the peak pressure (PP) for the 10 masked zones of a representative subject. (**A**) Curves of the PP in the left foot. (**B**) Curves of the PP in the right foot. T1 – hallux; T2–5 – toes 2–5; M – first metatarsal; M2 – second metatarsal; M3 – third metatarsal; M4 – fourth metatarsal; M5 – fifth metatarsal; MF – midfoot; MH – medial heel; LH – lateral heel. 1 N/cm^2=10 kPa.

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Table 1. The correlations between clinical and functional examination data of the right and left feet.

Variables	Means±SD		r	p
	Left	Right		
Dimeglio scores before treatment	14.10±1.68	13.70±2.05	0.923	<0.001*
Dimeglio scores after treatment	1.70±0.66	1.30±0.47	0.648	0.002*
Pirani scores before treatment	4.82±0.71	4.76±0.75	0.934	<0.001*
Pirani scores after treatment	1.03±0.51	1.01±0.42	0.823	<0.001*
Foot length [cm]	18.79±2.75	18.28±2.57	0.971	<0.001*
Foot width [cm]	7.85±1.16	7.96±1.12	0.975	<0.001*
Foot progression angle [°]	–4.24±7.08	–2.19±6.67	0.932	<0.001*

* P<0.05. CI – confidence interval. Values are expressed as means±standard deviation.

Table 2. The values of the variables in the left and right feet for the 10 masked zones.

Foot segments	Side	PP [kPa]	MaF [N]	CA%	CT%	PTI [kPa·s]
T1	Right	39.2±28.56	33.91±17.36	8.50±2.15	58.85±13.70	5.16±3.88
	Left	41.80±34.19	39.35±24.79	9.60±3.14	61.10±17.19	3.85±2.87
T2–5	Right	12.50±10.12	10.38±6.97	8.17±1.88	53.10±24.76	1.00±1.20
	Left	9.55±10.15	9.08±9.63	7.23±1.69	46.95±22.11	1.68±3.70
M1	Right	31.45±14.13	30.01±13.76	6.02±1.06	68.80±16.02	5.16±3.18
	Left	28.90±14.19	28.05±11.33	5.88±1.12	65.00±19.34	5.58±3.59
M2	Right	52.25±19.46	34.14±19.37	5.63±1.08	70.70±15.38	10.42±7.24
	Left	49.90±19.32	32.53±16.72	5.71±1.06	66.55±16.87	11.16±7.39
M3	Right	93.50±53.70	49.08±26.30	8.39±2.24	71.60±18.65	15.95±10.53
	Left	93.10±50.98	48.59±24.65	8.57±2.01	69.20±18.91	13.68±8.23
M4	Right	84.85±26.35	42.81±12.24	7.18±1.00	75.40±14.72	13.74±8.15
	Left	84.65±28.24	41.53±13.82	6.42±0.88	73.35±15.27	11.16±6.43
M5	Right	38.60±29.00	33.40±21.50	9.45±2.51	72.05±16.14	5.63±4.57
	Left	38.20±22.27	33.76±16.15	9.51±2.11	72.1±13.09	5.89±4.20
MF	Right	41.30±21.47	104.36±49.15	25.88±3.95	73.20±8.21	9.89±7.53
	Left	43.30±15.94	108.81±44.68	26.65±3.66	71.55±8.02	10.95±7.53
HM	Right	62.95±34.35	71.02±28.67	9.78±2.11	57.05±10.25	16.63±10.75
	Left	63.55±34.80	79.43±29.06	9.70±1.53	55.30±10.49	18.00±13.96
HL	Right	111.15±39.04	84.43±33.35	10.99±2.21	56.15±10.55	17.68±12.95
	Left	103.25±40.91	85.38±34.90	10.74±1.70	54.40±10.48	17.84±14.44

* Values are expressed as means±standard deviation. PP – peak pressure; MaF – maximum force; CA – contact area; CT – contact time; PTI – pressure-time integral; T1 – hallux; T2–5 – toes 2–5; M1 – first metatarsal; M2 – second metatarsal; M3 – third metatarsal; M4 – fourth metatarsal; M5 – fifth metatarsal; MF – midfoot; MH – medial heel; LH – lateral heel.

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Table 3. The Correlation between the variables of the left and right feet in the 10 masked zones.

Foot segments	PP [kPa]		MaF [N]		CA%		CT%		PTI [kPa·s]	
	r	P	r	P	r	P	r	P	r	P
T1	0.492	0.028*	0.457	0.043*	0.548	0.012*	0.558	0.011*	0.512	0.021*
T2–5	0.368	0.111	0.428	0.060	0.336	0.113	0.510	0.022*	0.535	0.015*
M1	0.583	0.007*	0.540	0.014*	0.543	0.013*	0.486	0.03*	0.587	0.007*
M2	0.671	0.001*	0.648	0.002*	0.505	0.023*	0.589	0.006*	0.652	0.002*
M3	0.711	<0.001*	0.765	<0.001*	0.739	<0.001*	0.613	0.004*	0.699	0.001*
M4	0.701	0.002*	0.673	<0.001*	0.600	0.005*	0.831	<0.001*	0.638	0.002*
M5	0.603	0.005*	0.635	0.003*	0.579	0.007*	0.895	<0.001*	0.635	0.003*
MF	0.605	0.005*	0.662	0.001*	0.802	<0.001*	0.757	<0.001*	0.793	<0.001*
HM	0.659	0.002*	0.706	0.001*	0.745	<0.001*	0.864	<0.001*	0.788	<0.001*
HL	0.776	<0.001*	0.790	<0.001*	0.636	0.003*	0.839	<0.001*	0.831	<0.001*

* P<0.05. PP – peak pressure; MaF – maximum force; CA – contact area; CT – contact time; PTI – pressure-time integral; T1 – hallux; T2–5 – toes 2–5; M1 – first metatarsal; M2 – second metatarsal; M3 – third metatarsal; M4 – fourth metatarsal; M5 – fifth metatarsal; MF – midfoot; MH – medial heel; LH – lateral heel.

internal rotation of the foot, whereas a negative angle indicated an external rotation of the foot [8]. We analyzed 5 of the most clinically relevant variables for each region: peak pressure (PP, kPa); maximum force (MaF, N); contact area reported as a percentage of the total foot area (CA%); contact time reported as a percentage of the stance time (CT%); and impulse (pressure-time integral, PTI, kPa.s). The values recorded for each parameter were the mean values of the 3 representative trials.

Statistical analysis

Statistical analysis was performed using SPSS 23.0 software (IBM, Armonk, NY, USA). The mean value and standard deviation (SD) were calculated for each variable, and the data were investigated using the one-sample Kolmogorov-Smirnov test to ensure that they met the parametric assumptions. All the data were normally distributed and are presented as mean±SD. The Pearson's correlation coefficient (r) and 95% confidence interval (95%CI) were calculated to study the relationship between the plantar pressure measurements of the feet in bilateral clubfoot cases. The strength of the correlation between feet of bilateral clubfoot cases was determined using the guidelines provided by Cohen [18], in which r=0.10–0.29 represents a poor correlation, r=0.30–0.49 represents a semi-strong correlation, and r=0.50–1.0 represents a strong correlation. A *P* value less than 0.05 was considered statistically significant.

Results

A review of medical records was conducted, and 35 patients with bilateral clubfoot who underwent the Ponseti method of treatment in infancy were identified. Among them, 15 patients did not meet the inclusion criteria: 7 patients required further surgery, 6 patients were unable to cooperate with pedobarographic data collection, and there were 2 patients with incomplete clinical examination data. The study group consisted of 20 patients with bilateral clubfoot (11 males and 9 females) who had complete clinical evaluation records and pedobarographic data. The patients' average age at the time the first cast was placed was 3 months old, then they were released from the brace at the age of 5.3 years (range 3–5 years), and the last follow-up and the time of testing was 1 year later, at 6.9 years (range 4–8 years).

In all measurements, there were significant correlations between the left and right foot (Table 1). The mean Dimeglio score before treatment was 14.10±1.68 for the left and 13.70±2.05 for the right foot. After treatment, the mean Dimeglio scores for each side were 1.70±0.66 and 1.30±0.47, respectively. The Pirani score before treatment was 4.82±0.71 for the right and 4.76±0.75 for the left, and 1.03±0.51 for the right, and 1.01±0.42 for the left after treatment. The mean Dimeglio scores for the left and right foot were significantly correlated (before, r=0.923, *P*<0.001; after, r=0.648, *P*=0.002), as were Pirani scores (before, r=0.934, P<0.001; after, r=0.823, P<0.001). The size of the foot (length and width) at the time of pedobarographic analysis for each side was significantly positively

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correlated. The mean FPA during their gait was –4.24±7.08° for the left foot and –2.19±6.67° for the right foot, which were highly correlated (r=0.932, P<0.001).

The mean value and SD of all the variables of each foot in the 10 masked zones are shown in Table 2, and the results of correlation analysis between the left and right foot are shown in Table 3.

All the PP, MaF, and CA% values of the left and right foot were significantly correlated with each other in all foot segments except for T2–5 zone (PP, r=0.368, *P*=0.111; MaF, r=0.428, P=0.060; CA%, r=0.336, p=0.113). In addition, there was a semi-strong correlation of the MaF between the left and right foot in T1 zone (r=0.457, *P*=0.043), and a semi-strong correlation of CT% was found in M1 zones (r=0.486, *P*<0.001). For PTI, all the foot segments showed a strong positive correlation.

Discussion

In this study, we attempted to further verify previous relevant research. In Table 1, we summarized the clinical examination data of the left and right foot in bilateral clubfoot cases. The present study showed that in our cohort of bilateral clubfoot, the Dimeglio and Pirani scores prior to the treatment and the last follow-up between the left and right foot were highly correlated. Similar to previous studies [12,13], these findings indicated that the initial severity and the response to intervention of casts between the right and left foot of each patient were highly correlated.

The mean FPA in this study was –4.24° for the left foot and –2.19° for the right foot, indicating that feet in our cohort of children tended to be internally rotated during their walk, which is comparable with previous studies [19,20]. In addition, we found that the correlation coefficient for FPA of each side was significantly positive. Previously conducted studies suggested that FPA influences distribution of foot pressure in children [21]. Hence, we analyzed the correlations of plantar pressure measurements and achieved the expected results, in which the majority of plantar pressure variables related to the left and right foot were correlated.

The PP and MaF are widely used for assessment of foot loading. An abnormally distributed PP or MaF is an important risk factor for foot development, which has been associated with pain, corns and calluses formation, overuse injuries, and strain diseases [22]. Table 2 shows that PP and MaF had similar distribution in the left and right foot, which indicates that the foot loading in the left and right foot was consistent, and the 2 sides of the foot tend to have similar risk of injury.

In addition, our findings related to CA% suggested that in our cohort of bilateral clubfoot, the left and right foot had similar foot segments. The foot segments are subdivided on the basis of anatomical landmarks, which has been proved to be accurate in assessing residual deformity of the treated clubfoot [10,11]. The similarity between the left and right foot segments in size and orientation suggests that the 2 sides of the foot might have similar residual deformities, which can have a significant effect on the dynamic function of the foot [4].

The PTI is a measure of the cumulative exposure to pressure over time in a predetermined region of the foot, and is calculated as the area under the pressure-time curve [23]. The pressure-time curves present the dynamic changes of plantar pressure during the gait cycle, which can represent more visual relations among the PTI and the CT%. With observation of the curves of PP for 10 masked zones of a representative subject, it was revealed that shapes of the curves of left and right foot have a similar pattern, indicating that each side of the bilateral clubfoot had the same walking pattern during the stance phase, as supported by the strong correlations of the PTI and CT% in all foot segments.

We believe that the poor correlation of the PP, MaF, and CA% in T2–5 zone was caused by the reliability of the test equipment. Previous research on the reliability of the Footscan® platform system has reported that the higher values of foot loading parameters correspond to better consistency and less variability compared with lower values [5]. As mentioned before, the values recorded for each parameter were the mean values of the 3 representative trials; therefore, the measurements in T2–5 zone had poor consistency due to the low value, resulting in a poor correlation. However, we found high correlations in most foot zones, which is sufficient to prove the hypothesis that the distributions of plantar pressures between the right and left foot of each bilateral clubfoot patient who was treated by Ponseti method are correlated.

Some previous studies have focused on statistical analysis problems associated with paired data in the human body [24,25], in which the issue of concern is that when correlated data are analyzed as independent data, there can be a false finding of statistical significance [24]. The present study demonstrates that the left and right foot of the bilateral clubfoot patients after treatment with the Ponseti method are highly correlated. Statistical tests commonly assume that multiple feet from each participant are independent, and their subjects are mainly described as X participants with Y feet (e.g., 35 participants with 47 feet). For patients with bilateral clubfoot, data are often collected from both feet and analyzed as a single independent observation [26]. It should be noted that some previous studies conducted on the basis of pedobarography have pooled the data from all feet when dealing with bilateral

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clubfoot [10,11,27], since the plantar pressures between the 2 feet in a single patient are highly correlated; if both feet were included in the study, this part of sample size may be incorrectly doubled (i.e., counting each bilateral clubfoot patient twice), and therefore may cause that the results to be more inclined to the pattern of bilateral clubfoot cases, which is called a false-positive or type I error in statistics. Hence, definition of unit of measurement can significantly influence the findings and interpretation of several investigations; however, further research is needed to determine how to combine data from all cases into a single analysis.

A number of previous studies have considered bilateral clubfoot in other methods, such as selecting 1 foot for inclusion (e.g., the more severe foot), which helps avoid any effect of inter-foot correlation; however, it can cause redundancy and insufficient use of resources, leading to poor representation of the cohort [12]. Moreover, the above-mentioned methods reduce the sample size and reduce the test power, potentially obscuring the true significant outcome (false-negative or type II error). A similar point of view was presented by Stewart et al. [28], who compared statistical efficiency of different methods, and suggested that when dealing with paired data, effects of a linear model can improve efficiency and robustness. There are also complex statistical modelling approaches for analysis of paired data [29,30]; however, these methods cannot be extensively utilized because they require extremely specialized skills [31].

In the present study, we confirmed that the distributions of plantar pressure after treatment between the right and left foot were highly correlated; however, 2 patients of our cohort had different treatment outcomes between feet, and there are also case-reports about the 2 sides of bilateral clubfoot being different in initial severity [12]. Although a strong correlation was reported in the majority of cases, this minority needs to be considered separately. Considering all these factors, for subjects with bilateral clubfoot who have been confirmed to have strong internal correlation, we suggest that taking the average from both feet may be more appropriate, as several previous studies have used this method for pedobarographic analysis of normal subjects [5,32]. In any case, it is improper to include the data of both feet in patients with bilateral clubfeet. If an investigator attempts to include all the data, a conceptual or statistical justification should be provided to prove the independence between the 2 feet. Until a superior statistical solution is developed, these methods appear to be very promising.

Study limitations

Our study has some limitations. Firstly, the small sample size limits the strength of our conclusions; however, strong correlations were noted even with this limited sample size. Nevertheless, a study with larger sample size should be conducted in the future. Secondly, the statistical approach has some limitations, as the Pearson's correlation coefficient only reflects the correlation between the pedobarographic data. Additional follow-up is still needed, which is essential to clarify whether the recurrence rate or complication rate are correlated between the 2 sides of feet. Thirdly, selection of the representative trial and manual corrections to the masked zones were undertaken by just 1 author, which led to selection bias. In addition, some children were nunable to complete pedobarography because they were extremely young. Toys, candies, or parental guidance were used to obtain their cooperation, which might affect the quality of the data. However, many other studies have used similar experimental protocols in young children [8–11,19,20], and their influences were neglected. Finally, we did not provide a detailed description of the statistical models developed for paired data, because those models were beyond the scope of this study and our profession. Hence, for detailed information about these methods, readers may refer to studies conducted by Stewart et al. [28] and Glynn and Rosner [29].

Conclusions

We found that the plantar pressure measurements between the 2 feet of 1 patient with bilateral clubfoot were highly correlated; therefore, it is improper to treat each foot as independent data, and we recommend taking the average of both feet. Researchers should be aware of these inter-correlations and take them into consideration during study design and analysis. Further studies should be conducted to better address this issue.

Conflict of interest

None.

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