

Repeatability and Reproducibility of the F-Scan System in Healthy Children

Andrea Coda^{1*} and Derek Santos²

¹The University of Newcastle, 10 Chittaway Road, Ourimbah, NSW, Australia

²Queen Margaret University, Musselburgh, Scotland, Edinburgh, UK

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***Corresponding author:** Andrea Coda, The University of Newcastle, Faculty of Health and Medicine, School of Health Sciences, Precinct Building, BE154, PO Box 127, NSW - 2258, Ourimbah, Australia, E-mail: Andrea.Coda@newcastle.edu.au

Abstract

This study investigated the repeatability and reproducibility of the F-scan system with regards to Peak Pressure Values (PP) and Pressure Time Integral (PTI) in healthy children, ranging between 5 to 18 years of age. Participants took part in two non-invasive clinical assessments, at baseline and one week later. Standardized footwear was supplied and each child was fitted with the equivalent F-scan insole size. A total of 3 trials of 7 meters distance each were conducted. Plantar pressure analysis was carried out using a novel approach of masking the recordings into 10 different areas; both peak pressure (PP) and pressure time integrals (PTI) values were investigated. The PP and PTI were investigated for the left, right and both feet analysed together. Interclass Correlation Coefficient (ICC) test was adopted for statistical analysis. Overall, 30 healthy children were recruited and 60 appointments were completed; 53.3% (n = 16) were female, mean age was 13.3 years (SD = 4.5). Results highlighted that overall the ICC for repeatability was > 0.75 for 95.8% (no = 115) and between 0.5 and 0.75 for 4.2% (no = 5); the ICC for reproducibility was > 0.75 for 85% (no = 51), and between 0.5 and 0.75 for 15% (no = 9). In conclusion, the F-Scan system can be utilised to record repeatable and reproducible data in paediatric gait analysis.

Keywords: Children; Plantar Pressure; F-Scan; Tekscan; Repeatability; Reproducibility

the approval for this study. Each participant received verbal and written information. Those participants willing to take part in the study were asked to attend the Gait Laboratory for data collection at baseline and one week later. On the day of the appointment, informed consent was obtained from the parents/carer. Both data collection sessions were carried out alongside with the consenting parent/carer for the entire duration of the appointment and the same parent/carer attended both appointments. The body mass index (BMI) and health status were recorded according to SIGN guidelines [8]. During data collection each child was supplied with standardized footwear and the appropriate F-Scan insole size was used without socks. Participants were included in the study if they presented without painful or pathological lower extremity joint involvement (hip, knee, ankle, foot) as it would have directly affected their natural gait; aged between 5 to 18 years old; if they were able to walk a minimum of 15 metres without assistive devices; and if they were not taking any medications. Participants were excluded if they were unable to walk barefoot or shod; or if they presented with concomitant musculoskeletal disease, central or peripheral nerve disease and endocrine disorders, especially Diabetes Mellitus. Finally, children that had previous foot surgery and using foot orthosis were also excluded from the study.

Each visit was completed within 30 to 45 minutes, depending upon the age of the child. The F-Scan insoles (model used 3000E) were completely new and they were accurately trimmed according to the instruction provided by the manufacturer. If the F-Scan was trimmed wrongly, without following the in-printed outlines of the sensors, some of the sensor became void and it would have been clearly highlighted by the software prior to commence a recording. During this trial, the same chief investigator prepared all sensors to be fitted correctly inside the standardized footwear (Figure 1). The

Introduction

The F-scan - Tekscan® (Boston, US) in-shoe pressure measurement system allows collecting objective quantifiable measures to study different types of lower limb pathologies, and it ensures a high degree of portability of the system in different clinical settings [1-6]. In-shoe measurement system is capable of capturing multiple footsteps data from both feet at the same time and record foot functional patterns directly inside the shoe. During in-shoe recording the participant is able to exhibit natural walking pattern without the influence of targeting a force plate positioned on the floor [7]. The F-Scan insole are 0.15 mm thick, pressure ranges from 345 to 862 kPa, and each F-scan insole comprises a total of 954 sensing elements (3.9 sensel per cm²) [7].

The F-scan system appears to be able to collect repeatable gait recordings in adult podiatric management [5]. At present, no evidence is available with regards to the repeatability and reproducibility of the F-Scan system especially in children. The findings of this research may support the application of modern in-shoes technology for future gait analysis clinical trials useful to clearly identify preventable pediatric biomechanical issues. The aim of this study is to test the reliability and reproducibility of the F-Scan system in the gait of healthy children.

Methods

Healthy children were recruited for the study and they took part in non-invasive clinical assessments. The Ethics Committee granted



Figure 1: The F-Scan system was carefully trimmed to fit the entire plantar surface of the standardised footwear

cover vinyl lamination layers were removed from the F-Scan prior initiate the gait recording.

The equipment was set up following the manufacturer's instructions [7]. Walking calibration was carried out before each gait recording (Figure 2). Each participant was calibrated using the Tekscan software, while wearing the F-Scan belt, the connecting wires, the battery and finally the ankle cuff, which overall weighted 1.7kg (Figure 3). The child was asked to perform two 7 metres walks along the entire length of the gait laboratory prior to starting the recording, simply to familiarize with the equipment. A tape attached to the floor defined the starting and the finishing point. Every participant was recorded walking three times a distance of seven metres each; overall five steps per trial were retained for analysis, always excluding the first and last step. All recordings were saved with their anonymous code number. The same procedure was repeated at one-week interval. Participants were advised to wear similar clothing for the following week's data collection, in order to limit and control the variables that could affect the final results.

The PP-Box approach was adopted during data analysis and consisted in uploading on the recording the equivalent of a magnifying lens that allowed extrapolation of pressure parameters from the selected plantar aspect of the foot [7]. The anatomical areas investigated during plantar pressure masking were: total contact area, heel, midfoot, forefoot, fifth metatarsal head, third-fourth metatarsal heads, second metatarsal head, first metatarsal head, lesser toes, first hallux (Figure 4). For each of the 10



Figure 3: Represents how each participant was set up with the F-Scan system prior to each calibration and recording

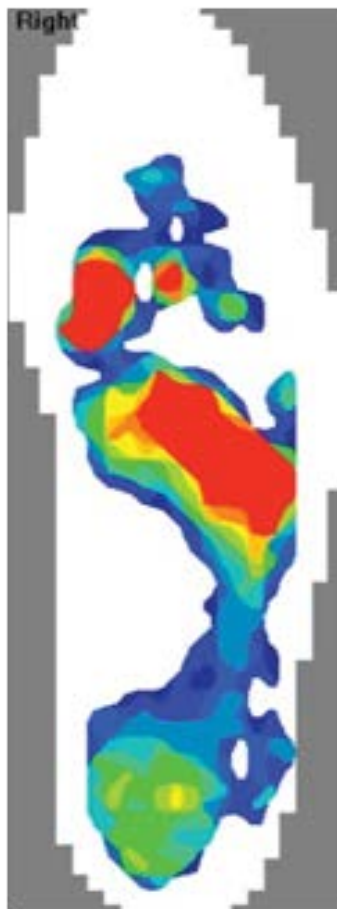


Figure 2: Represents a typical plantar pressure recording obtained using the F-Scan system, where high pressure areas can be easily identified; in this particular case: 1st distal phalanx and 2nd - 5th metatarsal heads

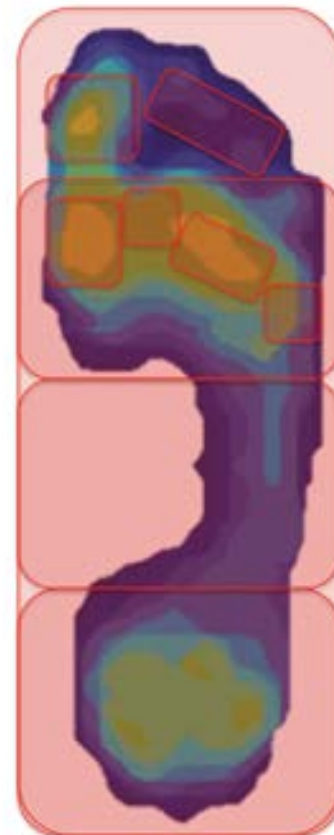


Figure 4: The anatomical areas investigated during plantar pressure masking were: total contact area, heel, midfoot, forefoot, 5th metatarsal head, 3rd-4th metatarsal heads, 2nd metatarsal head, 1st metatarsal head, lesser toes, 1st hallux

anatomical areas of the plantar surface of the foot, PP and PTI were investigated. The PP values identify the specific senses where there is the highest amount of pressure within a specific plantar region; instead, the PTI is defined as the relationship between the amounts of pressure of all sensors applied throughout a period of time within a specific plantar region [7].

Data Analysis

The repeatability is believed to be the ability of a measuring instrument to record the same value for repeated measure under the same experimental conditions, indicating the repeated measure of the same variables of the quantity being analyzed (identical sample) are taken by the same individuals using the same equipment and the same conditions [9,10]. In order to test for repeatability of the F-scan, recordings were carried out within the same environment using the same standardized footwear and same shoe size, utilizing the same equipment and the same distance was recorded by the participants. The repeatability tests involved the analysis between the three recordings taken at baseline and between the three recordings made at week 1.

Reproducibility of a measuring instrument describes the ability of the instrument to produce consistent results under different condition, that is, on different days [9,10]. Therefore, in order to obtain results from the reproducibility study, the average was calculated between the three recordings taken at baseline, and the average of the values gathered one week later. The two averaged values were compared and ICC one-way random analysis was carried out between each other. Where data was normally distributed, a paired t-test was used to test for differences between baseline and week 1 interval, and a Wilcoxon’s test for non-parametric pairwise comparison. Microsoft Office Excel (2007) and SPSS statistical software (version 17.0) was used for all statistical analysis.

According to Portney and Watkins [11], the ICC represents a valuable statistical test that should adopt in clinical research when comparing reliability of data [11]. In addition, the authors stated that the inter-rater reliability values are deemed to be: ‘good’ when ICC is > 0.75; ‘moderate’ when ICC value is between 0.5 and 0.75; ‘poor’ reliability is found if ICC values are less than 0.5 [11]. Comparably a much older publication carried out by Fleiss [12], reported that if the ICC values are greater than 0.75 ‘excellent’ reliability is attained. The ICC data obtained between 0.4 and 0.75 are meant to have ‘fair-to-good’ reliability [12]. Finally, an ICC value less than 0.4 is considered to be have a ‘poor’ reliability [19]. As Portney and Watkins [11] were the most recent evidence based and the score-classification is stricter, it was chosen for this study.

All 30 healthy children managed to attend the Motion Analysis Laboratory at baseline and at one-week intervals. Overall, 53.3% (n = 16) were female and 46.7% (n = 14) were male. Mean age was 13.3 years (SD = 4.5), with a range of 5 to 18.6 years. The health status showed that 6.7% (n = 2) were underweight, 73.3% (n = 22) participants were healthy; 13.3% (n = 4) were overweight and finally 6.7% (n = 2) were obese. Health status and weight of all participants remained unaltered between baseline and one-week interval.

Results

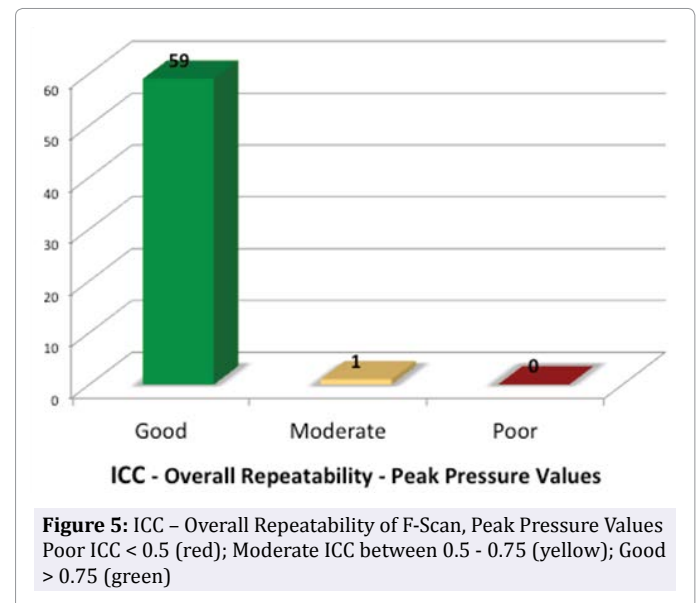
F-Scan Repeatability

For the data analysis of PP, positive results were obtained at baseline (Table 1). In all 10 anatomical areas investigated it was possible to observe ‘good’ ICC values for left, right and both feet. Similarly, after one week, the same ‘good’ ICC results were gathered in all anatomical areas with the exception of the right foot for the ‘lesser toes’, which scored ‘moderate’ ICC values. Therefore, results show a

Repeatability of F-Scan						
Peak Pressure Values						
Anatomical Area	Baseline			Week 1		
	Left	Right	Both	Left	Right	Both
Total	0.933	0.970	0.960	0.972	0.940	0.961
Heel	0.833	0.976	0.952	0.946	0.920	0.936
Midfoot	0.879	0.885	0.879	0.909	0.858	0.883
Forefoot	0.952	0.974	0.964	0.973	0.951	0.966
5 th	0.953	0.872	0.924	0.896	0.945	0.917
3 rd -4 th	0.947	0.952	0.949	0.941	0.945	0.943
2 nd	0.961	0.963	0.962	0.980	0.947	0.971
1 st	0.937	0.978	0.964	0.944	0.935	0.942
Lesser Toes	0.858	0.857	0.856	0.893	0.716*	0.807
Distal Phalanx	0.951	0.920	0.938	0.955	0.917	0.933
% (no)	Good		Moderate		Poor	
100% (30)	98.3%(no=59)		1.7%(no=1)		0%(no=0)	

Table 1: ICC repeatability results for F-scan regarding PP at baseline and at week 1

** means ‘poor’; * means ‘moderate’; ‘none’ means ‘good/excellent’. Poor ICC < 0.5 (red); Moderate ICC between 0.5-0.75 (yellow); Good > 0.75 (green)



high repeatability trend when PP was measured at baseline and one week later. Overall, 98.3% (no = 59) showed ‘good’ ICC, and 1.7% (no = 1) was ‘moderate’ ICC for PP repeatability (Table 1, Figure 5).

The PTI values at baseline for the left, right and both feet showed that ‘good’ ICC scores were found for all anatomical areas at baseline (Table 2). Only the left and ‘both’ for the lesser toes appeared to have a ‘moderate’ ICC score. The analysis carried out one week later confirmed the ‘good’ ICC scores in all anatomical areas; with the similar exception of the right and ‘both’ values of the lesser toes, which presented with ‘moderate’ ICC score. Finally, despite few ‘moderate’ ICC data gathered at the ‘lesser toes’, when PTI analysis was carried out, the ICC showed a highly repeatable trend for most anatomical areas investigated. Finally, 93.3% (no = 56) showed ‘good’ ICC, and 6.7% (no=4) was ‘moderate’ ICC for PTI repeatability (Table 2, Figure 6).

F-Scan Reproducibility

As shown below on Table 3, the PP reproducibility analysis

Repeatability of F-Scan						
Pressure Time Integral						
Anatomical Area	Baseline			Week 1		
	Left	Right	Both	Left	Right	Both
Total	0.959	0.924	0.947	0.943	0.951	0.928
Heel	0.856	0.786	0.827	0.933	0.830	0.893
Midfoot	0.846	0.761	0.809	0.836	0.847	0.838
Forefoot	0.970	0.904	0.950	0.954	0.832	0.917
5 th	0.885	0.915	0.897	0.884	0.899	0.889
3 rd -4 th	0.926	0.936	0.930	0.914	0.914	0.914
2 nd	0.937	0.963	0.952	0.970	0.898	0.954
1 st	0.889	0.910	0.901	0.929	0.871	0.913
Lesser Toes	0.674*	0.860	0.728*	0.763	0.675*	0.717*
Distal Phalanx	0.938	0.767	0.900	0.889	0.825	0.857
% (no)	Good		Moderate		Poor	
100% (30)	93.3%(no=56)		6.7%(no=4)		0%(no=0)	

Table 2: ICC repeatability results for F-scan regarding PTI at baseline and at week 1
 ** means 'poor'; * means 'moderate'; 'none' means 'good/excellent'. Poor ICC < 0.5 (red); Moderate ICC between 0.5 - 0.75 (yellow); Good > 0.75 (green)

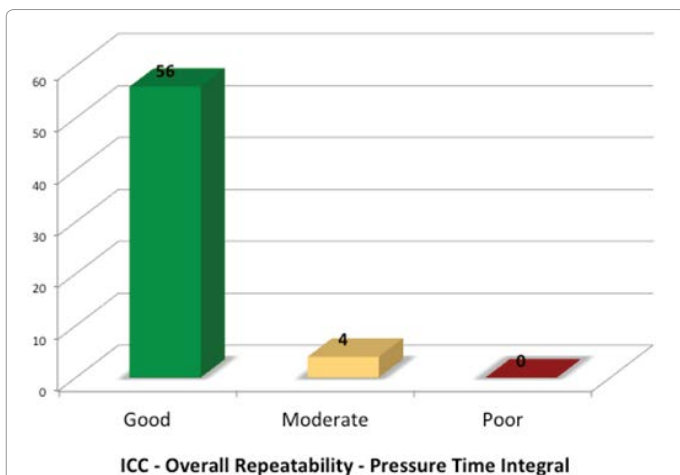


Figure 6: ICC - Overall Repeatability of F-Scan, Pressure Time Integral. Poor ICC < 0.5 (red); Moderate ICC between 0.5 - 0.75 (yellow); Good > 0.75 (green)

Reproducibility of F-Scan				
Peak Pressure Values				
Anatomical Area	Left	Right	Both	
Total	0.845	0.860	0.825	
Heel	0.803	0.801	0.704*	
Midfoot	0.961	0.823	0.901	
Forefoot	0.896	0.872	0.894	
5 th	0.857	0.676*	0.780	
3 rd -4 th	0.778	0.836	0.803	
2 nd	0.805	0.779	0.895	
1 st	0.846	0.939	0.857	
Lesser Toes	0.917	0.787	0.816	
Distal Phalanx	0.900	0.782	0.831	
% (no)	Good		Moderate	
100% (30)	93.3%(no=28)		6.7%(no=2)	

Table 3: ICC reproducibility results for F-scan regarding PP at baseline and at week 1
 ** means 'poor'; * means 'moderate'; 'none' means 'good/excellent'. Poor ICC < 0.5 (red); Moderate ICC between 0.5 - 0.75 (yellow); Good > 0.75 (green)

reported 'good' ICC values in all anatomical areas investigated for the left, right and both feet accounted together. The only exception consisted in a 'moderate' ICC score recorded for the 5th right metatarsal head and heel in both feet. These results show a positive trend indicating that the F-Scan system is able to record highly reproducible data between baseline and one week intervals. Overall, 93.3% (no = 28) showed 'good' ICC, and 6.7% (no = 2) has 'moderate' ICC for PP repeatability (Figure 7). Finally, no PP statistical difference was recorded between baseline and week 1 (Table 4).

As shown below in Table 5, PTI analysis appeared to have 'moderate' ICC results, particularly recorded on the: total contact for 'both' feet, heel on the right and both feet, third-fourth metatarsal heads on the left and for both feet; and on the lesser toes for both feet only. All remaining anatomical areas investigated appeared to have 'good' ICC reproducibility for PTI. Overall, PTI showed very positive reproducible data over one week interval; specifically, 76.7% (no = 23) showed 'good' ICC, and 23.3% (no = 7) had 'moderate' ICC (Figure 8). As illustrated on table 5, no PTI statistical difference was recorded between baseline and week 1. Finally, the trend of reproducibility ICC results for PP and PTI appeared very similar to the positive results gathered during the repeatability study.

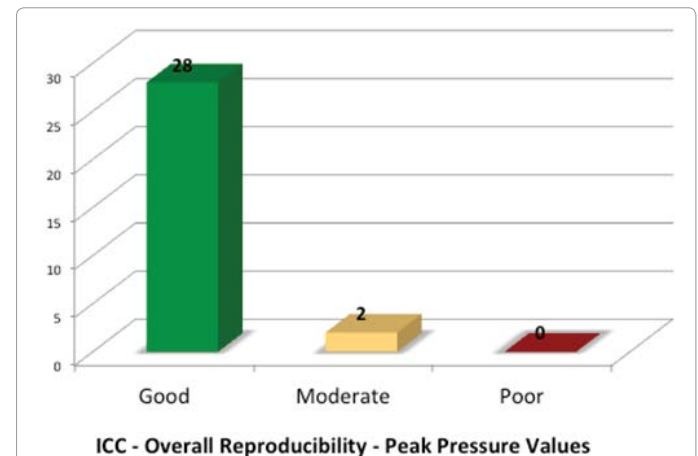


Figure 7: ICC - Overall Reproducibility of F-Scan, Peak Pressure Values. Poor ICC < 0.5 (red); Moderate ICC between 0.5-0.75 (yellow); Good > 0.75 (green)

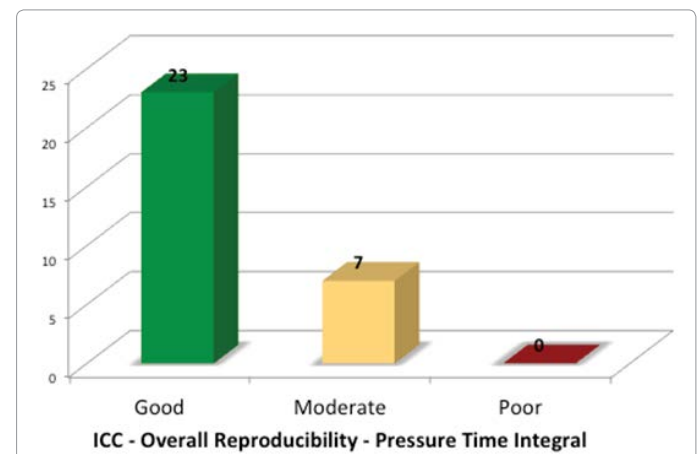


Figure 8: ICC - Overall Reproducibility of F-Scan, Pressure Time Integral. Poor ICC < 0.5 (red); Moderate ICC between 0.5 - 0.75 (yellow); Good > 0.75 (green)

Peak Pressure Values					
Anatomical Area	Baseline		Week 1		Wilcoxon's Test
	Means(SD)	Median(IQR)	Means(SD)	Median (IQR)	
Total	496.5(226.1)	430(361.17)	508.24(219.72)	487.25(276)	0.572
Heel	353.36(122.74)	335.33(172.5)	373.89(152.94)	340.33(272.5)	0.152
Midfoot	114.38(80.2)	103.5(105.17)	120.33(82.38)	117.17(106)	0.283
Forefoot	349.78(174.56)	304.83(260.42)	364.03(181.77)	319(262.75)	0.403
5 th metatarsal	163.55(123.17)	136.33(137.92)	187.91(143.97)	158.33(159.83)	0.07
3 rd -4 th metatarsals	273.75(159.12)	234.67(177.26)	282.14(160.68)	241.5(204.92)	0.303
2 nd metatarsal	318.7(158.63)	285.33(239)	318.6(177.52)	262.33(291.83)	0.584
1 st metatarsal	204.86(123.41)	168(132.33)	201.51(118.22)	181.33(165.67)	0.623
Lesser Toes	179.47(89.47)	161(97.49)	187.59(95.45)	172.33(145.5)	0.361
Distal Phalanx	273.19(203.1)	226(162.67)	252.04(186.39)	190.33(117.17)	0.054
Pressure Time Integral Values					
Anatomical Area	Baseline		Week 1		Wilcoxon's Test
	Means(SD)	Median(IQR)	Means(SD)	Median (IQR)	
Total	76.83(27.48)	72.66(41.4)	81.58(36.21)	76.65(48.97)	0.504
Heel	56.01(23.46)	50.7(22)	59.21(25.63)	58.76(32.58)	0.223
Midfoot	26.09(16.91)	24.76(21.56)	28.63(17.38)	28.75(24.36)	0.088
Forefoot	54.27(26.03)	48.11(29.31)	55.67(23.22)	50.51(39.02)	0.795
5 th metatarsal	51.75(39.7)	40.48(46.65)	53.5(38.14)	41.31(48.18)	0.355
3 rd -4 th metatarsals	67.51(43.02)	53.65(40.67)	69.67(42.17)	58.53(63.7)	0.236
2 nd metatarsal	73.01(39.64)	61.33(56.48)	70.41(39.76)	59.73(60.31)	0.416
1 st metatarsal	47.34(33.97)	35.51(35.67)	45.33(28.03)	36.39(36.11)	0.245
Lesser Toes	29.55(16.18)	26.05(22.59)	31.98(16.41)	26.29(21.1)	0.09
Distal Phalanx	44.18(23.81)	39.5(37.9)	40.44(24.56)	34.27(27.85)	0.118
Overall ICC					
% (no)			Good	Moderate	Poor
Repeatability - 100% (120)			95.8%(no=115)	4.2%(no=5)	0%(no=0)
Reproducibility - 100% (60)			85%(no=51)	15%(no=9)	0%(no=0)

Table 4: descriptive statistics for reproducibility results for F-Scan regarding PP and PTI for both feet accounted together. Details of the Wilcoxon's Test on PP comparison between the baseline and week 1 interval data (* means $p < 0.05$, ** means $p < 0.01$); and overall ICC values (%)

Reproducibility of F-Scan			
Pressure Time Integral			
Anatomical Area	Left	Right	Both
Total	0.853	0.850	0.638*
Heel	0.839	0.714*	0.746*
Midfoot	0.889	0.804	0.784
Forefoot	0.787	0.783	0.781
5 th	0.832	0.710*	0.773
3 rd -4 th	0.653*	0.786	0.705*
2 nd	0.915	0.758	0.835
1 st	0.888	0.838	0.833
Lesser Toes	0.787	0.777	0.733*
Distal Phalanx	0.827	0.765	0.755
% (no)	Good	Moderate	Poor
100% (30)	76.7%(no=23)	23.3%(no=7)	0%(no=0)

Table 5: ICC reproducibility results for F-scan regarding PTI at baseline and at week 1

** means 'poor'; * means 'moderate'; 'none' means 'good/excellent'. Poor ICC < 0.5; Moderate ICC between 0.5 - 0.75; Good > 0.75

Discussion

Reliability studies are often adopted to establish the reproducibility and repeatability level of different equipment used in clinical research; intra-class correlation coefficient (ICC)

has been extensively used to calculate reliability scores when quantitative studies are undertaken [11-14]. The ICC also describes how significantly units in the same group resemble one another [11]. It has been previously reported that when the numbers of investigated parameters are the same for each participant, one-way analysis of variance can be used when investigating the ICC [14]. Furthermore, in order to interpret ICC values, the Portney and Watkins [11] score-classification was adopted in this study, as it is one of the most recent evidence available in this field and similarly reflects the previous findings described by Fleiss [12].

According to Tekscan [7] it is necessary to perform the calibration procedure before any recording. The F-scan equipment utilized weighted 1.7kg, which was added to the participant's original body weight. The walking calibration was chosen because is the most clinically effective, as is carried out automatically [7]. In addition, it is faster than the standing calibration; therefore, it allows increasing the number of recording per participants that can be carried out within busy clinical environments. Walking calibration may also be beneficial for those young children who are not able to stand on one foot for prolong period of time [7]. In addition, using the 'stand-calibration' during clinical consultation it may expose symptomatic children to experience pain for an unnecessary prolonged time whilst standing on a single-foot. Continued calibration failure due to symptoms or balancing issues, could have increased the calibration time; thus children may become unhappy and may start adopting an altered gait because of

being tired or possibly in pain.

Unanimous consensus needs to be yet obtained as to the most suitable approach for the analysis of both feet or just one [15]. Menz (2004) stated that the easiest approach is to select only one side, for example: the dominant foot, the “worst” foot, or randomly selecting a single foot. On the other hand, this author also claims that there is a possibility that by adopting these approaches, it would miss important plantar pressure information, either by discarding meaningful data or obscuring potentially valuable results [15]. In order to avoid any criticism, for the nature of this repeatability and reproducibility study of the F-Scan system, the reader is informed on data from single foot (left and right) and both feet accounted together.

Recent studies into children and adults biomechanics reported that plantar foot pressure is often carried out for research and clinical consultations [16-20]. Previous researchers explained how plantar pressure masking was carried out into seven different anatomical areas (1st, 2nd, 3rd till 5th metatarsal head, medial and lateral portion of the midfoot, and medial and lateral portion of the heel) [19]. Digital areas were omitted during data analysis as considered negligible to non-existent [19]. However, technology has significantly improved since that time, and sensor resolution and software specifications are today able to investigate changes to those plantar pressure areas, which inevitably had to be previously disregarded. Although foot masking in 10 different plantar areas has been previously carried out [21-23], this research demonstrates for the first time that both PP and PTI provided repeatable and reproducible data in all 10 masked areas of the foot when using the F-Scan system in children.

Few studies suggested that the F-Scan is suitable for research and clinical applications [2,4,5]. Data obtained showed that the repeatability study presented with ‘good’ ICC score in most of the plantar pressure areas. Only in few occasions the lesser toes indicated ‘moderate’ ICC score. However, caution should be exercised when considering the pressure data during the final 10% of walking contact [2]. Possible factors that contributed to ‘moderate’ ICC scores may be linked to: inevitable human errors during data extrapolation process; different clothes worn by the participants; and finally different levels of attention exhibited during recording by the child. All these possible factors should be taken into account when interpreting the results obtained. However, with regards to PP and PTI, statistical analysis highlighted no significant difference of the average plantar pressure masking results between the baseline and one week interval (Table 5).

The process for extrapolation and analysis of the data had to be carried out manually which resulted to be quite lengthy. It can be argued that with the development of technology and new software updates, the extrapolation process will hopefully become automated, which certainly will help in reducing time and possible related human-error. Finally, these encouraging results may support the use of modern in-shoes technology for future pragmatic clinical trials in pediatric plantar pressure analysis.

Conclusion

The results attained suggested that the F-Scan system is able to record repeatable and reproducible plantar pressure data amongst healthy children. Predominantly ‘good’ ICC scores were gathered in most of the 10 plantar pressure areas when investigating PP and PTI. Only few moderate ‘moderate’ ICC values were recorded particularly on the ‘lesser toes’. Finally, these results strongly indicated that the F-scan system may be suitable for pediatric plantar pressure research purposes and for clinical investigation of children’s gait.

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***Corresponding author:** Andrea Coda, The University of Newcastle, Faculty of Health and Medicine, School of Health Sciences, Precinct Building, BE154, PO Box 127, NSW - 2258, Ourimbah, Australia, E-mail: Andrea.Coda@newcastle.edu.au

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