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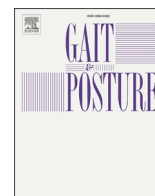
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Responsiveness of the Foot Profile Score in children with hemiplegia

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ABSTRACT

Background: The Foot Profile Score (FPS) is a single score that summarises foot posture and dynamic foot motion during the gait cycle based on the kinematic data of the Oxford Foot Model. The FPS enables clinicians and researchers to quantify foot abnormalities during gait, to monitor change in foot/ankle motion over time, and to measure the outcome of intervention. With the creation of a new outcome measure, it is important to test its responsiveness in a clinical population for whom it may be sensitive to change.

Aim: To evaluate the responsiveness of the FPS in a clinical population following isolated foot and ankle surgery.

Methods: Using previous work completed to validate the FPS, we defined the minimal clinically important difference (MCID) for the FPS. Using this MCID, we applied it to a clinical population of 37 children with cerebral palsy, spastic hemiplegia, comparing their FPS before and after foot and ankle surgery. A regression analysis looked at potential relationships between the change in FPS and their pre-operative FPS, age at surgery, and time since surgery.

Results: An MCID of 2.4 degrees was calculated through regression analysis. The mean change from the pre-operative FPS to the post-operative FPS was 4.6 (SD 3.7 with a range from −0.1 to 13.4). Twenty-eight children (76%) had a change in their FPS greater than the MCID. A regression analyses only showed a clear regression between pre-operative FPS and change in FPS ($R^2 = 0.58$ $p < 0.01$).

1. Introduction

The Foot Profile Score was created and validated in 2019 as a single score of foot posture and dynamic foot motion during gait [1] based on the kinematics of the Oxford Foot Model [2]. The FPS is calculated as the root mean square average of 6 key kinematic variable scores (Foot Variable Scores- FVS), each calculated as the root mean square difference over the gait cycle between a patient's data and normative data individually for right and left legs [1]. The 6 variables included in the FPS represent the motion of the hindfoot relative to the tibia in the sagittal, coronal, and transverse planes, as well as the motion of the forefoot relative to the hindfoot in the sagittal, coronal and transverse planes [1].

Hijji and colleagues state that an ideal outcome measurement tool should be 'relevant, reliable, valid, and responsive to a given pathology' [3]. In addition, the FPS should be able to detect a clinically meaningful

difference when analysing a progression in dynamic foot deformity over time, or a change in foot motion following an intervention [3]. The Oxford Foot Model has been shown to be repeatable in both adult and child healthy populations [2,4–6], as well as in children with foot deformity [7]. The FPS has been shown to be relevant and valid, particularly in populations where foot deformity is the predominant contributor to an altered overall gait pattern [1]. What hasn't yet been demonstrated is the responsiveness of the FPS to detect changes within individuals following an intervention.

Children with cerebral palsy who experience walking problems are commonly referred for three-dimensional gait analysis [8,9]. It is well documented that children with cerebral palsy develop musculoskeletal problems over time [9,10] often including progressive foot deformities requiring surgical intervention [11]. For example, children with spastic hemiplegia can present with a variety of foot deformities including equinus, cavo-varus and planovalgus and often benefit from isolated

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foot correction [11,12]. For this reason, the FPS is a relevant outcome measure for this population.

The aim of this study, is to analyse the responsiveness of the FPS following isolated foot and ankle surgery in children with cerebral palsy, spastic hemiplegia.

2. Methods

2.1. Defining the MCID for the FPS

The dataset previously reported by McCahill et al. [1] in the original validation of the FPS was used to define the minimal clinically important difference (MCID). The Clinical Foot Deformity Scale (CFDS) was created by the authors to validate the FPS in the absence of another published dynamic foot deformity scale as described in McCahill and colleagues [1]. Foot videos of 60 subjects were sent to 10 gait analysts affiliated with a 3D gait laboratory from 4 countries (5 physiotherapists, 2 orthopaedic surgeons, 2 clinical scientists/ engineers and 1 paediatric physiatrist). Each subject was scored by 5 gait analysts. The subjects (30 adults and 30 children) included a range of demographics and severity of foot deformity ranging from planovalgus to cavovarus. 23 Subjects had orthopaedic diagnoses, 21 had cerebral palsy and 16 had neurological diagnoses. The gait analysts rated the overall appearance of the foot using a scale from 0 to 3, which was termed the Clinical Foot Deformity Scale (CFDS: 0 =normal, 1 =mild, 2 =moderate, 3 =severe foot deformity) with no further instructions. The CFDS was taken as the mean of all 5 gait analysts' ratings for each subject. The FPS was calculated for the same leg as used for the CFDS scoring for each subject [1]. The MCID for the FPS was defined through linear regression of the FPS on the CFDS, corresponding to the change in FPS associated with a one unit change in the CFDS.

2.2. Responsiveness of the FPS pre-post intervention

A separate group of thirty-seven children with cerebral palsy, spastic hemiplegia was included for this study (mean age 11.9 years, SD 3.03, age range 7–17 years; 21 females/ 16 males; 18 left, 19 right side affected). All children had a pre-op and post-op gait analysis with OFM kinematics [2] collected using a Vicon MX/T-series motion capture

system (Vicon Motion Systems Ltd.) including 16 cameras collecting at 100 Hz. Subjects walked at self-selected speed over level ground. The predominant foot deformities (as defined by the gait kinematics) requiring surgical correction included pure equinus (12 children), planovalgus (8 children) and cavovarus (17 children). Surgeries included only procedures below the knee: muscle and tendon lengthenings, tendon transfers, bony osteotomies, and supra-malleolar tibial de-rotations (Supplementary Information). The post-op analyses were completed on average 7.7 months following surgical intervention (range 6–15 months) for all 37 subjects.

For the purposes of this study, the definition of *responsiveness* is – the percentage of subjects where the change in FPS exceeds the MCID following surgery. This would indicate what percentage of subjects had a clinically meaningful change in their dynamic foot function post-surgery. All 37 subjects were analysed for their pre- post-surgical differences in their FPS. The change in FPS was also regressed on the subjects' age at surgery, time since surgery, and on their pre-operative FPS.

All analyses were completed using SPSS version 25, IBM, Chicago. Significance level was set at $p < 0.05$.

3. Results

3.1. Defining the MCID for the FPS

The MCID for the FPS was defined at 2.4 degrees with a significance of $p < 0.001$ (Fig. 1) as the regression coefficient, corresponding to a one unit change in the CFDS.

3.2. Responsiveness of the FPS pre-post intervention

The mean change from the pre-operative FPS to the post-operative FPS was 4.6 degrees (SD 3.7 with a range from –0.1 to 13.4 degrees). Nine children (24%) did not reach the MCID of 2.4 degrees, one of whom worsened in their FPS by 0.1 degree. For the 9 children who did not reach the MCID, their pre-operative FPS ranged from 5.2 to 13.5 degrees and their pre-operative foot postures were: 3 cavovarus (18% of cavovarus feet), 3 planovalgus (38% of planovalgus feet), 3 equinus (25% of equinus feet) (Fig. 2). The mean change for all children treated for

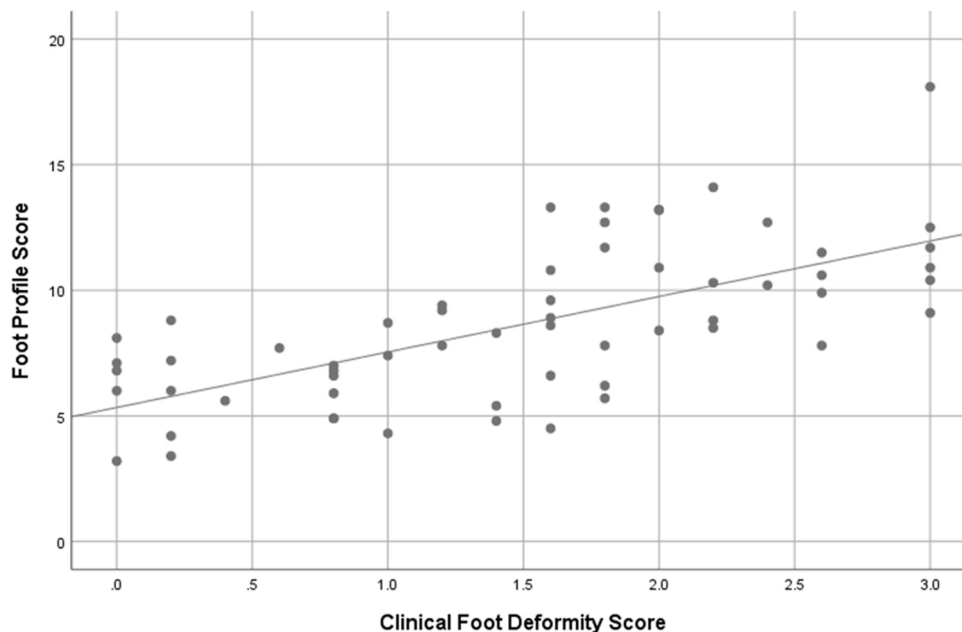


Fig. 1. Regression of the Foot Profile Score on the Clinical Foot Deformity Score Reprinted with permission from McCahill et al., 2019.

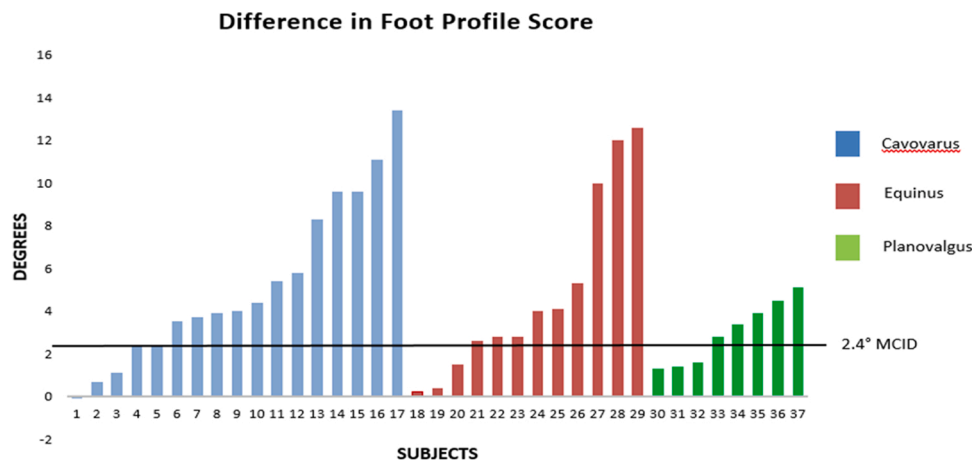


Fig. 2. The difference in the FPS for all subjects, grouped into cavovarus, equinus and planovalgus pre-operative foot deformities.

cavovarus foot deformities was 5.2 degrees (SD 3.9 with a range from -0.1 to 13.4), equinus was 4.9 degrees (SD 4.3 with a range from 0.2 to 12.6) and planovalgus was 3 degrees (SD 1.5 with a range from 1.3 to 5.1).

Regressing the change in FPS on the pre-operative value of the FPS yielded a significant result with $B = 0.67$ (SE 0.10) at $p < 0.01$, and $R^2 = 0.58$, indicating 58% of the variance in the FPS difference can be explained by the pre-operative value of the FPS (Fig. 3). Regressing the change in FPS on the subjects' age at surgery suggested a trend towards significance with $B = -0.362$ (SE 0.197) at $p = 0.074$. Regression of the change in FPS on the time since surgery was not significant, $B = -0.048$ (SE 0.271) $p = 0.86$.

4. Discussion

Children with cerebral palsy, spastic hemiplegia commonly have isolated surgery to the foot/ ankle and are therefore an appropriate population to determine the responsiveness of the FPS without the confusing factor of additional surgeries. The results showed in our cohort of 37 children with spastic hemiplegia that 28 children (76%) met or exceeded the MCID of the FPS indicating a clinically meaningful improvement in the dynamic function of their feet following isolated

foot and ankle surgery.

Our data shows, when regressing the change in FPS on the pre-operative FPS, the FPS fits with an established trend found by Rutz et al. when analysing the change in Gait Profile Score in children with cerebral palsy post multi-level surgery [13]. As well as an expected regression to the mean effect, a greater degree of abnormality in the FPS prior to surgery means a greater scope for improvement following surgery. This strengthens the confidence that the FPS is a responsive outcome measure. It also suggests a potential floor effect, as once the kinematics near the normal range, further improvements become less detectable. This raises an interesting dilemma about an MCID in general as the clinically important change in an outcome measure may be proportional to the original degree of deviation from norm, therefore those with minor deviations prior to surgery may not be expected to exceed a fixed MCID.

It is important to highlight that although the FPS offers an objective assessment of foot shape and dynamic motion during gait, it does not capture other aspects such as pain. There are other factors that influence the subjective success of a procedure; therefore, the FPS should always be considered in combination with other outcome measures as a part of pre/post-surgical assessment.

Interestingly our results suggest that two factors may have a role in

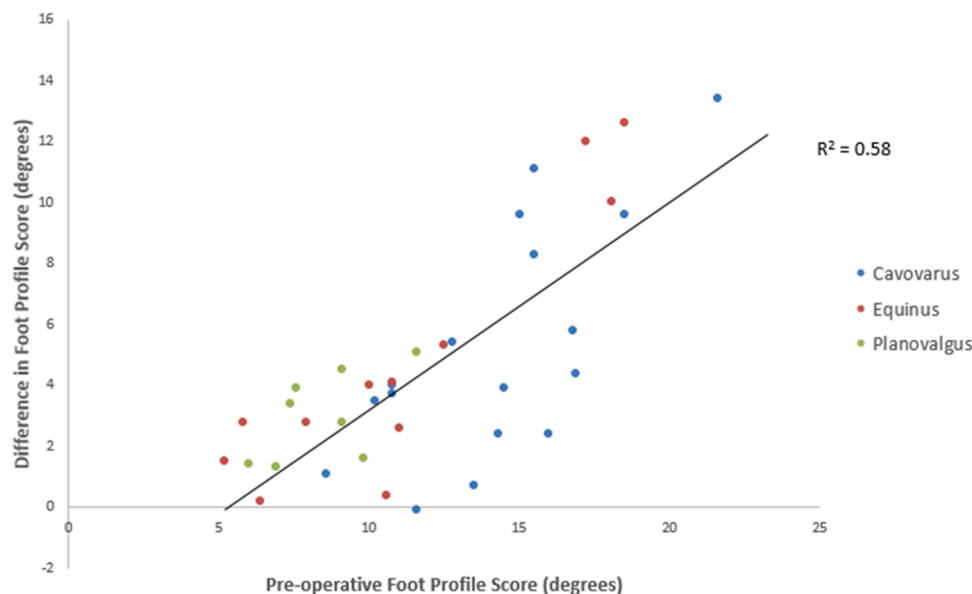


Fig. 3. Regression of the difference in the Foot Profile Score on the pre-operative Foot Profile Score in degrees.

the outcomes following foot corrective surgery in children with hemiplegia, which require further investigation. Firstly, we will consider the type of pre-operative deformity: cavovarus, equinus, planovalgus. Sees and Miller [11] state that foot deformity is the most common orthopaedic problem in children with cerebral palsy. Many authors suggest that equinus and cavovarus deformities are the most common in hemiplegia [11,14], and our convenience sampling supports this. However, a natural tendency to planovalgus does exist in this population, and it can also occur due to over-correction of an equinus or cavovarus foot posture [15]. Interestingly, no published study seems to compare the results of foot deformity correction based on the initial deformity. Further long-term follow up research is therefore justified to consider if one type of foot deformity in cerebral palsy is easier than the other to correct and maintain its correction.

The second factor which may influence the results of surgery is the age of the child at the time of surgery. Our results suggest that the younger children in our cohort (age range 7–17 years), had a greater difference in their FPS post-surgery than our older children, without this achieving statistical significance at the conventional 5% level. The FPS does not directly measure how well the foot was corrected but how well it is moving dynamically after treatment. Surgery in older children can be more extensive due to fixed deformity and stiffness. Therefore, surgery may improve the overall alignment of the foot, but not improve joint range of motion, or even come at the cost of that. This is particularly true if the surgery is more extensive (leading to more scarring) and/or if it includes bony surgery including joint fusions. Contrary to this, minor soft tissue surgery in younger children will often correct the foot shape but also improve range of joint motion. Two recent review papers have looked at longer term results of foot surgery in cerebral palsy. Review papers by both Koman et al. [16] and Shore et al. [15] concluded that age at first surgery is the greatest predictor of recurrent equinus deformity in children with CP, and therefore conservative methods of management should precede any surgical intervention. Both of their review papers included children with spastic diplegia and spastic hemiplegia and both sets of authors acknowledge this makes it very difficult to make recommendations on individual cerebral palsy subtypes [15,16]. In addition, the age at surgery for our included cohort is older than the majority of the reviewed papers indicating conservative management was likely employed prior to embarking on surgical intervention.

A limitation of this paper could be the MCID based on the association with the CFDS created to validate the FPS in a previous paper [1]. We chose to base the MCID on a full unit in the CFDS, corresponding to a difference in grade that was agreed by all five assessors. It might be argued that if four of five assessors were assessing at a higher grade, this is indicating a difference that is of clinical importance, and an MCID might be set at 2 degrees or lower. Therefore, the value of the MCID warrants further investigation to rigorously evaluate the change in FPS required to make a clinically meaningful difference in a large cohort of subjects. In addition, the repeatability of the FPS is assumed to be good as the repeatability of the OFM has been shown to be good; however, a follow up study of the test-retest repeatability of the FPS would be beneficial. Lastly, we have only assessed the responsiveness of the FPS in one clinical population, therefore we would recommend repeating this study in other populations.

5. Conclusions

An MCID of 2.4 degrees for the FPS indicated a clinically meaningful

improvement in 76% of children with hemiplegia post isolated foot/ankle surgery. Moreover, the FPS responded with larger improvements for more deformed feet. These findings suggest the FPS is sufficiently responsive in a clinical population and should be considered when indicating and evaluating foot surgery. Further testing of the MCID is suggested, as a lower value may still be indicative of clinically meaningful improvement.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.gaitpost.2022.04.012.

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