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Reliability Study of a New Electromechanical Device Designed to Measure the Relative Dorsal Mobility of the First Ray of the Foot

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Abstract

Introduction: A new electromechanical instrument has been developed to measure relative dorsal mobility of the first ray in an objective and reliable way by simulating ground reaction forces during gait. This device equally applies a standardized, electronically controlled, and precise force under the first metatarsal head M1 as well as under the heads of the lesser metatarsals M2 to M5. The relative dorsal mobility between these two bearings is then measured. The purpose of this study is to assess the intra- and inter-examiners reliabilities of the measurements obtained with this device. **Methods:** The protocol included two examiners and 36 feet (18 volunteers with healthy feet and no history of forefoot disorders). A total of nine measurements were performed on each foot separated into three sets of three trials for the assessment of inter-rater and intra-rater reliability. For this purpose, the interclass correlation coefficient (ICC), the error of measurement (SEM) and the Bland and Altman (B&A) graphical analysis were computed. **Results:** Excellent ICC values (≥0.91) were obtained with the novel device for inter-rater and intra-rater reliability when using the FRRM calculation. The B&A analysis presented a bias between examiners of −0.25 mm ranging from −1.66 to 1.18 mm. **Conclusion:** This study demonstrated the capability of the developed device to reliably measure the relative dorsal mobility of the first ray of the foot. This is a promising first step for further studies to better understand, qualify and quantify first ray hypermobility.

Keywords

First Ray Dorsal Mobility, Instability, Hypermobility, Medical Device,

*Contributed equally to this work.

Reliability Study, Foot

1. Introduction

The term hypermobility or instability of the first ray is used to describe an excessive range of motion of the joints related to the first ray of the foot beyond what is considered "normal" [1] [2] [3] [4]. The first ray hypermobility is associated with the development of several forefoot disorders such as hallux valgus, metatarsalgia, stress fractures, flatfoot, Lisfranc chronic dislocation or dislocation of the second metatarsophalangeal joint [2]. The biomechanical function of the first ray plays an important role in the dynamic balance of the foot, particularly by preparing the propulsive phase of the gait [5] [6] [7], thus leading to a high number of different surgical interventions when instability and other symptoms occur [8] [9]. However, clinical assessment of first ray mobility is mainly empirical for clinicians.

A manual examination technique was first described by Morton in 1928 [10] [11], in which a dorsal force is applied under the first metatarsal head with one hand, while the lesser metatarsal heads are held fixed with the other hand. Root *et al.* [12] proposed a modified version of this technique, in which the clinician's hand moves the first metatarsal head to a maximal dorsal, then to a maximal plantar position (**Figure 1(a)**). The evaluation of instability is carried out by comparing the distance between the thumbs in both positions.

Polokoff [13] suggested a different instability evaluation method, in which equal force is exerted, in a dorsal direction, to the second and the first metatarsal heads while comparing the difference in displacement, during a non-weight-bearing position. A modified version of this method was presented by Gérard *et al.* [14], which the authors believe to be more representative of the gait than the other methods.

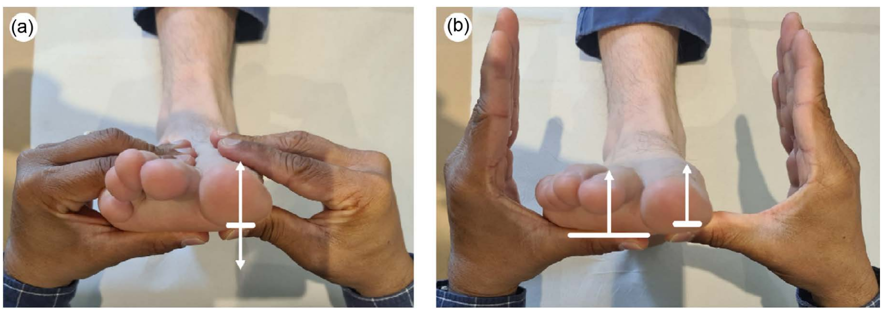

Figure 1. Clinical evaluation of the mobility of the first ray. (a) Examination method proposed by Root *et al.* [12] with the lesser rays *stabilized* by one hand, while the other hand moves the first metatarsal head to a maximal dorsal and then plantar position (absolute instability assessment). (b) The modified Polokoff method presented by Gérard *et al.* [14] with each hand *exerting* an equal force in a dorsal direction under M1 and M2 - M5 while evaluating the relative dorsal displacement (relative instability assessment). The white arrows show the direction of the forces applied by the hands during the examination.

During this method, the examiner applies equal force, in a dorsal direction, under the first and the lesser metatarsals by the use of both thumbs (**Figure 1(b)**). The relative displacement of the first metatarsal head (M1) related to the lesser metatarsal heads (M2 - M5) is evaluated by the distance between the examiner's thumbs.

Until this day, only manual examinations are performed by clinicians for the assessment of the first ray mobility. Nevertheless, Glasoe and Shirk demonstrated that manual examinations were unreliable since they provide wide variations even among experienced clinicians [15] [16].

The interest of the orthopaedic community in addressing this problem has been quite high for many years. The lack of a standardised and reliable technique for measuring first ray mobility motivated clinicians to conceive quantification methods by means of measuring devices. Rodgers and Cavanagh were the first to develop a mechanical experimental device in 1986 [17]. In the 1990s, Klaue and Glasoe proposed and validated technical solutions [18] [19] [20] [21], which were able to quantify instability in dorsiflexion. These mechanical devices perform a relative displacement measurement with the foot in a neutral position while an automatized fixed force or manual unquantified force is applied only under the first metatarsal head without addressing the lesser metatarsals. Recently, Morgan *et al.* [22] developed an electromechanical instrument, which measures the dorsal translation of the first ray by applying a controlled force at the plantar surface of the first metatarsal head. Several other solutions were developed over the years, which were based on handheld rulers [23] [24]. These simple solutions were complementary to the manual examination by attempting to add a quantification aspect to the evaluation of the first ray mobility.

The current study aims to determine the inter- and intra-reliability test of a novel electromechanical device named LaxiPed, which measures the relative dorsal mobility of the first ray related to the lesser rays. In contrast to the previously developed solutions [17] [18] [20] [22], LaxiPed allows an assessment that approaches the physiology of stance phase. During gait, ground reaction forces exert direct stress upwards on the forefoot into dorsiflexion. Theoretically, these normal forces should be equally distributed between the M1 and M2 - M5. In contrast, the load is not supported by the first metatarsal and shifted to the lesser rays in "hypermobile" (or "unstable") feet. Therefore, clinical measurement of dorsal mobility of the first ray is important and should be measured in the most physiological conditions (*i.e.* by applying measurable and equal stress under the first metatarsal and the lesser rays in order to simulate as much as possible the gait situation). This measurement is called: the relative dorsal mobility of the first ray.

2. Materials and Methods

2.1. Subjects Enrolment

The present study included 18 subjects (N = 36 feet), eight males and ten females, who were recruited from an employee pool at the clinic. All subjects enrolled in this study were adults with no history of foot and ankle trauma, surgery, or pain. They were healthy subjects with no history of neurological disease or systemic disease potentially affecting the foot and ankle. They did not have any apparent foot deformity on clinical examination, nor hypermobility of the first ray. The measurements were performed in January 2022 in our private practice in Geneva. The participation of each subject was voluntary and each participant gave consent before the test session. A waiver of consent was obtained by the local EC review board (Req-2021-01473).

2.2. Description of LaxiPed

LaxiPed was designed to assess the relative dorsal mobility of the first ray through a large range of applied force when the foot is in a lying position. **Figure 2** depicts the device comprising a custom-made orthosis with interchangeable right and left insoles configured to receive both feet. The lower limb of the foot is attached with adjustable straps at the shin and midfoot allowing free mobility of the forefoot in the dorsal direction. The measuring instrument is then positioned under the M1 and M2 - M5 metatarsal heads using a positioning module. This controls the relative position between the orthosis and the instrument while constraining the motion along the sagittal axis. As the clinician applies a force (through the handle), the instrument equally distributes this force into two equal forces under M1 and M2 - M5. Simultaneously, the instrument records the relative displacement as a function of the force applied by the clinician. The collected data are transmitted wirelessly to a software application, which displays the evolution of the measurement and calculates the relative dorsal mobility of the first ray.

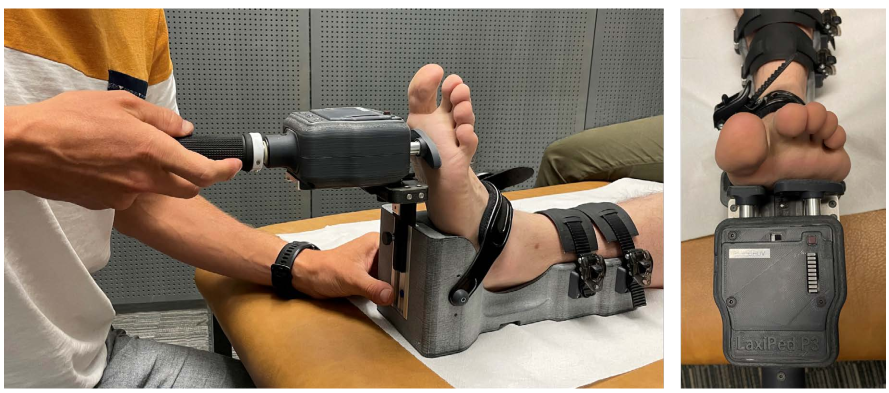

Figure 2. Measuring the relative mobility of the first ray with the LaxiPed device during clinical consultation.

So far, the mobility measurements obtained with the device have shown a characteristic curve described in **Figure 3**, comprising three distinct zones. The Resting Zone corresponds to a first plateau, which represents the initial position of the first and lesser metatarsals in the sagittal plane when the applied force does not result in a relative displacement. This zone corresponds to a force between 0 N and 20 N. Note that the initial relative displacement (Y1) depends on the position of the first ray compared to the lesser rays in the sagittal plane. The first ray can be higher, lower, or at the same transverse plane as the lesser rays depending on the structure of the foot (cavus, rectus or planus) [25]. The Elastic zone corresponds to an increase in relative displacement with an increase in the applied force. The equilibrium zone corresponds to a second plateau, at which the mobility of the first ray has reached its equilibrium state and no longer increases with the applied force. This zone is mapped to an applied force ranging between 60 N and 110 N. The maximum applied force of 110 N is equivalent to the 55 N force suggested by Glasoe to fully translate the first ray in dorsiflexion [20] [21]. This is due to LaxiPed's mechanical system that divides the applied force into two equal forces.

The relative dorsal mobility of the first ray of the foot (FRRM) is calculated at two points of this assessment using the following equation:

$$\mathrm{FRRM} = \mathrm{RM}_{\mathrm{F2}} - \mathrm{RM}_{\mathrm{F1}} \tag{1}$$

where, $\mathrm{RM}_{\mathrm{F1}}$ corresponds to the initial displacement at force F1 of 10 N and $\mathrm{RM}_{\mathrm{F2}}$ correspond to the final displacement at force F2 ranging between 70 N to 110 N.

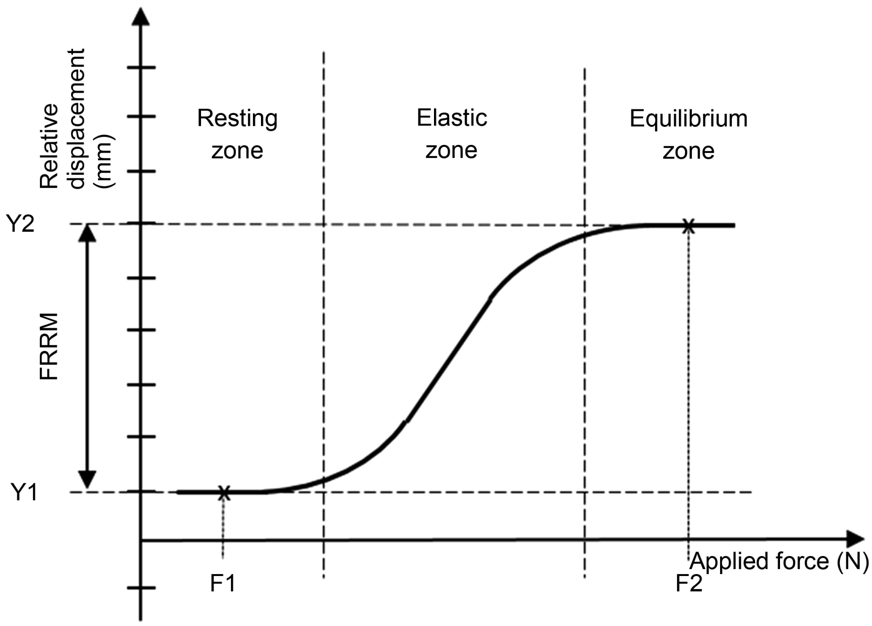

Figure 3. Characteristic curve of the relative mobility of the first ray obtained with the measuring instrument over the entire measuring range.

2.3. Testing Protocol

The inter-rater and intra-rater reliability were conducted by two independent examiners. They were both orthopaedic surgeons, who specialize in foot and ankle surgery and they were allocated randomly. None of them had any previous experience with the measuring device. A series of nine consecutive measurements divided into three sets of three trials were performed per foot. For each set of measurements, mean values were calculated for the variables RM_{F1}, RM_{F2} and FRRM.

The inter-rater reliability was evaluated from sets 1 and 2 by examiners 1 and 2, while the intra-rater reliability (test-retest) was evaluated from sets 1 and 3 by examiner 1. A time interval of five minutes was respected between two consecutive sets. The measuring device was removed after each trial.

Before the first trial, the examiner applied a 10 sec passive stretch on the subject's forefoot in dorsal and plantar directions. This stretch was followed by a 30 sec rest period before the first trial. Between each trial, a 30 sec rest period was respected to allow relaxation of the tendon unit. All trials were performed on the same day.

2.4. Statistical Methods

The sample size was estimated according to the formula of Giraudeau and Mary [26] with a confidence interval (CI) width (w = 0.2), a risk of Type I error (alpha = 0.05) and a repeated measurement (m = 3). The obtained sample size by the use of the formula was 27.1, *i.e*., 28 feet. For each set of measurements, descriptive statistics were used to extract the mean, the standard deviation (SDs) and the standard error of measurement (SEMs). The inter-rater and intra-rater reliabilities were estimated by the intra-class coefficient (ICC) based on a single-rating, absolute-agreement and the two-way random-effects model, considering that examiners were representative of the pool of examiners. Each ICC value was computed with 95% of confidence intervals and was interpreted as poor (<0.5), moderate (0.5 - 0.75), good (0.75 - 0.9), and excellent (>0.9). A Bland and Altman (B&A) analysis was also performed, which evaluates the systematic errors between the set of examiners 1 and 2. The statistical analysis was conducted with SPSS Statistics (version 26, IBM Corp, Armonk, NY).

3. Results

Excellent ICC values (≥0.91) were obtained for the intra-rater and inter-rater reliability for the FRRM. Regarding the variables RM_{F1} and RM_{F2}, their ICC values were ranging between 0.68 and 0.73 for the test-retest and 0.83 and 0.92 for the inter-rater test. Table 1 presents the obtained results.

Figure 4 depicts the B&A graph for the FRRM inter-rater values, which revealed a bias of −0.25 mm with the limits of agreement ranging from −1.66 mm to 1.18 mm.

Table 1. Calculation of the Mean, SD, ICC score and SEM for the intra-rater and inter-rater reliability.

	Intra-rater (test-retest)			Inter-rater		
Variables	Mean ± SD (mm)	ICC [95% CI]	SEM	Mean ± SD (mm)	ICC [95% CI]	SEM
RM_{F1}	2.44 ± 3.47	0.73 [0.53, 0.86]	1.80	2.76 ± 3.52	0.92 [0.84, 0.96]	1.00
RM_{F2}	5.34 ± 3.18	0.68 [0.53, 0.86]	1.80	5.62 ± 3.04	0.83 [0.68, 0.91]	1.25
FRRM	2.90 ± 2.91	0.91 [0.82, 0.96]	0.87	2.86 ± 2.12	0.94 [0.87, 0.97]	0.52

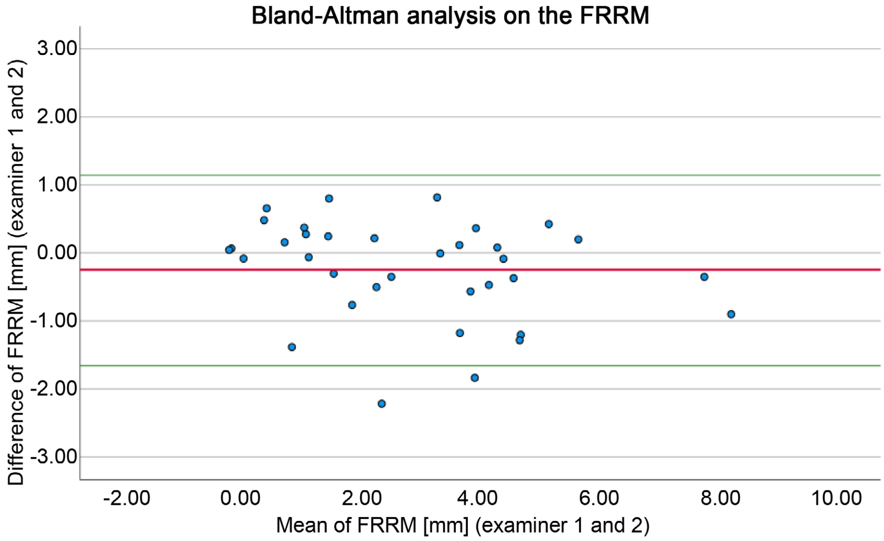

Figure 4. Graphical analysis with the B&A plot on the FRRM of the inter-rater reliability.

Figure 5 depicts a graph of two measurements on the same subject's foot performed during the inter-rater test. The presence of an offset of 0.59 mm in the Resting zone at F1 of 10N and 0.43 mm in the Equilibrium zone at F2 of 70N is revealed by comparing these curves.

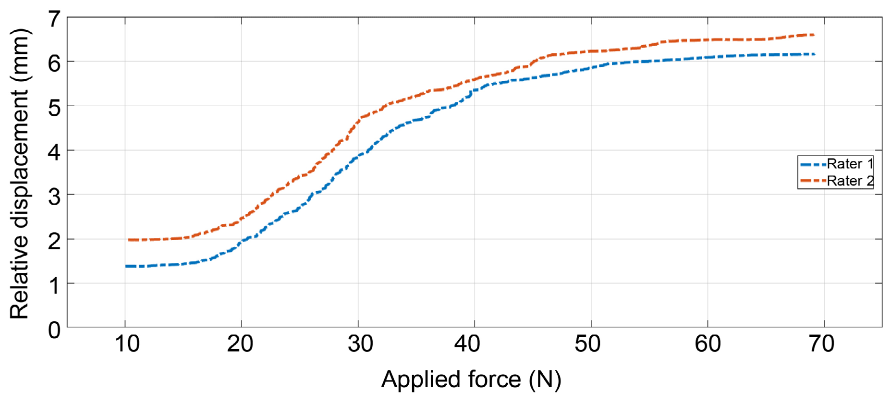

Figure 5. Comparison between two measurements on a subject's foot during the inter-rater test. The graph reveals an offset over the full range of measurement between the obtained curves, which is mitigated by calculating the FRRM.

4. Discussion

The purpose of the present study was to evaluate the reliability of a novel instrument designed to measure the relative dorsal mobility of the first ray of the foot. The authors support the notion that the measurement of first ray dorsal mobility should be conducted by the application of an equal force under the M1 and M2 - M5 metatarsal heads, which is more representative of the stance phase of gait. A novel instrument has been developed that simultaneously measures the force applied by the clinician and the resulting relative displacement. The relative dorsal mobility of the first ray (FRRM) is expressed as the difference between the mobility obtained at the Equilibrium zone (RM_{F2}) and the Resting zone (RM_{F1}). To the best of our knowledge, there is no other device that simulates the ground reaction forces that act during the stance (during which the pressure is equally distributed to the first and the lesser metatarsal heads) while measuring first ray relative dorsal mobility.

The inter-rater and intra-rater reliability of this study demonstrated excellent results for the FRRM values (ICC scores > 0.9). The RM_{F1} and RM_{F2} ICC scores, which ranged from 0.68 to 0.92 were significantly lower than FRRM due to small variations in the positioning of the instrument under the metatarsal heads. These variations in the positioning are represented by an offset between the measurements as observed in **Figure 5**. By computing the FRRM, the offset can be mitigated and therefore reducing the influence of the user on the measurements. Nevertheless, the obtained ICC scores of the FRRM were comparable to other studies conducted with Klaue and Glasoe devices [19] [21].

Another factor that could lead to a bias in the FRRM measurement between examiners is related to the position of the foot inside the orthosis. As described by Grebing and Coughlin [27], the position of the ankle plays an important role in the measurement of first ray mobility. For this reason, the orthosis was designed to immobilize the ankle in a neutral position, while ensuring a tight fit over the midfoot. However, care was taken not to overtighten the midfoot strap in order to not influence medial column motion. Further studies are necessary to understand completely the influence of this last parameter on the measurement. A variation of the FRRM was also observed between successive trials of each set. This effect could be related to the relaxation time necessary for the tendinous structure to return to its resting position. An insufficient time between trials may lead to an increase in the initial displacement (RM_{F1}).

In general, the clinical assessment of the first ray dorsal mobility is influenced by multiple factors [15] [16]. The amount of force applied to the foot during examination and the anatomic landmarks used to measure the dorsal displacement are the most important ones. To control them, a novel instrument has been developed, which has the ultimate goal to provide clinicians and researchers with more objective and reproducible measurements of first ray dorsal mobility. This measurement will allow standardization of the clinical assessment and improve the clinician's decision-making process. The current study suggests that the developed instrument is an appropriate tool for assessing the discussed foot parameter. This is a promising step for further studies that will help to better understand, qualify and quantify hypermobility of the first ray.

5. Conclusion

A novel instrument has been developed to measure the relative dorsal mobility between the first and lesser rays in order to investigate instability-related disorders of the foot. The relative mobility of the first ray is expressed with a new parameter "FRRM", which mitigates the influence of the positioning of the instrument under the metatarsal heads. Results of this study showed excellent reliability and practicality of the instrument in a clinical setting.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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