Validation of a new Equinometer device for measuring ankle range of motion in patients with cerebral palsy
An observational study

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Abstract
The goniometer is the gold-standard measurement tool of ankle range of motion (ROM). However, several studies have questioned its inter- and intra-rater reliability. Therefore, we conducted this validation study to assess the reliability of a different tool, named Equinometer, as a measurement device of ankle ROM in addition to comparing the reproducibility of their results.

Sixteen healthy individuals were included. They underwent both goniometer and Equinometer measurements in knee extension and 90° knee flexion (Silfverskjöld Test). Three raters reported the values of dorsiflexion (DF) and plantarflexion (PF) in each session using both measurement tools. Intra-rater reliability was assessed between 2 raters on another study group of 24 participants. Intraclass correlation coefficients were used to determine the reliability of the used device.

The age of study subjects ranged from 22 to 85 years. Fifty percent were males, and the right ankle joint was the most examined side (68.75%). In terms of DF and PF during knee extension and flexion, our analysis revealed that the measurements recorded by the Equinometer were equivalent to the goniometer. Of note, the intra-rater reliability of the Equinometer was excellent for both DF and PF assessment during both knee flexion and extension (Intraclass correlation coefficient ranged from 0.90 to 0.98), with minimal mean differences from goniometer measurements. Subgroup analysis based on age did not reveal any significant differences ($P > .05$).

Given the high intra-rater correlations of the Equinometer, we suggest that it is reliable and precise in recording ankle ROM in outpatient clinics, particularly to obtain reproducible, comparable and unbiased data from different observers.

Abbreviations: CP = cerebral palsy, DF = dorsiflexion, ICC = intraclass correlation coefficient, PF = plantar flexion, ROM = range of motion.

Keywords: ankle, range of motion, cerebral palsy, equinometer, equinus foot, goniometer

1. Introduction
Equinus foot is recognized as the most common deformity in patients with Cerebral Palsy (CP).\cite{[1]} The diagnosis of equinus foot remains challenging, and Silfverskjöld test is commonly used for initial assessment; however, its validity is questioned by some experts.\cite{[2,3]} Equinus deformity of the ankle joint, associated with reduced passive dorsiflexion, leads to increased and prolonged tension on the Achilles tendon along with increased loading of the forefoot.\cite{[4]} In most cases, the main cause is the shortening of the gastrocnemius muscle, characterized by
reduced ankle dorsiexion upon knee extension and vice versa upon knee flexion. Of note, foot and ankle pathology contribute to discomfort, decreased range of motion (ROM), and decreased quality of life. Mobility and involvement may be impaired by limited ranges of motion. Thus, one of the main purposes of rehabilitation is to enhance ROM in the joint.

For the purposes of both research and therapeutic decision-making, accurate evaluation of ROM is necessary. It is widely used to test the success of treatments as an impact measure. During weight-bearing, the measurement of ROM is known to be more related to everyday life activities mimicking tasks such as stepping, walking, and going from sitting to standing. Radiographic measurements are involved in the evidence-based standard for precise determination of ankle joint ROM. However, for a variety of reasons, including sensitivity to radiation, this procedure is not acceptable for routine use in clinical settings. This has resulted in a variety of noninvasive methods being developed, although no single technique can be considered as the favored methodological approach.

In order to properly diagnose the shortening of the gastrocnemius and triceps surae muscles and to accurately measure the effect of gastrocnemius release, a reliable and reproducible method of measuring ankle dorsiexion should be designed. In clinical practice, goniometry is widely used for the calculation of non-weight-bearing ankle dorsiexion ROM. It requires the assessment by an observer of joint angles, who positions the arms of the instrument instantly proximal and distal to the joint around the bones, giving an approximate angle in degrees. That being said, evidence indicates that, in either a scientific or clinical setting, goniometry might not be a reliable tool. For instance, the interrater reliability of the measurement of ankle joint ROM dorsiexion was found to be very poor (0.03 in flexion and 0.05 in extension). The variability in the reported reliability of the standard goniometer in the literature is related to many factors, including the improper control of the position of the foot and the use of variable amounts of torque that is applied to the ankle joint. Another contributing factor is the challenges associated with the application of this method, where the examiner is required to identify landmarks on the leg and foot, and at the same time hold the foot and leg in the correct position, apply the correct torque, and properly align the goniometer.

For weight-bearing ankle ROM estimation, a consistent measurement methodology needs to be provided, and simplicity of use and portability are both crucial elements for clinical application. In this context, an “Equinometer” has been designed to further standardize these measures by the use of a unique platform measuring system that has highlighted good intra-rater and interrater reliability. In the treatment of a single patient, several measures may be taken by the same practitioner and by different colleagues. Therefore, it’s of great importance to determine whether a newly designed device (aimed to evaluate ankle ROM in CP patients) provides consistent results in the observations of the same rater and reliable observations between different raters. Many devices have been investigated, but most of them include the whole foot, or at least the midfoot, which can lead to incorrect measurements, especially in CP patients, who often have a forefoot equinus and/or hindfoot equinus.

Therefore, the main aim of this current study is to develop and examine the reliability of a method for standardized and reproducible measurement of ankle dorsiexion that leads to proper control of the foot during the application of a controlled torque.

2. Materials and methods

2.1. Participants

This validation study was conducted on healthy individuals with no medical conditions affecting foot mobility or anatomy at the clinic of the Orthopedic University Hospital in Heidelberg, Germany, during the period from July to October 2020. Individuals who had previous operations on the lower extremities and those who had any anatomical or functional disorders of the hindfoot were excluded. Also, those who were not willing to...
participate, and those who withdrew during the study period were ruled out. Prior to conducting this study, the study protocol was approved by the Institutional Review Board (IRB) - Ethics Committee of the Medical Faculty of the University of Heidelberg (S-487/2019) and registered in the German Register for Clinical Studies (DRKS, Number: DRKS00018350). Written informed consent was taken from each participant prior to performing any examinations. Baseline data, including age, gender, and which foot was operated upon, were collected. Baseline data, including participants’ gender and age, as well as which foot was measured, were recorded. This research was conducted in line with the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) for reporting observational studies.

2.2. Equinometer

The Equinometer was developed and manufactured by the hospitals’ technical orthopedics department in Heidelberg based on that of Molund et al.[3] Here, the individual components are positioned and adjusted using bony landmarks. Care was taken to ensure that the subtalar joint was in a neutral or slightly inverted position and that the footplate only fixes the hindfoot. A built-in electrical goniometer was recalibrated before each measurement and for each patient. The measurement was carried out analogous to the goniometer measurement. The Equinometer is shown in Figure 1. A list of the relevant points is shown below. Figure 2 shows the Equinometer in place with the foot in dorsiflexion (DF) (Fig. 2A), whereas Figure 2B shows plantarflexion (PF).

2.3. Outcomes and examination

All participants underwent an examination of the ankle joint range of motion by 2 devices: the standard goniometer and the newly designed Equinometer. Each participant was examined by 3 raters (goniometer only twice, as it is a well-established instrument and Equinometer 3 times). Our main outcome was to detect the inter-rater and intra-rater reliability of the new Equinometer, as well as to identify any significant changes in the reliability of the examined devices. The 3 raters were experienced clinicians. All raters received sufficient practice to use the Equinometer prior to conducting any examinations. Also, they received preparatory training on how to report measurements of hindfoot movement with the goniometer.

2.4. Goniometer measurements

The goniometer measurement was performed on the 16 volunteers in a non-weight-bearing position. The participant would lie down on the examination couch, and the examined side would be selected randomly by the rater. At the beginning of the measurement, the subtalar joint would be brought into a neutral or inverted position. The pivot point of the goniometer was then placed on the lateral malleolus, while the 2 legs were aligned parallel to the direction of the fibula and parallel to the fifth metatarsal bone (Metatarsal V). When force was exerted against the sole of the hindfoot, the maximum extent of movement of the upper ankle joint was measured. Raters had to ensure that the patient was completely relaxed and did not provide any active assistance. The maximum passive DF and PF were measured with the knee fully extended and again with the knee bent at 90 degrees. Of note, this measurement was performed by 2 raters who were unable to observe the measurements of each other. Each rater recorded 3 values per measurement. The average value was then calculated from the 3 measurements and used as the reported value in the analyses. The intraclass correlation coefficient (ICC) for the clinical goniometer measurement was determined with the collected values. Afterward, a comparison was made between these observations and the observations made through the Equinometer, based on the observations of 2 raters.

2.5. Equinometer measurements

The measurements of the Equinometer were carried out in all subjects in a similar manner to the goniometer measurements. Individuals would lie down on the couch in a non-weightbearing position, and the lower leg was uncovered to allow the Equinometer to be positioned correctly. Here, the individual components were positioned and adjusted using bony landmarks. Care was taken to ensure that the lower ankle joint was positioned in a neutral or slightly inverted position and that the footplate only grips the hindfoot. A built-in electrical goniometer was set to zero at a neutral ankle position before each
measurement and for each patient. The aim was to apply the device in the neutral-zero position, and this was also achieved in all examined subjects. If this was not possible with one of the patients, the device offers the possibility to read off the predominant deviation (mostly plantar) on the basis of a built-in plastic goniometer representing an offset. This offset would have to be included in the measurement results: positive or negative, depending on the deflection. This measurement was performed by 3 different practitioners, as mentioned above, all of whom had sufficient experience with handling and function. The measurement was performed analogously to the measurement described for the goniometer. Before each measurement, rater 1 checked the fit and whether, according to their assessment, the reference points had been chosen correctly. Three values were recorded per rater. Likewise, the average value was calculated, which was used for further analysis. An inter-rater reliability test was carried out, and a comparison was made with the results of the goniometer measurements based on the observations of 2 raters.

### 2.6. Equinometer intra-rater reliability testing

In order to determine the intra-rater reliability for the Equinometer, further measurements were performed on an additional study group of healthy patients (reported in Table 2) by rater 1. In this group, the maximum DF and PF were measured with extended and flexed knees, as described in the measurements of both the goniometer and Equinometer. The only change compared to these measurements is that the practitioners performed a total of 3 measurement runs on each tested subject. There were few minutes between the measurement sessions, but all measurements were taken on a single day, as stretching of the triceps surae muscle and a change in the soft tissue situation should be prevented by delayed measurement. The measurement results were recorded by rater 1 in this group. Three measurement results were recorded by each rater, and the intraclass correlation coefficient was determined then.

### 2.7. Statistical analysis

Categorical variables are presented as numbers and percentages, while numerical variables are presented as means and standard deviations (SD). The analysis of variance (ANOVA) test and paired t-test were used to determine the differences in the means of 2 groups. Intraclass correlation coefficients (ICC) were calculated, where a value between 0.7–0.8 is acceptable, 0.8–0.9 is good, and >0.9 is excellent.\textsuperscript{13} Subgroup analysis based on age was done to determine whether or not the measurements were independent of the age of the examined participant. The Statistical Package for Social Sciences (SPSS, IBM-Version 26) was used for data analysis, and the Prism software (GraphPad Version 8) was used to design the results’ graphs. A P value of <.05 was used as the cut-off value for statistical significance.

### 3. Results

#### 3.1. Baseline information of studied groups

The baseline characteristics of subjects in the goniometer and Equinometer measurements group are presented in Table 1. A total of 16 participants were examined and included in the final analysis. The age of participants ranged from 22 to 85 years, with a mean value of 46.62 (SD = 18.09). Fifty percent of participants were males, and the right ankle joint was the most commonly examined side (11/16, 68.75%).

The baseline characteristics of the studied subjects in the intra-rater reliability group are presented in Table 2. A total of 24 participants were examined and included in the final analysis. The age of participants ranged from 16 to 85 years, with a mean value of 43.71 (SD = 19.38) years. The majority of subjects were females (13/24, 54.2%), and the right ankle joint was the most commonly examined side (15/24, 62.5%).

| Case number | Age  | Gender | Examined side |
|-------------|------|--------|---------------|
| 1           | 52   | Female | Left          |
| 2           | 22   | Female | Left          |
| 3           | 55   | Male   | Right         |
| 4           | 31   | Male   | Right         |
| 5           | 85   | Male   | Right         |
| 6           | 61   | Male   | Left          |
| 7           | 16   | Male   | Right         |
| 8           | 54   | Male   | Right         |
| 9           | 28   | Male   | Left          |
| 10          | 32   | Female | Right         |
| 11          | 31   | Female | Left          |
| 12          | 59   | Female | Right         |
| 13          | 81   | Female | Left          |
| 14          | 23   | Female | Right         |
| 15          | 47   | Female | Right         |
| 16          | 28   | Male   | Right         |
| 17          | 42   | Male   | Left          |
| 18          | 67   | Female | Right         |
| 19          | 31   | Female | Right         |
| 20          | 31   | Female | Left          |
| 21          | 25   | Male   | Right         |
| 22          | 63   | Female | Left          |
| 23          | 27   | Male   | Right         |
| 24          | 58   | Female | Right         |

#### Table 1

Baseline characteristics of examined participants (N=16).

| Case number | Age  | Gender | Examined side |
|-------------|------|--------|---------------|
| 1           | 52   | Female | Left          |
| 2           | 22   | Female | Left          |
| 3           | 55   | Male   | Right         |
| 4           | 31   | Male   | Right         |
| 5           | 85   | Male   | Right         |
| 6           | 61   | Male   | Left          |
| 7           | 16   | Male   | Right         |
| 8           | 54   | Male   | Right         |
| 9           | 28   | Male   | Left          |
| 10          | 32   | Female | Right         |
| 11          | 31   | Female | Left          |
| 12          | 59   | Female | Right         |
| 13          | 81   | Female | Left          |
| 14          | 23   | Female | Right         |
| 15          | 47   | Female | Right         |
| 16          | 28   | Male   | Right         |
| 17          | 42   | Male   | Left          |
| 18          | 67   | Female | Right         |
| 19          | 31   | Female | Right         |
| 20          | 31   | Female | Left          |
| 21          | 25   | Male   | Right         |
| 22          | 63   | Female | Left          |
| 23          | 27   | Male   | Right         |
| 24          | 58   | Female | Right         |

#### Table 2

Baseline characteristics of studied subjects in the intra-rater reliability group (N=24).

The age of participants ranged from 16 to 85 years, with a mean value of 43.71 (SD = 19.38) years. The majority of subjects were females (13/24, 54.2%), and the right ankle joint was the most commonly examined side (15/24, 62.5%).
3.2. Inter-rater reliability of Equinometer measurements

The testing for the inter-rater reliability with the new ankle range-of-motion measuring device (Equinometer) revealed good inter-rater reliability in both situations where the knee was extended and flexed. The reported values of the 3 raters were compared, and no significant differences between all of them were observed ($P > .05$, Fig. 3).

3.3. Intra-rater reliability of Equinometer measurements

The testing for the intra-rater reliability with the newly designed Equinometer device revealed an excellent ICC in both PF and DF (both during knee extension and flexion), with ICC values ranging from 0.90 to 0.98 (Fig. 4 & Table 3). There were no statistically significant differences between the observations of the 3 raters ($P > .05$) (Fig. 4).

3.4. Comparison between Equinometer and goniometer measurements

The changes in the recorded values between the goniometer and Equinometer as regards PF and DF were estimated between the 3 raters, and no statistically significant differences were noted in their observations at both instances (flexed knees and extended knees) (Fig. 5). Based on the observations of rater 1, the Equinometer measurements were slightly higher than observed in goniometer measurements during PF (Mean difference (MD) = 1.60° in extended knees and 0.23° in flexed knees) and DF (MD = 1.08° in extended knees and 1.71° in flexed knees) (Table 3). However, these observations did not reach statistical significance ($P > .05$). Similar results, but with higher mean differences, were noted in the observations of rater 2 (Table 3). The subgroup analysis based on participants age showed no significant ($P > .05$) difference between the measurements of both the Equinometer and the goniometer either in the interrater group or in the intrarater group, respectively (Table 4).

4. Discussion

As a result of the poor and inconsistent reliability with the usage of goniometers in ROM measurements, some researchers have tried to create a more reliable method. An “Equinometer” has been developed to further standardize these measures through the use of a novel platform measuring system that has revealed good intra-rater and inter-rater reliability. In our study, we demonstrated that in both extended and flexed knee positions, both DF and PF measurements did not significantly differ between the measurements recorded through the goniometer and Equinometer, which highlights the applicability of the use of the Equinometer as an alternative for the gold standard goniometer in the general population with easier applicability. The sample size of our population was 16, which is larger than that of the previous study by Molund et al., which was conducted in 2018 on 12 healthcare personnel, and their sample size was of enough power to detect significant reliability, both inter- and intra-rater reliability.

The clinical measurements of ankle ROM have been previously mentioned in the literature, and they were noted to be challenging. This also highlights the need for a more reliable test to reliably record the ankle ROM at both dorsiflexion and plantarflexion. Our study provides a novel finding in the current literature with the excellent intra-rater reliability of the Equinometer in determining the degrees of ankle DF and PF when the knees are extended or flexed (ICC = 0.90 to 0.98). This observation is similar to the recent study of Meyer et al., who noted that the intra-rater reliability of the Equinometer was near perfect with ICC values of 0.98 and 0.99.
for knee extension and flexion, respectively. The authors also noted that these measurements are way better when compared to normally used clinical measurements both during knee extension (interobserver correlation of 0.89 vs 0.03) and knee flexion (interobserver correlation of 0.97 vs 0.38), respectively. These findings, in addition to ours, provide a novel insight into the measurement of ankle ROM in normal individuals. The Equinometer allows estimation of ankle ROM in a highly precise and reliable manner, compared to clinical measurements, with no significant difference from the standard goniometer.

![Figure 4](image-url)
As many scholars have pointed out,[18–20] a systematic measuring instrument and methodology appears mandatory in order to achieve accurate clinical measurements. However, the methods mentioned to date have some pitfalls that we intended to prevent in the construction of this new measuring tool. First, the description of the long axis of the lower leg and foot relies on the individual opinion of the rater and can therefore vary.[18,20,21] This point is known to be the key challenge in clinical trials. Second, the movement of torque to the foot is normally achieved by squeezing the forefoot. If the length of the forefoot and hence of the lever arm,[18,19,22] which is variable with the dorsiflexion of the foot, is not specified, the resulting torque cannot be calculated precisely. Third, dorsiflexion of the ankle relies on the rotation of the foot, as well as pronation and supination.[18,20,23] If the position of the foot is not controlled, the range of motion of the ankle can differ between observers. Forth, the instrument must make it easy to calculate with the patient lying in different positions. The majority of these requirements are met in our new device; the Equinometer uses established landmarks (fibula and fifth metatarsal bones), which allows the introduction of a solid connection to the ankle joint independently from the center of rotation, directs the foot in a certain neutral position along the movable transverse axis, and is easy and straightforward to mount. Our analysis revealed that the interrater correlation was good with both knee flexion and knee extension as regards DF and PF.

The concept of the Equinometer is similar to an instrument intended to quantify isometric joint moments.[24,25] Basically, it is not restricted to the use on the ankle joint but may also, in principle, be used on the knee or elbow. Alternatively, the manipulation of the torque could be achieved with a mechanical torque-limiting lever, which would simplify the tool and eradicate all circuitry. Of note, good visibility of the landmarks and good alignment of the goniometer was essential for accurate measurements. Finally, our study highlights the easy usability of this new device in measuring ROM especially in the outpatient clinic, and it can also be used intraoperatively or postoperatively for measuring outcomes. In the same context, this device can be used to measure the success or improvement in clinical outcomes (namely ROM) following physiotherapy and rehabilitation programs.

Despite the fact that our study provides a valuable insight into ankle ROM measurement through the application of Equinometer, the number of studies examining the reliability and applicability of the Equinometer in determining DF and PF remains scarce. Also, our study has several limitations. First, the small sample size of our population limits the conclusions that can be drawn from this study. Second, the results of this study are applicable to normal individuals; however, the Equinometer’s ability to discriminate or diagnose cerebral palsy will be assessed in a future study. Third, no blinding was done when carrying out the measurements using both the Equinometer and goniometer. Given the high intra-rater correlations of the Equinometer, we suggest that this instrument is reliable and precise in recording the ankle range of motion in outpatient clinics, particularly to obtain comparable, reproducible, and unbiased data from different observers. Furthermore, the Equinometer has the advantage that it only measures hindfoot ROM. This is particularly important in CP patients, as they often have a forefoot equinus or midfoot break, which can disguise the true extent of the hindfoot equinus.

### Table 4
Subgroup analysis of the measurements of the equinometer and goniometer based on age of participants.

| Subgroup        | Position | Goniometer Mean | Equinometer Mean | P     |
|-----------------|----------|----------------|------------------|-------|
| Young (16–32)   | Extended Knee - PF | 13.6          | 13.8             | <.05  |
|                 | Extended Knee - DF | 34.5          | 36               |       |
|                 | Flexed Knee - PF   | 18.5          | 19.6             |       |
|                 | Flexed Knee - DF   | 35.5          | 36               |       |
| Old (42–85)     | Extended Knee - PF | 14.2          | 14.7             | <.05  |
|                 | Extended Knee - DF | 30.6          | 33.8             |       |
|                 | Flexed Knee - PF   | 17.6          | 20.7             |       |
|                 | Flexed Knee - DF   | 31.7          | 32               |       |

DF = dorsiflexion, ICC = intraclass correlation coefficient, PF = plantarflexion, SEM = standard error of the mean.
Figure 5. The comparison between goniometer and Equinometer observation as recorded by (A) rater 1 and (B) rater 2 during both knee flexion and extension. PF = plantarflexion, DF = dorsiflexion.
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