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A new method for evaluating ankle foot orthosis characteristics: BRUCE

D.J.J. Bregman [a,*], A. Rozumalski [b], D. Koops [c], V. de Groot [a], M. Schwartz [b,d], J. Harlaar [a]

[a] MOVE Institute for Human Movement Research, VU University Medical Center, Amsterdam, The Netherlands
[b] Gillette Childrens Specialty Healthcare, Center for Gait and Motion Analysis, St. Paul, USA
[c] VU University Medical Center, Department of Physics and Medical Technology, Amsterdam, The Netherlands
[d] University of Minnesota, Orthopaedic Surgery and Biomedical Engineering, Minneapolis, USA

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ABSTRACT

The mechanical characteristics of ankle foot orthoses (AFOs), such as the stiffness and neutral angle around the ankle and metatarsal-phalangeal (MTP) joints, are rarely quantified.

Paradoxically, it is expected that these characteristics determine the function of the AFO in pathological gait. Therefore a device to determine these AFO characteristics named BRUCE was designed based on multidisciplinary consensus. The design is based on a replicated human leg that is manually driven and continuously registers joint configuration and force exerted by the AFO onto the device. From this information, neutral angles and stiffnesses around the ankle and MTP joints are determined using a linear fit.

The reliability of the stiffnesses and neutral angles was studied by repeatedly measuring the mechanical characteristics of four different AFOs, and evaluating the inter-session, intra-session, and inter-observer errors. The reliability study revealed that ankle and MTP stiffness could be measured with very high reliability (ICC = 0.98–1.00). Ankle and MTP neutral angles showed reasonable reliability (ICC = 0.79–0.92). Measurement error in the neutral angles could mainly be attributed to the difference in testers. With a fixed tester excellent reliability was obtained (ICC = 0.99–0.99).

The results derived using BRUCE can help to gain insight into the role of the mechanical characteristics of AFOs in correcting pathological gait. Objective information of AFO characteristics is expected to lead to a better founded prescription of AFOs, resulting in optimal functional benefit for the patient.

1. Introduction

In clinical practice, ankle foot orthoses (AFOs) are frequently prescribed to treat gait related problems. These problems include limited foot clearance in the swing phase, poor foot placement at initial contact, and a reduced stability in the stance phase [1–3]. The wide variety of AFOs that are used in clinical practice, are commonly characterized by their overall design as well as the material used. However, from a mechanical point of view, AFOs can also be characterized by the stiffness and neutral angle about the ankle [4,5]. AFO ankle stiffness is defined as the moment around the ankle joint exerted by the AFO per degree of ankle joint rotation. There is evidence indicating that an optimal match exists between the patient's gait related problems and the AFO ankle stiffness [6]. New materials like carbon-fibre composites enable the fabrication of so called "energy storing" AFOs [7–9]. This reinforces the need to quantify stiffness, which determines the amount of energy stored in the AFO at a given joint excursion.

Although mechanical AFO characteristics are an important factor in the prescription of an AFO, these characteristics are rarely objectively quantified in clinical practice. Several devices have been developed to determine the stiffness characteristics of the AFO [10–18], mostly for research purposes. Unfortunately, the clinical applicability of the devices is limited, and apart from the devices designed by Cappa et al. [11,17] and Katdare et al. [12] the reliability of these devices remains questionable. Furthermore, currently available devices only measure the characteristics of the AFO around the ankle joint. However, the stiffness around the metatarsal-phalangeal (MTP) joint region of the AFO, as well as the AFO in combination with the shoe, may also significantly influence the patient's gait [7,19]. Previous attempts at quantifying AFO properties have neglected the neutral angle, i.e. the configuration of the AFO when no external moment is applied. This parameter may also influence the patient's gait [4].

* Corresponding author. Tel.: +31 20 444 3062; fax: +31 20 444 0787.
E-mail address: d.bregman@vumc.nl (D.J.J. Bregman).

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In this study, a mechanical testing device that measures AFO stiffness and neutral angle around the ankle and MTP joints in a clinically applicable manner is developed. The requirements and the design of this device, and the reliability of the results acquired with the device are discussed.

2. Requirements

The requirements of the device were determined by an international group of researchers, physicians (orthopaedic and rehabilitation medicine), engineers, orthotists and physical therapists. The AFO stiffness tester was named BRUCE, which is an acronym for the Bi-articular Reciprocating Universal Compliance Estimator. The following requirements for BRUCE were established:

1. The device must be able to measure the mechanical characteristics (i.e. stiffness and neutral angle) of the AFO, shoe, and AFO-shoe combination, around the ankle and MTP joints, over a functional range in the sagittal plane. The functional range is defined as the range of deflections an AFO experiences during gait.
2. The device has to be able to accommodate a wide variety of AFOs designs, ranging in size from a small paediatric AFO to a large adult AFO.
3. The device must be able to measure the mechanical characteristics of AFOs as perceived by patients with deformities such as tibial torsion. Also, the device has to accommodate for patients with forefoot deformity. It is known that such deformities may influence the effectiveness of AFOs [20].
4. The measured results of the device must be functionally interpretable. Therefore, the definition of moments and angles measured by the device should be the same as the definitions that are generally applied in instrumented gait analysis [21].
5. The device has to be user friendly in clinical practice, which means fast in donning and doffing, by a single operator, who does not need any special knowledge or skills to control the device.

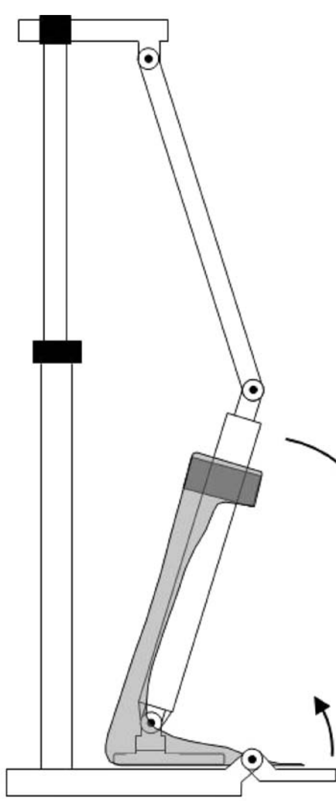

Fig. 1. A schematic overview of BRUCE as it was designed according to the requirements. The arrows indicate ankle plantar-dorsalflexion motion and MTP flexion-extension motion. Note that the mechanism to clamp the AFO by pressing the dummy foot onto the groundplate is not depicted.

3. Design

3.1. Physical design

Fig. 1 shows a schematic overview of BRUCE as it was realized according to the requirements. The design is based on a dummy leg, i.e. a model of the human leg and foot with anatomically based joint centers. To accommodate for different AFO sizes, six dummy feet are available corresponding to foot lengths ranging from 17.5 to 30 cm. For each dummy foot, the axis locations are based on anthropomorphic data of the corresponding foot-size [22]. The AFO can be mounted in the device using a non-destructive clamping system (not shown in Fig. 1). With the AFO mounted into the device, ankle plantar-dorsalflexion motion can be manually applied to deform the AFO, and MTP flexion-extension motion can be enforced to deform the AFO, or AFO-shoe combination. The joint excursions and the resulting forces from the AFO onto the device are continuously registered. The force sensors are located in such a way that the moment of the AFO onto the device can be calculated, regardless of the point of force application on the device. The registered forces and joint configurations are transferred to a standard PC for further processing. For a detailed description of the design refer to Appendix A.

3.2. Measurement procedure

The measured data are displayed real time in custom made software, based on Matlab 2006a (The Mathworks, Natick, MA, USA). User feedback during operation is provided by plotting the measured angle versus the net moment. We used a protocol where data are acquired within an interval ranging from 10° plantarflexion to 20° dorsalflexion for the ankle, and 0–30° flexion for the MTP joint. These ranges are determined from the functional ranges during gait [23,24]. For further analysis, at least one complete cycle from the previously mentioned interval minimum to interval maximum, and vice versa, is required.

3.3. Data postprocessing

A linear model was used to characterize the AFO angle–moment relationship in the above-mentioned functional range. Prior to determining the ankle stiffness, all data were checked for non-linearity that may be caused by buckling of the lateral sides of the AFO. We defined non-linear behavior of the AFO as a more than 10° change in the slope of the angle–moment curve, when compared to the slope at neutral position. If necessary, the interval was adapted to exclude the non-linear data. Subsequently, the ankle stiffness and neutral angle were determined by a linear fit through the mean of the moments during increasing and decreasing angles respectively.

For the MTP region, a linear fit was made through the data within the function range (0–30°) during which a moment larger than 0.02 Nm was recorded. Again, the mean of the moment at both the increasing and decreasing angle interval was used. There was no need to adapt the interval for non-linearities in the MTP region.

4. Reliability study

In order to test the reliability of the measurements of the neutral angles and stiffness, we assessed the influence of tester (operator), occasion (the complete positioning and removal of the AFO in the device) and repetition (repeated measures within one occasion). A Generalizability-study (G-study) [25,26] was used to determine the influence of these multiple sources of error variance. In a G-study, all expected sources of error variance are applied, so that the variance caused by each of these possible sources of error can be estimated. This error variance can be reported either in absolute measures, such as the Standard Error of Measurement (SEM) or the Smallest Detectable Difference (SDD), or relative to the variance that can be attributed to the object of measurement, as is done with the Intraclass Correlation Coefficient (ICC). The reliability of the measurement in any specific measurement design can be calculated by including all sources of variance that are present in that specific study design (D-study). For example, if a study design with a single tester is used, error variance due to difference in testers does not need to be included in the calculation of the reliability for that specific study. For further information on the G-study and the D-study, the reader is referred to the clear tutorial by Roebroeck et al. [25].

4.1. Methods

The objects of measurement in our G-studies, were the four AFO characteristics: (1) stiffness around the ankle joint, (2) the neutral ankle joint angle, (3) stiffness around the MTP joint, and (4) neutral MTP joint angle. Four different AFOs (afo) were tested by three different testers (t), who repeated the measurement three times (r) while the AFO remained fastened in the device. The entire procedure was repeated 2 days later, giving two occasions (o). This was done for all four AFO characteristics. The AFOs tested were all made for a right foot and included two custom made carbon-composite posterior leaf spring AFOs of different stiffness, one "rigid" custom made polypropylene AFO, and a medium size Dynafo posterior leaf spring confection AFO (Maramed Orthopaedic Systems, Hialeah, USA). The three custom made AFOs were based on the cast of a healthy subject with a foot length of 25 cm.

Prior to the first measurement, each tester was individually instructed on how to use the device. The order in which the AFOs were measured was randomized between testers and occasions. All collected data were parameterized following the procedure described in the section "data postprocessing".

The variance components of all four AFO characteristics were estimated with the "Variance Components" procedure in SPSS 15.0. Negative estimates were set to zero. The variance of the object of measurement was defined as the variance caused by the difference in AFO characteristics. The error variance was defined as the sum of all other variance components including the residual variance. The ICC was calculated as the variance of the object of measurement, divided by the sum of the variance of the object of measurement and the error variance. The SEM was calculated as the square root of the error variance, and is therefore expressed in the same units as the object of measurement. The SDD was also expressed in these units, and was calculated as the SEM $\times \sqrt{2} \times$ 1.96 [25].

4.2. Results

For visual impression, the raw data of the first repetition of each tester, at the first occasion of all four AFOs are presented for the ankle (Fig. 2) and for the MTP joint (Fig. 3). The data of the other repetitions, occasion and trials were quite similar to the data shown in Figs. 2 and 3. Fig. 2 demonstrates that AFO C behaves non-linearly, which is due to buckling of the lateral side of this AFO in the ankle region. Therefore the interval for parameterization for this AFO was adapted to 10° plantarflexion and 7° dorsalflexion. The other AFOs did not show non-linear behavior. As can be seen in Table 1, the ankle stiffness ranged from 0.20 to 1.56 Nm/° over the four AFO's, while the neutral angle ranged from −1.93° to 6.54°. The MTP stiffness was markedly lower than the ankle stiffness, with values ranging from 0.09 to 0.53 Nm/°. A wide range in the mean neutral MTP joint angle was observed ranging from 3.24° to 15.79°.

The results of the G-study (Table 2) revealed that, as expected, most of the variance in the data could be attributed to object of measurement, i.e. the different AFOs. The largest error variance components were found for the neutral ankle and MTP joint angles.

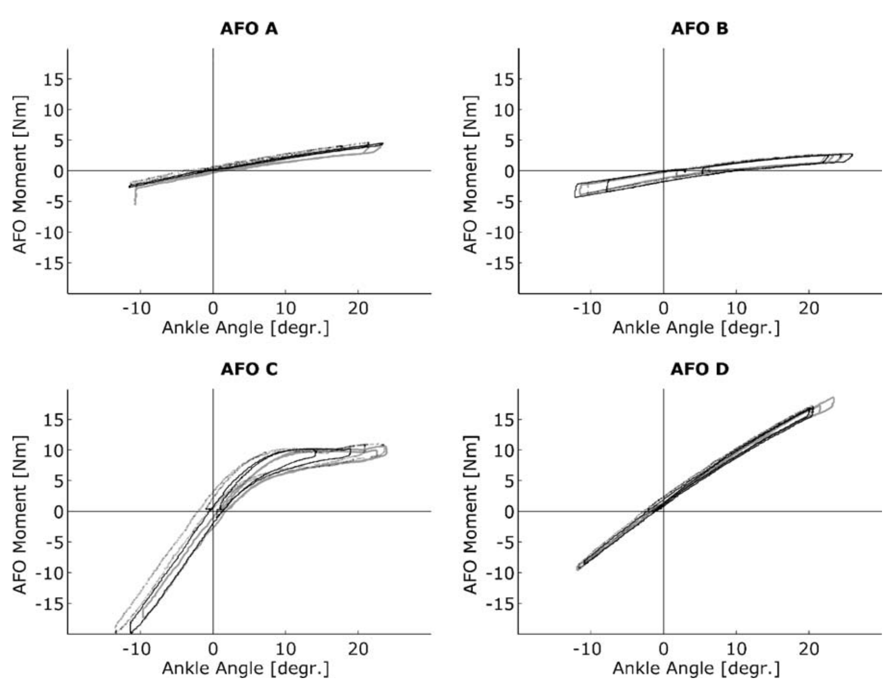

Fig. 2. Results for the measured AFO characteristics around the ankle joint, for four measured AFOs (panels), measured by three different testers (solid, dashed, gray). One trial per tester is shown. AFOs A and D are carbon fibre, and AFOs B and C are polypropylene.

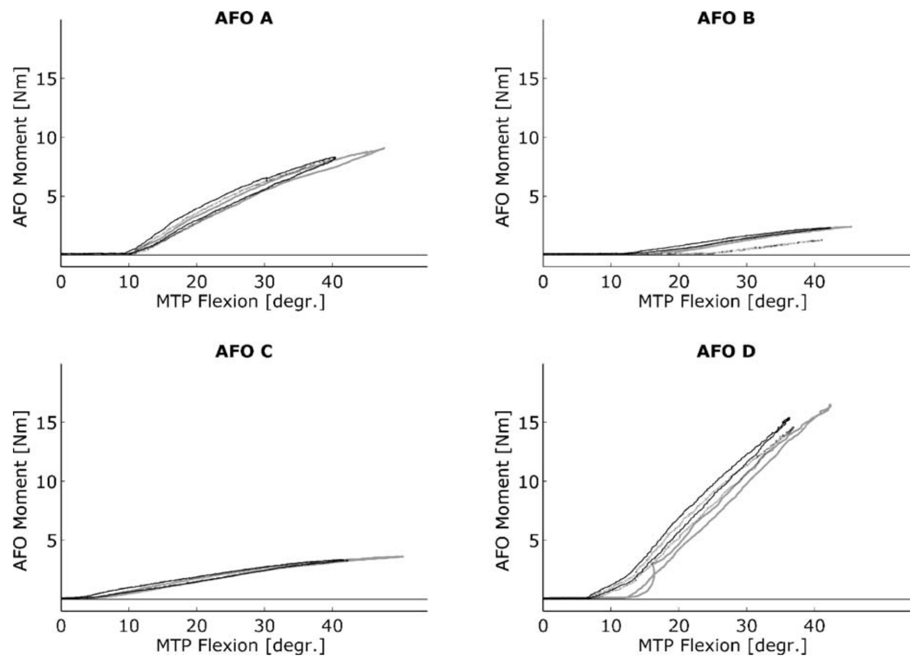

Fig. 3. Results for the measured AFO characteristics around the MTP joint, for four measured AFOs (panels), measured by three different testers (solid, dashed, gray). One trial per tester is shown. AFOs A and D are carbon fibre, and AFOs B and C are polypropylene.

Table 1
AFO characteristics.

AFO	Material	Dummy foot-size	Ankle		MTP	
			Stiffness (Nm/°)	Neutral angle (°)	Stiffness (Nm/°)	Neutral angle (°)
A	Carbon-composite	4	0.20 (0.01)	−.69 (0.38)	0.28 (0.04)	10.95 (0.70)
B	Polypropylene	3	0.16 (0.00)	6.54 (0.53)	0.09 (0.01)	15.79 (0.77)
C	Polypropylene	4	1.56 (0.04)	0.17 (0.25)	0.09 (0.00)	3.24 (0.71)
D	Carbon-composite	4	0.79 (0.01)	−1.93 (0.47)	0.53 (0.04)	9.52 (0.69)

All AFO characteristics are averaged over 18 trials (three testers, two occasions and three repetitions per AFO). Standard deviations between brackets.

Table 2
G-study results: sources of variance for the stiffnesses and neutral angles around the ankle and MTP joints.

Source of variance	df	Ankle		MTP	
		σ^2 stiffness	σ^2 neutral angle	σ^2 stiffness	σ^2 neutral angle
Object of measurement					
AFO (a)	3	0.4322	14.059	0.044	25.891
Main factors					
Tester (t)	2	0.0000	0.226	0.000	0.792
Occasion (o)	1	0.0000	0.000	0.000	0.247
Repetition (r)	2	0.0000	0.000	0.000	0.032
Two-way interactions					
to	2	0.0000	0.117	0.000	0.865
tr	4	0.0000	0.000	0.000	0.001
ta	6	0.0000	0.273	0.000	0.264
or	2	0.0000	0.000	0.000	0.000
oa	3	0.0000	0.053	0.000	0.000
ra	6	0.0001	0.000	0.000	0.004
Three-way interactions					
tor	4	0.0000	0.000	0.000	0.000
toa	6	0.0004	0.542	0.001	4.583
tra	12	0.0000	0.000	0.000	0.000
ora	6	0.0000	0.001	0.000	0.004
Residual					
Residual	12	0.0001	0.032	0.000	0.018

Sources of variance for the stiffnesses and neutral angles around the ankle and MTP joints. Error variance is defined as all variance except the variance that can be attributed to the object of measurement. The size of the error variance components indicates influence on the measurement error.

Table 3
Measures of reliability for various study designs (D-study).

Measurement result	t	o	r	Ankle						MTP					
				Stiffness			Neutral angle			Stiffness			Neutral angle		
				ICC	SEM (Nm/°)	SDD (Nm/°)	ICC	SEM (°)	SDD (°)	ICC	SEM (Nm/°)	SDD (Nm/°)	ICC	SEM (°)	SDD (°)
Random															
Single score	1	1	1	1.00	0.02	0.06	0.92	1.12	3.09	0.98	0.03	0.09	0.79	2.61	7.23
Mean score	2	1	1	1.00	0.02	0.05	0.96	0.81	2.23	0.99	0.03	0.07	0.88	1.88	5.22
Fixed															
Single score	1	1	1	1.00	0.01	0.03	0.99	0.29	0.82	0.99	0.02	0.04	0.99	0.55	1.53

t: tester; o: occasions; r: repetitions; ICC: Intraclass Correlation Coefficient; SEM: Standard Error of Measurement; SDD: Smallest Detectable Difference.

All error variance components were low when compared to the intended variance in AFO characteristics. "Tester" was the factor that attributed most to the error variance, both as a single factor (t), and interacting with other factors (to, ta, toa).

Since the error variance depends on the study design, the ICC, SEM, and SDD can also vary by study design, as calculated using a D-study. For the simplest case, in which a random tester performs a single measurement on a single occasion, the ICC, SEM and SDD can be found in the first row of Table 3. Table 3 shows excellent reliability of the AFO stiffness measurements both around the ankle and MTP joints for all study designs. However, the neutral ankle and MTP joint angles are measured less reliably for the simplest design, as can be concluded from the SEMs of respectively 1.12–2.61°. Using two, instead of one, random tester, will reduce all variance components which include the tester factor (t), with a factor of two [25]. This can be seen in the second row of Table 2. Alternatively, when a fixed single tester performs all the measurements, all variance components which hold the tester factor (t) can be neglected to calculate error variance [25]. This effectively increases the reliability of the measurements of the neutral ankle and MTP joint angles, as can be seen in the last row of Table 3.

5. Discussion

A new device to measure the mechanical AFO characteristics around the ankle and MTP joints has been designed and validated. The design of the device, based on multidisciplinary consensus, accounts for most requirements from both a clinical and research methodological point of view. The evaluation of the device revealed that the mechanical characteristics of an AFO can be reliably measured.

The device is fast in donning and doffing and does not require special user skills. This is essential if the device is to be incorporated into clinical practice. Previous methods designed to quantify mechanical function of the AFO did not include measurement of the mechanical characteristics of the sole/forefoot, i.e. around the MTP joint. Around the MTP joint, the device is also able to measure the characteristics of the AFO-shoe combination. This is important because an AFO is always worn in combination with a shoe. Further, is the first study that describes AFO stiffnesses in combination with AFO neutral angles, which is essential because the neutral AFO (ankle) angle is a factor influencing the patients' gait [4,5].

We choose to enforce the rotation axis to the AFO, of which the locations were identical to those that are commonly used in gait analysis [21]. This enables a comparison between the result from the device and the results from gait analysis. However, attention should be paid to the uniformity of the zero-angle definition in the device and in gait analysis. Differences may eventually lead to misinterpretation of the relative contribution of the AFO to the wearers' gait.

A limitation of the device is the location of the MTP-joint axis. The axis cannot be vertically adapted to the shoe or AFO size which limits the thickness of the sole of the shoe that can be tested. However, in practice most shoes can still be measured.

The reliability of the stiffness measurements using the current device is excellent. When the tester is kept constant, neutral angles can also be determined in a reliable manner, and differences in neutral angles larger than 1.5° can be detected. This is a large improvement over the subjective interpretation of AFOs that is common in clinical practice.

As in our study, the reliability of the devices developed by Cappa et al. [11,17], and Katdare et al. [12,18] was good for ankle stiffness. Sumiya et al. [6] suggested that the tester should be kept constant in order to consistently measure AFO ankle stiffness. The results with the current device suggest that AFO ankle stiffness can be measured reliably with different testers. However, the tester should be kept constant in order to measure neutral angles in a reliable manner.

In our reliability study, we did not control for differences in speed. However, it is unlikely that velocity has had major influence on the results, given the low residual variance in our G-study. Ongoing, the results from studies in which AFOs were measured at various velocities [16,18], do not show a substantial influence of velocity. In our data, we also observed hysteresis, i.e. a difference in the joint moment during flexion and extension movements. This could be attributed to the dry friction occurring between the AFO and the device. During data postprocessing the influence of hysteresis is ruled out, as the mean of the extension and flexion movements is used for further analysis.

The current study shows that it is feasible to construct an easy to use AFO stiffness testing device that can be implemented in clinical practice and research. Furthermore, AFO characteristics can be measured in a reliable manner, when the appropriate study design is used. In research, the mechanical characteristics of an AFO can be used in combination with the results of instrumented gait analysis in order to study the mechanical contribution of various types of AFOs to pathological gait, as has been proposed by Stanhope et al. [27]. For the recently introduced energy storing AFOs [7–9], it may be possible to calculate the energy stored in and released by the AFO per step using the current device. The mechanical contribution of the shoe to the shoe AFO combination can also be determined. This would allow objective investigation of the claims that have been made on the contribution of the shoe in attempting to correct pathological gait [19].

For clinical practice, objective information on the AFO properties will improve our understanding of the relationship between the design of an AFO and the biomechanical properties. This will lead to better insight into the impact of AFOs on a patient's gait.

Overall, this new device can help us to gain insight in the match between patient gait deficits and AFO characteristics. This is expected to add to the standardization of the prescription process that is currently taking place [28], and will eventually lead to a better prescription of AFO's in the future.

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Conflict of interest

The authors have no conflicts of interest related to the work presented in this manuscript.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.gaitpost.2009.05.012.

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