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Performance specification for lower limb orthotic devices

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Abstract

Objective. To establish the range of forces and moments applied to lower limb orthoses during ambulation by routine users.

Design. Well-established gait analysis techniques were used to determine the loading at the major joints. It was assumed that the joint moments were transmitted by the orthosis encompassing any particular joint. Two hundred and five assessments of 164 patients were successfully completed by a consortium of four gait laboratories in Europe. The orthosis specification and patient clinical data were also recorded.

Background. The design and development of orthoses has occurred largely by evolution rather than by formal engineering methods. In particular, formal design has been hampered by a lack of information on the forces and moments applied during ambulation.

Methods. A standard gait analysis procedure was employed to capture the data. In-house biomechanical models were used to calculate the joint loading. Data were normalised with respect to patient weight and leg length.

Results. It was found that the median maximum normalised ankle moment transmitted by an ankle foot orthosis was 0.15 and the maximum knee moment was 0.09. The greatest moment transmitted by the hip joint of a hip knee ankle foot orthosis was also 0.09. There was a wide variation in the data due to differences in the impairments of the test subjects.

Conclusion. It is possible to estimate the loads transmitted by an orthosis using established gait analysis procedures without the need for load measurement transducers. There is now a need both to collect a larger representative dataset and to perform validation studies with transducers.

Relevance

The methodology developed in this project has formed an important step in the development of standards and the incorporation of new materials and technologies into orthotic design.
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Keywords: Orthosis; Gait analysis; Inverse dynamic approach; Specification; Clinical evaluation

1. Introduction

Lower limb orthoses are used by a wide variety of people having impaired gait (American Academy of Orthopaedic Surgeons, 1975). On the one hand a limb paralysed by polio may call for a knee ankle foot orthosis, while in another situation the walking problems of a child with cerebral palsy may be reduced by an ankle foot orthosis (Gage, 1994; Evans et al., 1994; Butler and Nene, 1991). In summary, lower limb orthoses may be required to perform a variety of functions including full stabilisation of paralysed limbs during walking, or weight bearing to relieve loading on lower limb joints (Pandy and Berme, 1989a,b). In achieving this goal, the

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orthotic structures must be subjected to a variety of complex loads and associated stresses. There have been a few attempts to collect in vivo data on the loading of particular types of orthosis. In particular, there has been an interest in the degree of unloading of the lower limb provided by Hip Knee Ankle Foot orthosis (Lehmann et al., 1970). However, this study examined the influence of design features on the axial loading during standing of a normal subject only. The same author examined the axial loading of patellar tendon bearing ankle foot orthosis using these force transducers (Lehmann et al., 1971). However, both of these studies were concerned with the control of skeletal loading rather than the likely loading of the orthotic structure. Furthermore, it was shown that these axial loads were only significant when using a Patten end orthosis in which all of the ground reaction force is transmitted through the orthosis and the foot is effectively unloaded. Such a situation is rare in clinical practice being restricted to cases where there is a need to spare skeletal loading as opposed to improving locomotion, normally achieved by the control of moments across the joints.

The most obvious approach to measuring structural loads is to insert load measurement transducers (Beck et al., 1997; Havey et al., 1996) and this has been demonstrated (Trappitt and Berme, 1981). However, while they demonstrated the practicability of the technology, the authors were not able to apply the approach to the large numbers of orthoses required for a representative data set. In summary, whilst beneficial advances in design have been made in recent years, the design and development of orthoses has occurred largely by evolution rather than by formal engineering methods. Formal design has been hampered by the lack of information on the applied forces and moments.

The majority of lower limb orthoses are assembled from standard structural components incorporating hinges (usually with locks). The manufacturers of these components must be confident that they will not fail in such a way as to cause injury to the user; however, they play no part in the supply to the end user and so must cater for the highest loading likely to be encountered. Therefore, in the absence of the necessary data, issues of safety have been addressed only from the point of view of mode of failure rather than required strength (Scothern and Johnson, 1984). However, the regulatory frameworks now in force (e.g. in Europe, the now mandatory EC Medical Devices Directive) make such an approach untenable in the future. This paper addresses this issue by applying traditional gait analysis techniques combined with appropriate assumptions regarding the load transmission through the orthoses. Although the calculated loads may be approximate, the knowledge gained will form an important step in the development of standards and the incorporation of new materials and technologies. This methodology has been used to study the loading of four types of orthosis—ankle foot orthoses (AFO), knee orthoses (KO), knee ankle foot orthoses (KAFO) and hip knee ankle foot orthoses (HKAFO). In order to collect sufficient data for statistical analysis, the study was performed by a consortium of four gait analysis laboratories in Europe.

2. Methods

2.1. Instrumentation and techniques

All the data were collected using the now accepted standard gait analysis laboratory having infra-red cameras and force-plates as described (Whittle, 1996, Winter, 1991a; Cappozzo, 1984; Vaughan et al., 1992). Three of the Centres used the system produced by Vicon™ (Vicon Motion Systems Ltd. Oxford, UK) and the fourth by Elite™ (BTS, Milano, Italy). All the data analysis was performed by a single laboratory using biomechanical models developed with a high-level computer language (*BodyBuilder for Biomechanics*™ (Vicon Motion Systems Ltd., Oxford, UK)). This software allowed the calculation of the external joint forces and moments (referred to anatomical joint centres) from the collected raw data. These calculated forces and moments were normalised with respect to patient weight and weight multiplied by leg length, respectively.

2.2. Comparability between Laboratories

It was recognised that there was potential for variability of data from the different laboratories. These could arise from calibration errors but were most likely to be associated with differences in marker positioning and the resulting changes in co-ordinates and reference frames. Therefore, early in the project, the protocol for marker positioning was tested by allowing members of each laboratory team to position markers according to the protocol on a single subject. These studies were performed on two normal subjects. The first subject was used to refine the procedure of marker placement to ensure a visual consistency between the four laboratories. The second subject, wearing a knee ankle foot orthosis was used for comprehensive comparisons of marker placement and data collection procedures. Following the attachment of markers, each Team collected a full set of gait analysis data. The resulting data sets were then transmitted to a data analysis centre for objective comparative analysis. It was established that all the computed moments were within ±10%.

2.3. Assumptions of the analysis

The orthosis and limb represent a statically indeterminate structure in which the forces and moments are

probably shared between the joints and the orthosis (Ferrarin et al., 1993; Rose, 1976; Stallard et al., 1989). In order to avoid the problems of indeterminacy and to ensure that the highest possible estimates of orthotic loading were made, it was assumed that the moments at the joints were carried completely by the orthotic structures which encompass them (i.e *muscular and ligaments contribution are zero*). This assumption is justified by the objectives of the work which were to establish the greatest loading likely to be encountered by the orthosis.

In addition, since it is likely that there is some (unknown) relative motion between the orthosis and the limb during walking, the assembly was assumed to behave as a single rigid body. In reality, these movements are likely to be small since a major part of the fitting of an orthosis is the manufacture and adjustment of the components to ensure the best possible fitting of the load bearing interfaces.

2.4. Protocol

2.4.1. Data collection protocol

In order to ensure the greatest possible uniformity of data between the four data collection centres, a strict experimental protocol was defined as follows:

(1) *Subject recruitment criteria*. The overriding criterion for subject selection was the ability to walk independently and consistently during the trial. The other agreed inclusion and exclusion criteria are shown in detail in Table 1.
(2) *Orthotic device specification*. Information regarding the type, material and prescription of orthosis and any walking aid being used was defined using the system shown in Table 2.
(3) *Clinical evaluation and measurement*. Clinical examination of all subjects was carried out by a qualified physiotherapist to assess muscle strength (MRC scale) and tone, the range of movement at the hip, knee and ankle joints (De Brunner's notation), spasticity, and fixed muscular contractures. In addition, the following anthropometric measurements were made: height, leg length, weight, anterior superior iliac spine (ASIS) width, and thigh and calf length and circumference.
(4) *Marker placement*. The retro-reflective marker set recommended by Vicon, a modification of that proposed by Kadaba et al. (1990) and Davis et al. (1991), was used in this project. Nine 20mm diameter markers were used for one leg, comprising two on the ASIS, one at the sacrum, one at the thigh on a 100 mm stick, one knee marker on *the* lateral femoral condyle, one tibial marker on a 100 mm stick, one ankle marker on *the* lateral malleolus, one foot marker between 2nd and 3rd metatarsals position placed on *the* shoe, and one heel marker. In cases where the orthosis could obscure the normal marker position, some markers were attached directly to the orthosis making it necessary to use a technical reference frame to re-create the orientation of the embedded limb segment frame. In this case, a pointer technique was employed to locate the appropriate anatomical landmark (Erdemir and Piazza, 1999; Cappozzo et al., 1995).

The measured knee and ankle half width were used to calculate the joint centre. The leg length was defined as the distance from the ASIS to the most distal point of the lateral malleolus. In the case of *a* flexion contracture, the length was taken from ASIS to the joint space of the knee, and from the knee to the most distal point of the lateral malleolus. This measurement was taken with the subject lying in a supine position.

2.4.2. Data analysis protocol

(1) *Kinematic data*. The marker coordinates determined by *the* movement measurement system *were* used to determine the segmental rigid body kinematics, and the instantaneous anatomical joint centre location. The limb segments (pelvis, thigh, shank and foot) for a targeted leg were defined as follows (Erdemir and Piazza, 1999; Cappozzo et al., 1995):

Table 1
Patient inclusion and exclusion criteria

Inclusion	• Over 4-years-old • Over 1 m tall • Can walk 15 m independently, and unsupervised for short distance • Co-operative and able to follow command • Reasonable step length and step width (in order to collect kinetic data) • Used the orthosis satisfactorily for one month (exception is KO which may have been used for a short period of time)
Exclusion	• Variable gait pattern • Pain related to walking • Using either AFO(s) or KO(s), needs walking aid(s)

Table 2
Category of orthosis

Type of orthosis	• AFO, KO, KAFO, HKAFO • Shoes wedge, Shoes raise, Shoe insole
Orthotic material	Steel, alloy structure, composite material structure, polypropylene, ortholene, leather
Purpose of orthosis	Prevent/correct deformity, reduce axial load, protect joint, improve ambulation, fracture treatment, other
Walking aid used	Axillary crutch, elbow crutch, multipoint stick, walking stick, gutter crutch, rollator (wheeled frame), walking frame (no wheels), posterior walker, none
Orthotic prescription	Description of the control of designated hip/knee/ankle joint motion: • Free motion allowed, assisted, limited, resisted, no motion, bilateral control

Embedded segment frame

The *pelvic segment frame* was established by using the left and right ASIS marker and a sacrum marker together with the calculated hip joint centre using methods described by Davis et al. (1991) and Leardini et al. (1999).

The *thigh segment frame* was established by using the thigh and knee marker together with the hip and knee joint centres. The knee joint centre was estimated *from* the half width of the knee.

The *tibia segment frame* was established by using the tibia and ankle markers together with the knee and ankle joint centres. The ankle joint was estimated *from* the half width of the ankle joint.

The *foot segment frame* was established by using the ankle and toe markers together with the ankle and knee joint centres.

(2) *Kinetic data*. An inverse dynamics approach was used to calculate the joint forces and moments at the hip, knee and ankle referred to the anatomical joint centres in the directions defined by the segment frames. The joint forces and moments acting on the orthoses were determined at each of the joints *and were normalised* against subject weight and weight multiplied by leg length, respectively.

2.5. Subjects

A total of 205 limbs of 164 subjects were studied (age range 5–85, mean age (see Tables 3 and 4)). The dominant pathologies of the subjects were cerebral palsy (CP), past poliomyelitis, cerebro-vascular accidents (CVA), spinal cord Injury, spina bifida and anterior cruciate ligament deficiency (Fig. 1). The age range for patients with spastic CP, polio and CVA were 5–30, 40–70 and 30–70-years-old, respectively. Seventy eight percent of the subjects were wearing AFO or KAFO. Although all of the subjects were able to walk at least 15 m independently, 29 of the KAFO users and all of the HKAFO users required walking aids.

The data were stored in the form of force and moment graphs versus time. For analysis of the maximum

Table 3
Mean (SD) age, walking speed, body mass and leg length of each type of orthosis

Orthosis type	Mean (SD) age (Year)	Mean (SD) walking speed (m/s)	Mean (SD) body mass (kg)	Mean (SD) leg length (mm)
AFO	29.1 (21.9)	0.86 (0.37)	55.0 (23.8)	806.6 (127.6)
KAFO	43.5 (21.1)	0.68 (0.28)	66.6 (16.28)	838.6 (107.0)
KO	38.4 (15.5)	1.17 (0.34)	73.5 (15.9)	897.3 (77.8)
HKAFO	37.7 (7.6)	0.19 (0.11)	75.4 (15.5)	915.3 (46.5)

Table 4
Statistics of monitored orthoses

Orthosis type	Number of monitored patients	Number of left side	Number of right side
AFO	75	47	55
KAFO	47	29	29
KO	29	9	22
HKAFO	13	4	10
Total	164	89	116

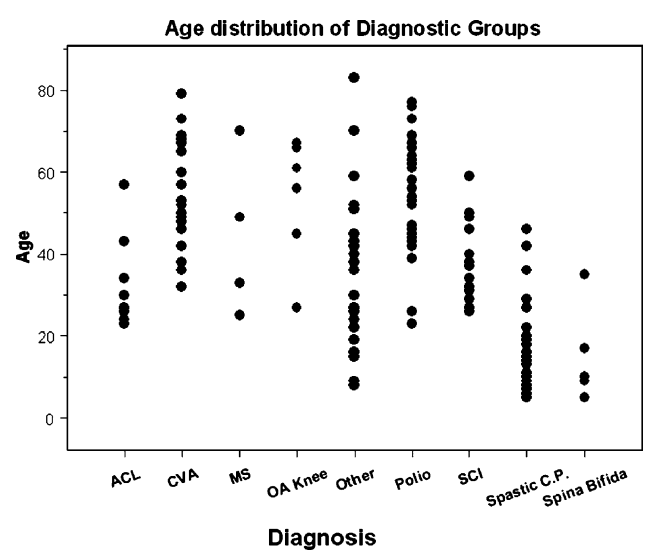

Fig. 1. Age distribution of the test subjects according to diagnosis.

loads to be carried by an orthosis, the maximum and minimum values were identified using custom written software.

3. Results

It has previously been pointed out that the predominant role of an orthosis is to modify the moments transmitted at the joints. The role of unloading (i.e. transmitting axial loads) is relatively minor and, even if present is likely to produce rather lower stresses than those due to bending. Therefore, this study has concentrated on the moments transmitted at the joints encompassed by the orthosis.

All of the data collected in this study have been stored in a database containing the moment versus time graphs for all the experiments performed. For purposes of illustration, some typical data are shown in Figs. 2 and 3 where they are compared with the published data of Vaughan et al. (1992) and Carlson et al. (1997).

Fig. 2 shows the ankle moment transmitted by wearers of HKAFO, KAFO and AFO compared with that seen in normal walking. It can be seen that ground reaction force acted at forefoot in the early stance phase of the patient with AFO producing a dorsiflexion moment after a brief heel strike. A similar event occurred for the patient with KAFO. For the patient with HKAFO, there was little joint motion during the initial 35% of stance phase (foot flat), probably explained by

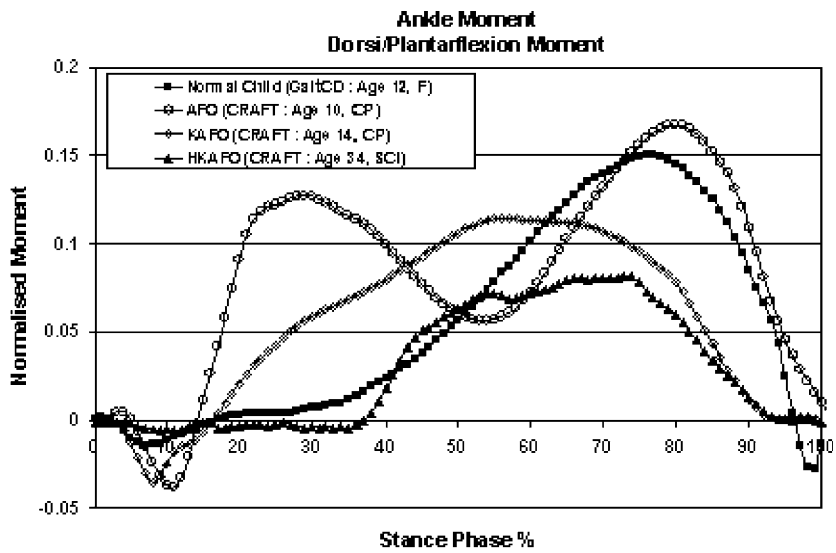

Fig. 2. Graph of the normalised ankle moment for three test subjects compared with normal data from Vaughan, Davis and O'Connor.

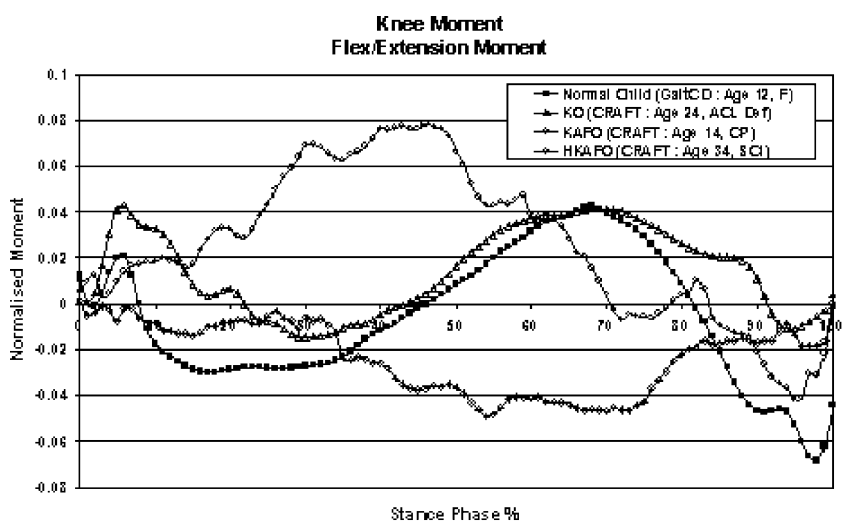

Fig. 3. Graph of the normalised knee moment for three test subjects compared with normal data from Vaughan, Davis and O'Connor.

Table 5
The median of the maximum normalised moments (flexion/extension of hip, knee and ankle)

Orthosis type	Hip joint moment (N m)	Knee joint moment (N m)	Ankle joint moment (N m)
HKAFO	0.031–0.090	0.031–0.060	0.091–0.120
KAFO		0.031–0.060	0.031–0.060
KO		0.061–0.090	
AFO			0.121–0.150

the need of the patient to achieve a stable standing posture after foot contact.

Fig. 3 shows the distribution of knee flexion/extension moment of patients with HKAFO, KAFO and KO during stance phase. In general, the KO data exhibited similar but larger knee moment pattern to that for normal gait. The peaks of knee extension moment (positive moment) occurred at initial contact and 70% stance phase. For the KAFO user, there was a maximum extension in the mid stance phase (in contrast to normal gait). In the case of the HKAFO, there was an initial stationary period followed by a flexion moment at 35% of stance phase.

The statistical summary of the data is presented in Table 5 showing the range of the median of the maximum normalised moments in the sagittal plane. It will be noted that the ankle joint moment was the largest of the three, and the ankle moment for AFO was the largest of all.

4. Discussion

Data on loading are vital to the design of all structural components—all the more so when there are implications for safety of medical devices. However, in the case of lower limb orthoses, the necessary data have, until now, been almost entirely lacking. This situation has probably arisen for a number of reasons. The majority of orthoses in current use have evolved over the last century and have not been subject to the normal engineering design process. Presumably, their relative safety can be attributed to structural over-design! While some researchers have used load transducers to collect the necessary data, this has never been performed on a large scale primarily because of the prohibitive costs of producing the large number of bespoke orthoses with the necessary instrumentation.

The technique used in this study represents an alternative solution to the problem. The use of routine gait analysis techniques ensures that the work can be performed in a large number of laboratories thus making it relatively easy to achieve the required number of subjects. However this approach calls for a number of assumptions. First, it is necessary to assume that all of the joint moments are carried by the orthosis whereas in reality there is likely to be load shared with muscles, and joint structures. However, since the primary function of an orthosis is to balance moments about anatomical joints in which there is no effective internal active control in the plane in which stabilisation is being provided, the torque measured using this technique will be that which must be resisted by the structure of the device. In those cases where there is limited active control, the maximum moments applied to the orthosis will be ameliorated to the extent that can be generated by the patient, so that the orthosis will experience lower moments than those computed. Aberrant internally generated torque that can increase the moments on the orthosis above those measured by the method used are a theoretical possibility, but the situations in which this occurs will be rare, and should in any case be considered a special case by competent designers. The authors accept that quantitative validation of these effects in future work would add further weight to the findings, but this will require considerably greater resources than have hitherto been made available in orthotics research.

Secondly, the kinematic measurements depend upon the assumption that the limb and orthosis behave as a single rigid body. For gait assessment of the lower limb this is a well-established and accepted assumption (Winter, 1991b; Davis et al., 1991). The majority of structural orthoses have a rigidity exceeding that of the anatomical structure they seek to control, so any movement within this element of the combined structure will be small in comparison with anatomical deformations. There remains the additional possibility of relative movement between the limb and the orthosis. This is an important factor that professional orthotists take care to minimise by appropriate measurement and fitting procedures.

Third, the use of a multi-centre study requires the assumption that the instrumentation in each laboratory would produce identical data for the same subject. There are a number of possible contributions to variability—particularly differences in the calibration of instrumentation and variability in marker placement. This latter aspect has been addressed in a small study in which representatives of each of the participating laboratories were required to position a lower limb marker set on a single subject who was not permitted to comment on the marker configuration chosen by each team. The procedure was performed blind. In this simple study, there was no statistical difference on the resulting gait data. This gives some confidence regarding this aspect of variability.

To ensure ease of use, it is important to choose an appropriate format and convention for the final output. It is necessary, first, to decide on the points to be used for the calculation of joint moments. It was decided to use the anatomical joint centre as this reference point; this was chosen in preference to the centre of the

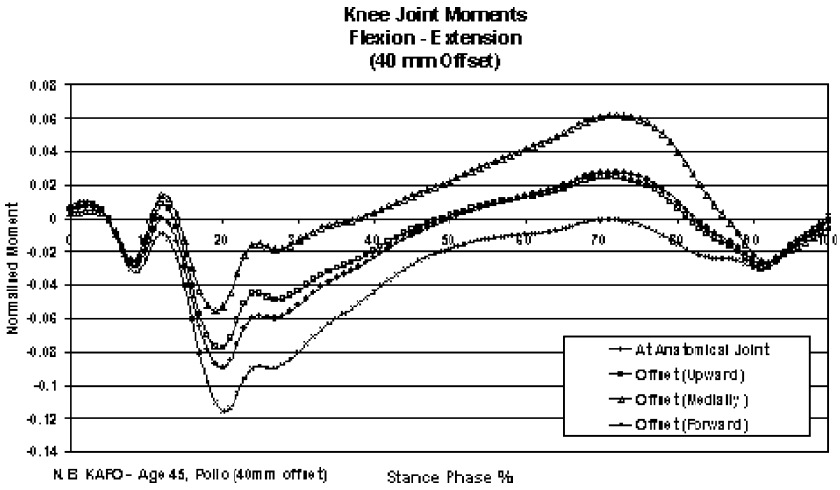

Fig. 4. Graph to show the influence of offset of the knee centre. It can be seen that a medial offset of 40 mm can transfer the maximum (positive or negative) moment from 20% approximately of stance phase to 75% approx.

orthosis, in order to generalise the data to the greatest possible extent. It is acknowledged that the orthotic designer may wish to evaluate novel devices in which the critically stressed component is not aligned with the anatomical joint (e.g. for an offset hinge at the knee). This calls for careful use of the data. While, in Table 5, the maxima have been calculated at the anatomical joint, it is necessary to view the full time course of the data before finding the areas of greatest stress. In Fig. 4 the time course of the knee moment has been calculated at points offset from the anatomical joint centre. It can be seen that, for an offset of 40 mm, the instant of maximum moment within the gait cycle can change. Furthermore, it was found empirically that this effect was unpredictable making it unsafe to calculate the greatest expected orthotic moment from the maximum occurring about the anatomical joint centre. Examination of all the data collected in this study has suggested that this is not a problem provided that the offset is not greater than 25 mm in the sagittal plane. In situations where the distance of the orthosis from the anatomical joint is greater than this, further detailed analysis would be required on an individual basis, and involve reference to the specific time course for an individual orthosis.

Medio-lateral offset is of no consequence for flexion/extension moments and can be specified at some reasonable value consistent with the anatomy. However, since this offset does influence the valgus/varus moment, a limit of ±75 mm was applied.

Finally, it has been shown that there is a wide variation in the loading experienced by the same type of orthosis used by different subjects. Bearing in mind that the structures are presumably of sufficient strength to support the greatest loading, there is an implication that a large number of orthoses are constructed from heavier and more bulky structures than are necessary. It is suggested that the approach to measurement which has been demonstrated here could allow the orthotist to select structural components which are appropriate to the needs of a particular user with a corresponding improvement in construction and cosmesis.

5. Conclusions

This study has demonstrated that the loading patterns of lower limb orthoses can be determined using well-established gait analysis techniques without the need for load transducers. Furthermore, the use of appropriate harmonisation techniques has made it possible to collect data from a large number of users in laboratories within Europe. This is particularly important because of the wide variations amongst the walking patterns of orthotic users. This opens the way for future multi-centre studies concentrating on particular pathologies where the patient numbers at any one centre would be too small to allow statistical analysis.

Finally, it should be emphasised that the data used for discussion represent a small proportion of the large data set collected in this project. The degree of variability can be appreciated only by examining this database in detail. Clearly, since the data are so variable, further understanding could be gained from further studies using the same technique. It is hoped that other Centres will adopt this approach to broaden this initial dataset.

The complete dataset derived on this project is freely available on www.ncl.ac.uk/crest/orload.

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