An approach to establishing the loads carried by lower limb orthoses

P. Mak and G.R. Johnson
Centre for Rehabilitation and Engineering Studies (CREST)
University of Newcastle

Introduction
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. This lack of information results from a lack of research and because of the wide variations between users which makes the determination of maximum loads particularly difficult. In particular, a project based on the incorporation of load transducers into the large numbers of orthoses is probably not practical and would certainly be very costly. A different approach has been used in which, by the choice of particular assumptions, the orthotic loads have been derived using well-established gait analysis procedures. While it is accepted that 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.

Method
Kinematic and kinetic data were captured using the standard gait analysis approach. The raw data were analysed using biomechanical models written in a high level language (*BodyBuilder for Biomechanics™†*). The calculated forces and moments were normalised with respect to patient weight and height and were referred to anatomical joint centres.

Assumptions
In order to simplify the analysis, two major assumptions have to be made. First, because the orthosis and limb represent a redundant structure, it is assumed that all moments at the encompassed anatomical joints are provided by the orthosis (i.e. *muscular and ligaments contribution are zero*). Second, in order to simplify kinematic measurement, the limb segment encompassed by an orthosis is considered as a rigid body.

Protocol
1. Data Monitoring
Four Data Collection Centres (consisting of a Clinical Centre, Orthosis Manufacturer and Gait Laboratory) were participated with data collection. They measured, fitted and reviewed a range of patients for whom one of the four generic types of orthosis had been prescribed, which were Ankle Foot Orthoses (AFO), Knee Orthoses (KO), Knee Ankle Foot Orthoses (KAFO) and Hip Knee Ankle Foot Orthoses (HKAFO).

For each of those patients the centres subsequently implemented protocols agreed within the Project for the collection of kinematic and kinetic data during ambulation. This involved three dimensional gait analysis using appropriate instrumentation, specific retro-reflective marker sets (Fig 1) devised for each category of orthosis and a six component force platform. Each patient was monitored over four separate walks. In addition information relating to the orthosis specification and patient clinical data was recorded. Since, for visibility, markers had to be located on the orthosis, it was necessary to use dummy segment axes to re-create the orientation of the embedded limb segment axes.

To ensure that the research complied with the EC Medical Devices Directive each Centre received local Ethical Committee approval for the proposed work.

†*BodyBuilder for Biomechanics™is a modelling software of Vicon, Oxford Metrics Ltd.*
(2) Data Analysis
The protocol for analysis of the data was established by consultation between the research partners and validated for the initial patients from each of the Data Monitoring Centres. Inverse dynamics approach was used in the calculation of joint forces and moments. It integrated ground reaction forces (GRF) measured from forceplate, positional components from each of the markers and anthropometric data of patients.

Results and Discussions
(1) Results Presentation
A total of 205 assessments were successfully completed. There was a variation of pathological groups presenting in each Centre, though all of them were specialists in treating severe disability.

Anatomical joints for which results are provided for each generic type of orthosis were as follows:-

<table>
<thead>
<tr>
<th>Orthosis Type</th>
<th>Hip</th>
<th>Knee</th>
<th>Ankle</th>
</tr>
</thead>
<tbody>
<tr>
<td>HKAFO</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>KAFO</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>KO</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>AFO</td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

There were 6 data sets for the overall spectrum of ranges of the median of the maximum force and moment (in three planes) for the four walks of each patient for each joint. Normalised forces and moments against patient weight and leg length were presented. By way of example, normalised joint forces and moments for Ankle Foot Orthoses were shown in Fig 2. For KO there are also 6 data sets (i.e. one joint), for KAFO 12 data sets (2 joints) and for HKAFO 18 data sets (3 joints).

(2) Implications for Specific Applications of data
In the case of the analysis of computation of moments about axes which was not coincident with the monitored anatomical joint, which will be required for orthoses with offset hinges for example. It was showed that for offsets of 40mm or greater the instant of maximum moment within the temporal range of the gait cycle can change phase with respect to the anatomical joint. This effect was unpredictable and could lead to errors in design calculations. Since large offsets are unlikely in most lower limb orthotic applications this would predominantly have no significance. Consequently the results can sensibly (and safely) be validated within a space envelope of 25mm from the anatomical joint centre in the sagittal plane (Fig 3). In situations where the distance of the orthosis from the anatomical joint is greater than 25mm further detailed analysis would enable the effects to be computed. This would be required on an individual basis, and involve reference to the specific time course for an individual orthosis. It is therefore beyond the immediate scope of this CRAFT Project.

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 +/- 75mm has been applied.

Key Achievements
• The First Comprehensive DataBase of Forces & Moments in Lower Limb Orthoses
• The First Multiple Gait Laboratory Collaborative Project for Collection of Three Dimensional Kinematic & Kinetic Data in Lower Limb Orthopaedics
• Achievement of All Project Objectives to Budget and on Schedule
• Establishment of a practical means of public and professional access to the Fundamental Data
• Establishment of a European Network of Clinical Centres, Biomechanical Research Units and Orthopaedic Commercial Organisations which has a common objective for further Research & Development
• A clear strategy, via a Collaboration Agreement, for peer reviewed publication of the Innovative Methodology and Fundamental Data
Acknowledgements
This project was funded by EC CRAFT programme. CRAFT is a European Community Programme which supports R&D in Small & Medium sized Enterprises (SMEs).


Fig 1 Marker set

Fig 2 Force and moment data in three planes for Ankle Foot Orthoses (AFO)

Fig 3 Phase change occurred for offsets of 25mm & 40mm at knee joint of moment in the sagittal plane