MASS CUSTOMISATION OF FOOT ORTHOSIS FOR RHEUMATOID ARTHRITIS

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Abstract

Rheumatoid arthritis (RA) is an inflammatory disease, which can cause pain, stiffness, and swelling in the joints of hands and feet. The foot is a major site for RA involvement and a major source of disability resulting from this disease. This paper introduces research which aims to create a mass customisation process for customised orthoses for patients with RA. 3D laser scanning, and gait analysis will be used to generate the orthosis geometry and rapid manufacturing, namely the selective laser sintering (SLS) process, will be used to produce the orthoses. The SLS process enables the incorporation of compositional functional elements, such as locally adjusted stiffness or flexibility, into the orthosis design.

The process involved two central elements. The first was a literature survey to identify orthotic design rules for foot impairments in RA. This survey will form a platform for the design rule development and will be complemented by data obtained from two patient trials. The second is a virtual three-segment foot model, created in Anybody dynamics modelling software which can be motivated by data measured from patients using 3D motion capture and force plate systems. Once the measured data has been applied to the model, a virtual insole can be used to simulate the effects of various features in the orthosis.

Considerable variation was noted in the literature for types of material, design and methods of orthotic construction. Pressure redistribution using cushioning materials was consistently mapped to painful deformed joints. Orthoses with contoured surfaces, either custom- or mass produced in thermoplastic materials of varying stiffness and density were mapped to joint motion control and deformity prevention. The paper will also describe applying patient gait data to the Anybody model, and then altering the gait pattern by applying the insole model. Future work will also be discussed.

Introduction

The purpose of this project is to create a process that will produce customised foot orthoses for rheumatoid arthritis sufferers. Currently, the production of foot orthosis is time-consuming, and expensive, with delivery times up to six weeks, during which the disease can alter the foot further. Improved clinical outcomes can be connected to custom foot orthoses, when compared against mass-produced orthosis.

The novelty of this project is the application of mass-customisation principles and layer-manufacturing technology to existing clinical processes. Currently the design of orthoses is very much a craft and there are only a few standardised procedures when subscribing them. To assist the design, a set of design rules and a virtual gait model will be created.

These rules will drive a semi-automated process to produce a custom orthotic with the most effective combination of shape and stiffness for each patient.

Rheumatoid arthritis (RA) is an inflammatory disease, which can cause pain, stiffness, and swelling in the joints of hands and feet. The foot is a major site for RA involvement and a major source of disability resulting from this disease. It cannot be cured but it can be treated with drug treatments, physical therapy and with orthotic devices. Foot orthoses are applied to the foot to improve foot function, to correct deformities, and/or to relieve pain.

Equipment

The following equipment was used to do all necessary measurements required by this project. The details of how the equipment was used will be elaborated later:

- Polhemus FastSCAN Cobra 3D scanner

FastSCAN Cobra (figure 1) is designed to scan non-metallic, opaque objects. The scanner works by casting a fan of laser light over the object, while the camera on the wand views the laser to record a cross-sectional profile of the object.

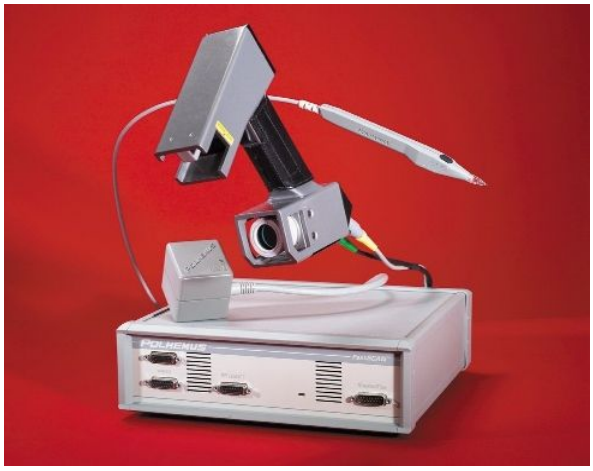

Figure 1. Polhemus FastSCAN scanner [Polhemus 2006]

When the scanner was characterised, it was observed that the scanner has the accuracy of ±1.5mm at 300mm. The fit of all prototype parts produced with the scanner has been excellent, so this error appears to be acceptable. The associated software is FastSCAN, and it enables the inspection of the scanned surface, various cleanup-, processing-, and export options for the data.

- Motion Analysis Falcon motion capture system

The system used consists of six cameras, and a PC that does the processing. The system can track the trajectory of reflective markers through the measurement space. The markers are usually attached to bony landmarks on a person being observed. The resulting data can be used to motivate various body models to analyse various aspects of human motion. The marker trajectory data from the motion capture analysis can also be imported into Visual 3D, and Anybody, where it will be used for further analysis.

- Novell Pedar In-shoe pressure sensor

This system is used for monitoring local loads between the foot and the shoe.
It is usually used to analyse human walking, running, climbing stairs, or other such activities. The system has a flexible, thin sensor plate shaped like an insole that is placed between the patient's foot and the shoe. The application in this project is to measure the local loads on the foot to determine if the orthoses have any effect on the loads.

- C-Motion Visual 3D

Visual 3D is a visualizing and motion capture analysis tool widely used in clinical applications. Here it is used as a clinical analysis tool, and to verify the results form the Anybody kinematic model.

- Anybody by Anybody Technologies A/S

Anybody is a 3D dynamics modelling system designed for musculo-skeletal simulation. It has applications in biomechanics and ergonomics and it is expected that it can further the analytical and a quantitative analysis of orthoses design.

- Magics RP

This software is produced by Materialise in Belgium. It is a widely used software tool to prepare parts for layered manufacturing production. It has some features that enable its use for design purposes, but this is not its main function.

Orthoses have been created in Nylon using a 3D Systems Vanguard Selective Laser Sintering (SLS) process. This layered manufacturing method enables the creation of complex and/or unique parts in a reasonable time and with a reasonable cost, as no tools are required.

Design rule literature survey

From the research articles surveyed, considerable variation was noted for types of material, design and methods of orthotic construction. Pressure redistribution using cushioning materials was consistently connected to painful deformed joints. Orthosis with contoured surfaces, either custom-, or mass produced in thermoplastic materials of varying stiffness and density were connected to joint motion control and deformity prevention.

Here is an example of how a “rule” is created:

Most sources in the survey, agree that a medial post, in addition to other features is appropriate for symptoms such as rear/forefoot deformities, and/or valgus, but the amount of posting is open to discussion (Nicolopopolous 1999, Li et al 2000, Kavlak et al 2003, Hodge et al 1999, Lusardi et al 1999, and many others). Nicolopopolous and Shrader suggest the angle required to correct the valgus to vertical (Nicolopopolous 1999, Shrader 2003). Lusardi’s textbook however suggests a more complicated approach. The basic assumption is that the normal range of motion is 4-6 degrees, and to apply a definite change in the gait pattern, this motion should prevented, and the change applied on top of that (Lusardi et al 1999). Nester provided an example where a 10 degree wedge caused a 5 degree change and explains that this is caused by the normal varus/valgus motion of the foot (Nester at al 2003). However, in his study, only healthy volunteers were used, and even if this study is in agreement with Lusardi, it is unclear if this way of thinking can be applied to RA feet, since RA causes stiffness in the foot. Lusardi further suggests that initially the correction should be only 50% of the total correction (Lusardi et al 1999).

To create the rule, it was decided to take the average of these two approaches. If X is the standing valgus angle, the initial rearfoot wedging angle (W) should be:

Nicolopopolous & Shrader

Lusardi

$$W = \frac{X + \frac{(X+5)}{2}}{2} = \frac{3X+5}{4} \qquad \text{|| degrees}$$

The complete list of rules derived is too long to be presented here.

The source material has also some limitations. In most papers, very little detailed information about the orthoses used, and/or the details of the features in the orthoses was given. Material properties were also not often mentioned. In many sources, the features were not connected to any specific trials or studies, they were simply stated.

3D dynamics modelling

This foot model was built in collaboration with Anybody Technologies A/S.
The purpose of this model is to assist in determining the interventions required to correct problems with the patients gait. The insole model, which will be described later in this section, will be applied on the gait model, once the model is running and the various rotations are verified.

The model consists of (see figure 2):

- Four rigid elements – shin, rearfoot, forefoot, and the hallux
- Three degree of freedom joints between the segments, except for forefoot - hallux, where there are only two degrees of rotation, dorsiflexion/ plantarflexion, and abduction/adduction
- 8 markers providing the necessary translations

The joint between rearfoot and forefoot does not represent an actual physical joint, because the midfoot area consists of a large number small bones, muscles, tendons and ligaments. Constructing a model to accurately represent all these would be very complex, and verifying the results given by such a model would be very difficult. Because of this, the area is simply approximated with a spherical joint.

From the motion capture measurement, the 3D trajectories for each marker were be imported into the model as necessary. Not all axes of these trajectories were imported however. Some markers were only moved using one or two axes of translation. The axes were selected depending of the marker in question. This was done to avoid overconstraining the model, and to keep it as simple as possible.

The Visual 3D model is in everyday use in gait laboratories around the world to analyse various aspects of patient's gait, can be used to verify the accuracy of the simulation by comparing the inter-segment rotations at the joints. For example, the rotations in the ankle joints occur between the shin, and the rearfoot segment. The Visual 3D model however cannot be used to simulate the effects of orthoses.

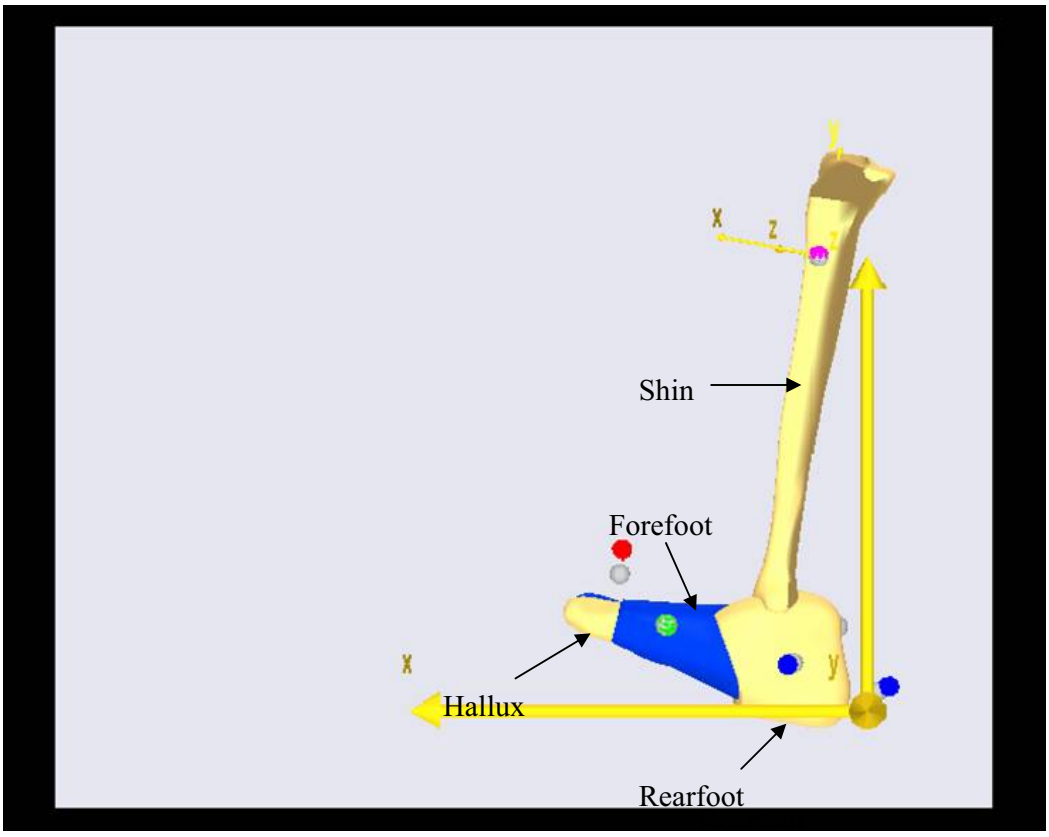

Figure 2. The Anybody foot model.

The insole model is based on a simple concept of modifying the input marker trajectory data for selected markers. If an insole with a wedge is applied to a foot, the part of the foot on the wedge is elevated. If one would place a motion capture marker on that part, and measure the trajectory with the insole, and without, one would see a change in the trajectory. The change would mostly be on the elevation (z-direction) of the marker. One can also measure a change in the joint rotations of that foot.

If the marker trajectory measured without the insole is modified in the z-direction, one should be able to simulate the changes that the wedge causes into that part of the foot. By placing four markers on the foot, that each correspond to a different wedge, one should be able to simulate the changes that medial/lateral fore/rearfoot wedging have on the foot. The changes will be indicated by the changes in the joint rotations.

The original objective of the project was to create customised gait models for the patients. However, only one model was created because of the time-consuming fine-tuning of the model to match the individual gait pattern. This one model was then used with the insole model to determine the effect of fore/rearfoot wedging to the joint rotations. This can then be further linked to the design rules to assist in determining the correct amount of wedging. The results from this model are not yet presented, as the results have not been verified.

Design process and manufacturing

After the measurements have been taken from the patient during the trial, the data from these measurements is combined. The clinical analysis and the design rules should then inform the designer of the required features to the orthoses, and the specific details of each of these features, such as wedging angles, and the locations of various features. These instructions are then combined with the scanned foot geometry to create the actual design. The design and production of the parts is straightforward after this stage. This process is outlined in figure 3. The clinician also uses the measurement results as a part of the clinical analysis.

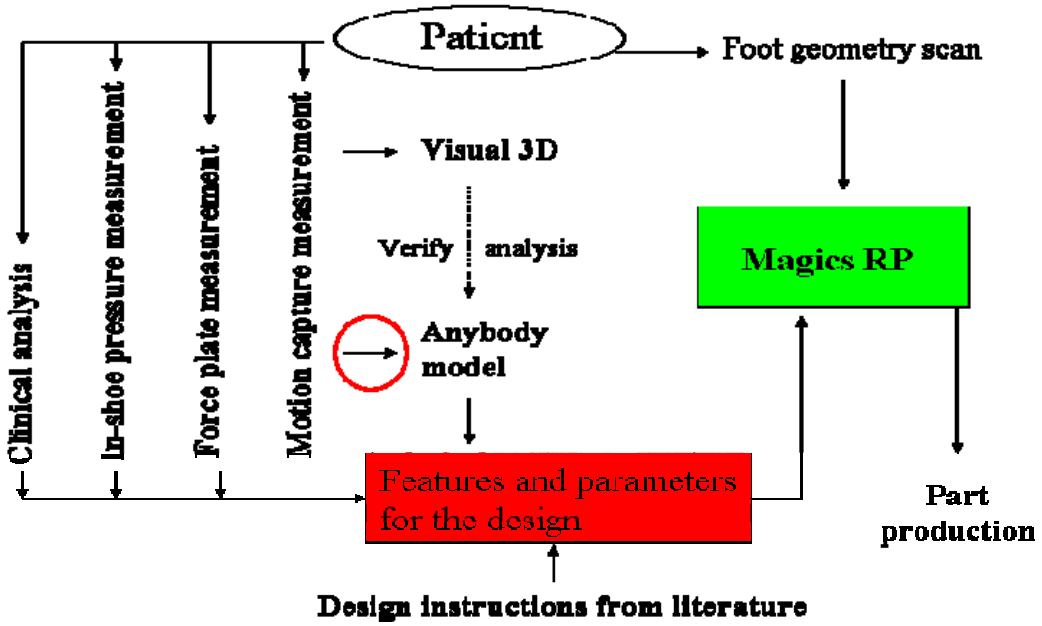

Figure 3. The outline of the design process. The red circle indicates the point where the insole model is applied.

The .stl file manipulation was performed in Magics RP, which did not have some of the features desired for a design software, such as putting on a radius for sharp edges. Because of this, more post-production had to be done than was initially expected. This work included grinding off all sharp edges, and smoothing the transitional area between the main body of the orthoses, and the forefoot/metatarsal region. The work was done manually with a drill with a grinding tool. This solution is not ideal, as the finishing work is manual and inconsistent between different people. It is however required at this stage.

Patient trials

The purpose of the trials was to determine how well the orthosis designed in this project work with RA sufferers. The trial consisted of basic gait parameter measurements (stride length, walking speed, etc), in-shoe foot pressure, and the Leeds foot scale questionnaire, which measures subjective issues, such as comfort, and fit.

At the time of writing, the patient trials are underway, and four patients of ten had been in for the trials.

Based on the four trials out of ten that we have so far had, we can note that:

- Comfort and fit were reported to be good, especially around the heel area.
- We can observe some beneficial pressure distribution changes, such as improved pressure distribution around the foot arch (see figure 4).
- Some problems with surface features (see figure 4). The reason for the elevation in this case was a small elevation in the surface of the insole. This elevation could be traced back to the original foot scan of the patient.
- Orthoses had to be modified to fit them into the shoes. Especially the forefoot support was considered too rigid and the cause of most modifications.
- When the patient had forefoot problems, the forefoot/toe segment of the orthoses had to be cut out, as cushioning this area was required.
- Insoles were reported to be very hard. When the in-shoe pressure sensor was inside the shoe, the comfort was improved.

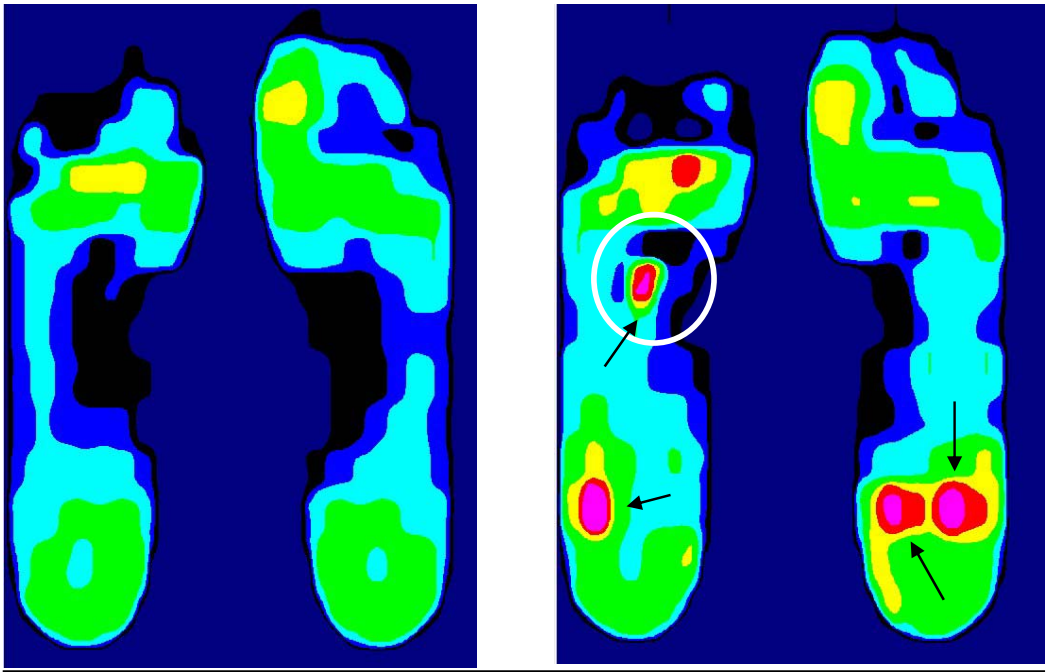

Figure 4. Pressure distribution from the in-shoe sensor with the patient's old insoles (left), and the prototype insoles (right). Peaks in the pressure are pointed out with arrows, and the area, that the patient reported painful is indicated with a

The design rules will be revised before the rest of the patients will be called in to improve the orthosis. The changes to the rules include:

- Decrease the wall thickness of the orthoses to 3mm, as the orthoses were reported to be too rigid.
- Not to include metatarsal bars, or cut-outs for metatarsal heads, as they cannot be located accurately enough, and were in the wrong locations in the orthosis made so far.

- Decrease the thickness of the extension between the toes and metatarsal heads from 2mm to 0.75mm to increase flexibility in this region.
- Decrease the width of the orthoses 3-5mm each side, to improve fit inside the shoes.

After the next trials, where the remaining six patients will participate, further changes will be made to the rules if necessary.

Conclusions and future work

A mass customisation process has been created, and the orthoses resulting from this process have an influence in the pressure distribution on the patients feet. Work will continue to improve the process.

A kinematic three-segment foot model has also been created with an insole model that will be able to simulate the effect of medial and lateral rear-, and forefoot wedging.

Future work includes the completion of the patient trials, and finishing and verifying the Anybody model, and incorporating the simulation results into the design rules.

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