DESIGN AND ADDITIVE FABRICATION OF FOOT AND ANKLE-FOOT ORTHOSES

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Abstract

Foot and ankle-foot orthoses are prescribed in order to promote mobility through supporting and/or realigning the lower leg and alleviating pain in the foot in different parts of the gait cycle. This paper will outline new approaches to the design and manufacture of personalised foot and ankle-foot orthoses (FO and AFO) using additive fabrication technology. The research is addressing the need for specific software design tools for orthosis design which enable their properties to be locally tailored within a mass customisation framework. Structure/material testing to support that activity is also being undertaken and will be described.

Introduction

An orthotic device is often prescribed to support, re-align or redistribute pressure across part of a person's musculoskeletal system. The use of these devices can lead to a reduction in symptoms, improvement in function, and may result in an increase of the patient's overall quality of life. Customised devices have been found to be most effective for the treatment of many conditions in terms of clinically relevant benefits and patient compliance, most likely a result of taking the individual patient's anatomy and functional requirements into account during the design process (Hawke et al., 2008, Trotter & Pierrynowski, 2008). However, the production of these customised orthotic and prosthetic devices is currently based around artisan skills. The processes involved are time-consuming and require experienced craftpersons who generally make their decisions based on experience and trial and error, rather than systematic engineering and evidence-based principles.

Furthermore, the mechanical properties of these traditionally produced orthotics can only be grossly estimated since factors such as controlling wall thickness can only be partially achieved. Overall this approach can result in inconsistent designs and patient care.

The work reported in this paper examines the feasibility of using an additive fabrication (AF) technique for the manufacture of customised orthoses and prosthetics and describes the potential of this approach for improving lead times, quality, consistency and patient care. The design freedom made available though this method presents a range of opportunities that are not possible with current orthotic CAD/CAM packages. Examples of where improvements to current systems can be made with tailored software solutions. Some examples of manufacturing prosthetic devices are also mentioned in this paper. This is relevant as the current manufacturing of both prosthetic and orthotic devices is very similar and the research done so far regarding these devices has also been similar in nature.

Additive Manufacturing

Figure 1 gives a schematic overview of the traditional versus an AF process. Additive fabrication processes have been available to produce low volumes of components with short lead times since the early 1980's (Levy et al., 2003), and have more recently been exploited in the production of medical devices, including the manufacture of customised in-the-ear hearing aid shells (Tognola et al., 2003), and the creation of drill guides for dental surgery (Kim et al., 2008), and has also been evaluated for their potential in creating ankle-foot orthoses (AFOs) (Faustini et al., 2008).

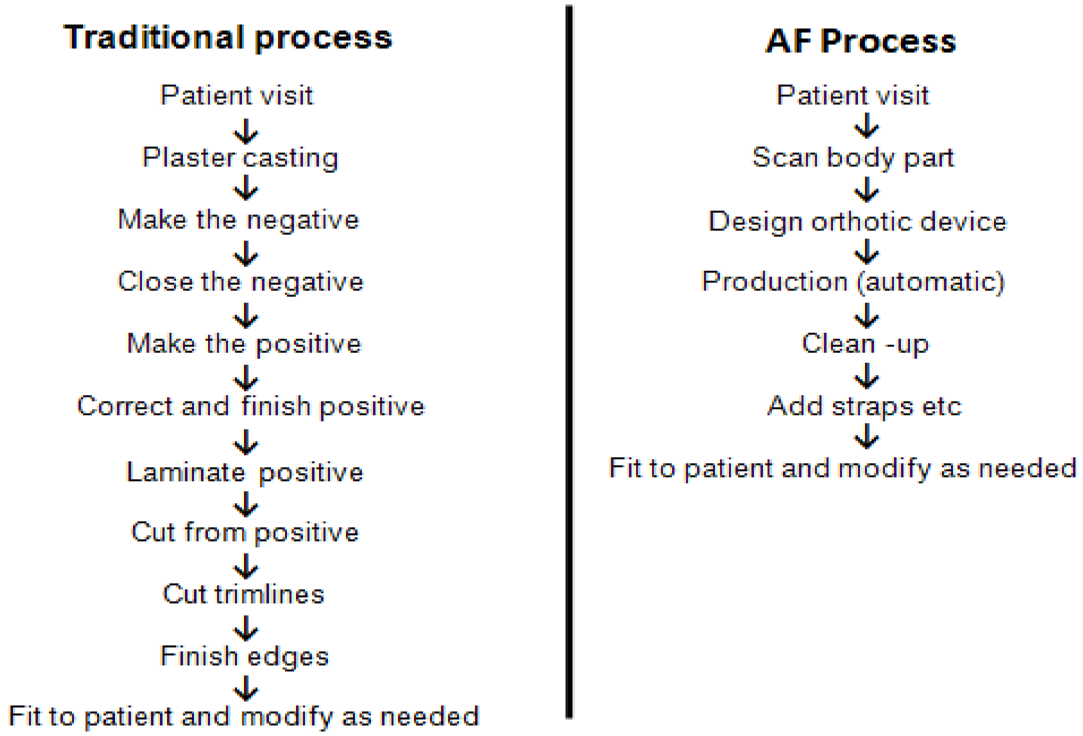

Figure 1. The traditional orthoses manufacturing process (left) and the same process using additive fabrication technology (right).

It is suggested that a mass customisation system to deliver orthoses, together with exploitation of the design freedom offered by the manufacturing method, will give the devices produced through the AF approach significant clinically relevant potential. Some of the advantages of this approach are as follows:

- Faster production over the traditional process and more consistent quality.
- A more comfortable experience for the patient during the prescription process (no plaster casting required). Optical 3D scanners can be used to capture the patient geometry in a precise and consistent way.
- Fewer and less experienced technicians can be used as there is a reduced need for manual work and hands on experience is not as crucial.
- Design rules and company specific protocols, lending themselves more easily to systematic evaluation of finished products, can be implemented into the design system.

- The orthoses/prosthesis designs can be archived and reproduced when needed.
- A reduction in the production management required as a result of a more streamlined production processes.
- Fewer items of production equipment and less storage space needed.
- More possibilities in new product development.

Feasibility

To establish the feasibility of AF for orthotic and prosthetic manufacturing, several research efforts have been made in recent years:

- In research conducted at the University of Texas, Austin, the feasibility of using AF for prosthetic socket manufacturing has been investigated in a number of projects. In one thesis project, compliant structures were developed and analysed using the finite element method (FEM). In a patient trial, it was found that contact pressures between the residual limb and the AF produced socket could be significantly reduced with an integrated compliant surface (Faustini 2004, Rogers et al., 2008).
- Further research was conducted in Austin to investigate the feasibility of custom made AFO's and on how to adjust their stiffness. It was concluded that the AF approach is well suited for AFO production (Faustini et al., 2008).
- In research by the author, it was concluded that the clinical performance of foot orthoses (FOs) fabricated using selective laser sintering (SLS) was comparable to those produced using traditional methods in a seven patient trial where the patients were assessed using gait analysis and questionnaires (Pallari 2008, Pallari et al., 2010).
- Other, non-technical aspects of the "shift" to AF have also been investigated. Wagner investigated how the role of prosthetists and prosthetic workshop technicians would change if the manufacturing of prosthetics would change to utilise AF (Wagner et al., 2008). They concluded that the more experienced prosthetists would have to learn new computer skills, but they would still utilise their experience and craft skills. The more junior technician's role would be reduced as the need for their craft skills would be reduced.
- A literature survey by Rogers et al reviewed ten research projects investigating the feasibility of AF orthotics or prosthetics (Rogers et al., 2007). Some limitations to the AF approach are identified (cost and lack of suitable design software) but it is concluded that the basic concept of using AF for orthotic and prosthetic production is viable.

A common feature of all the studies which involved working with patients was that the number of patients in each study was small (as would be expected for an initial study) and the time to customise the devices and the various integrated features was not seen as an issue. However, in orthotic practice, time is however not always abundant and the interventions to the positive casts need to be made quickly. With AF, the final orthotic product can be designed directly, but the same time pressure problem remains. Adding various design features further increases this design time.

Optimising the properties of orthoses with finite element analysis

Due to the small number of manufacturing constraints, AF and the SLS process in particular can be efficiently used to fabricate tailored, patient-specific orthotics with a predefined optimal stiffness level. The finite element method is potentially a useful tool here and has been used to assess the mechanical characteristics and functional performance of AFOs (Chu, 2001, Syngellakis et al., 2000).

Following traditional methods, a custom-made polypropylene AFO was designed for a healthy test subject (female, 25 years old). The model was scanned and converted into a surface shell (3-matic 5.01, Materialise, Haasrode, Belgium) based on which a finite element mesh was generated (Patran 2008r1, MSC Software, Gouda, the Netherlands). Boundary conditions simulating dorsiflexion movement were implemented in the numerical model (Creylman et al., 2009). The effect of different materials and different design characteristics on functional parameters of ankle foot orthosis was studied (Muraru et al., 2010). These results combined with features of structural optimisation could lead to optimal and personalized designs of such devices.

Topology optimization was used to find the optimal material distribution for the AFO described above and presented in figures 2 and 3.

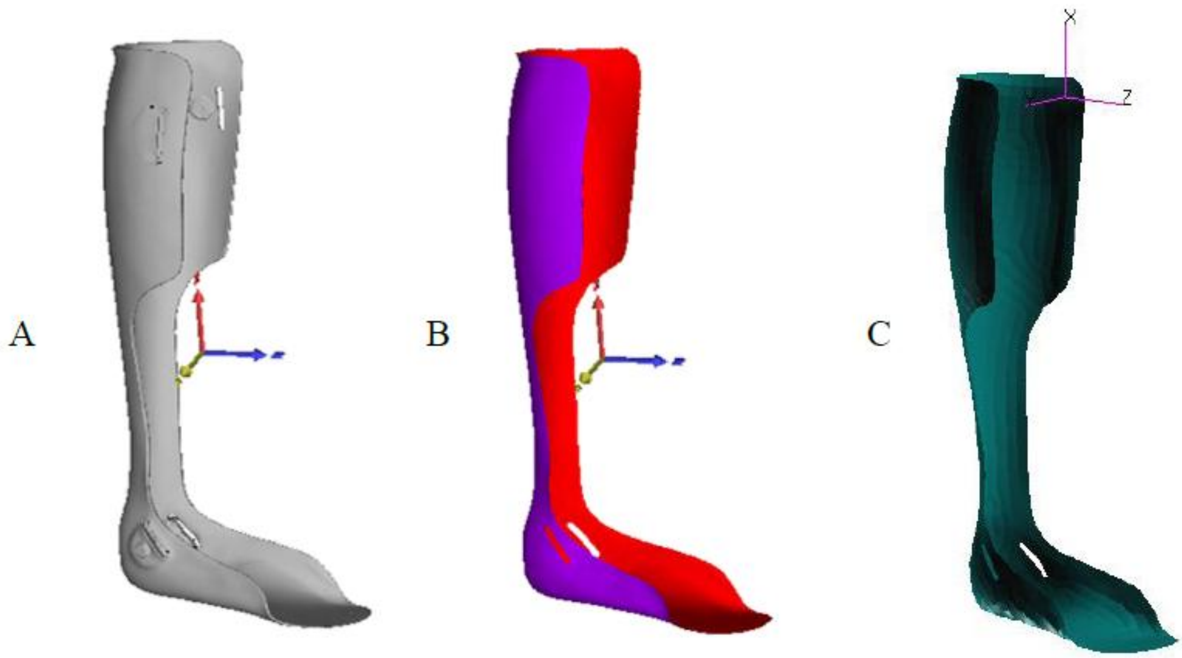

Figure 2: A 3D model of an ankle foot orthosis is presented in A. In B the inner surface is separated and in C the initial design space of 61920 square elements (global element size = 1 mm) is shown.

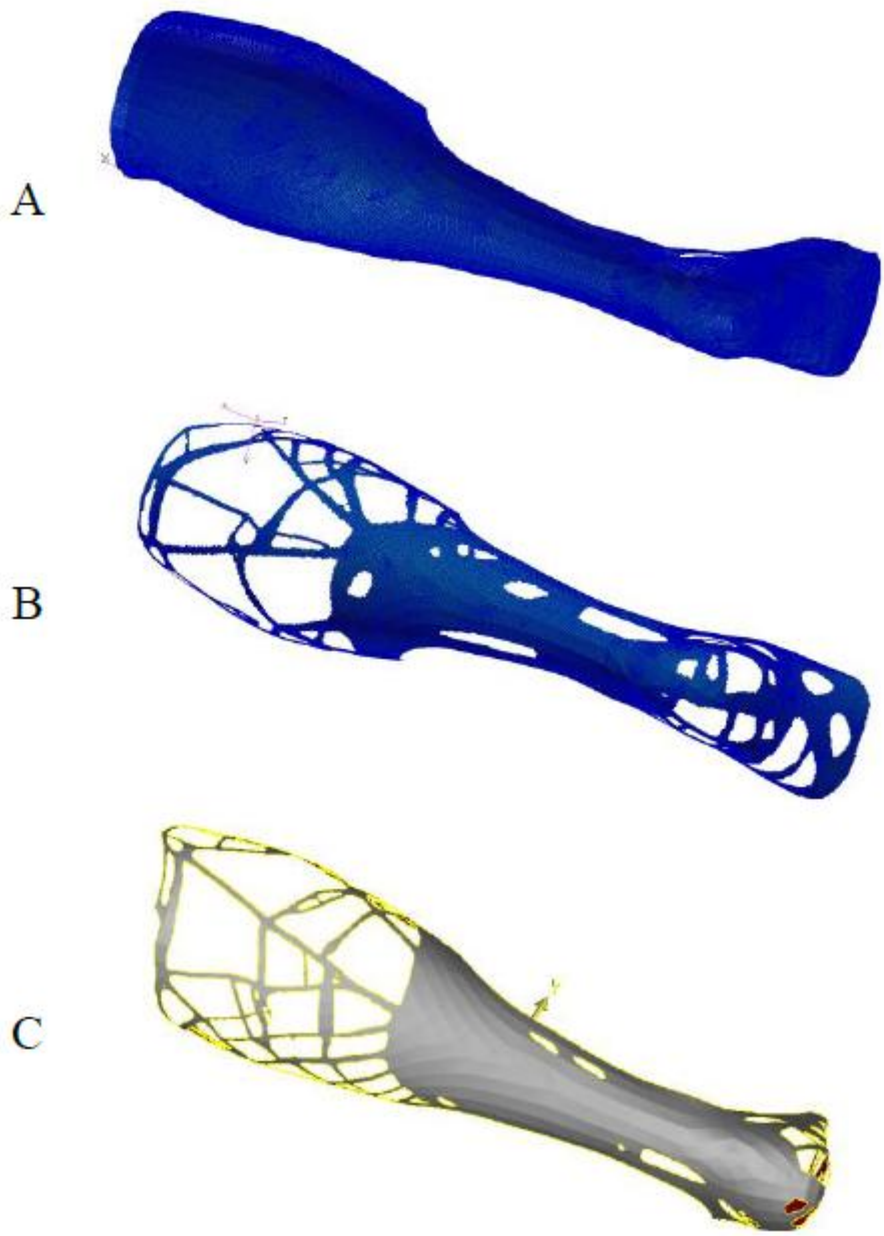

Figure 3. In A the initial design space is presented, in B the optimisation solution and in C the .stl description of the optimised solution.

The initial design space consisted of a shell of 4-noded quadrilateral elements which described the inner surface of the physical orthotic (figure 2C).

The density method (Bendsoe & Sigmund, 1999) implemented in MD Nastran (MD Nastran R3b, MSC Software, Gouda, The Netherlands) was used for topology optimisation. The design variables in the optimisation problem were the normalized densities of each element from the design space. A power law is used to relate the density with the material properties:

$$\rho = \rho_0^x$$

$$E = E_0 x^p$$

Where ρ_0 and E_0 are the fully solid density and Young's modulus respectively. A penalty factor p is introduced to enforce the design variable to be close to a 0-1 solution when p>1. In this way, intermediate densities are penalized and the result of the optimisation is a black and white structure (with clearly defined solid and void regions) (MSC Software 2007).

The load implemented in the analysis model was static equivalent to dorsiflexion movement. In the optimisation process this is considered independent and but in relation to the mesh. The objective was to minimize the compliance while the mass target was 50%.

The final, optimised AFO shape is presented in figure 4. The triangulated surface generated by the analysis was imported into 3-matic 5.01 and aligned with the original scanned AFO. The curves separating the open and closed areas were then used to cut material from the AFO model. Alternatively, only some material could have been removed from the model in indicated locations. These types of CAD operations are easy to automate.

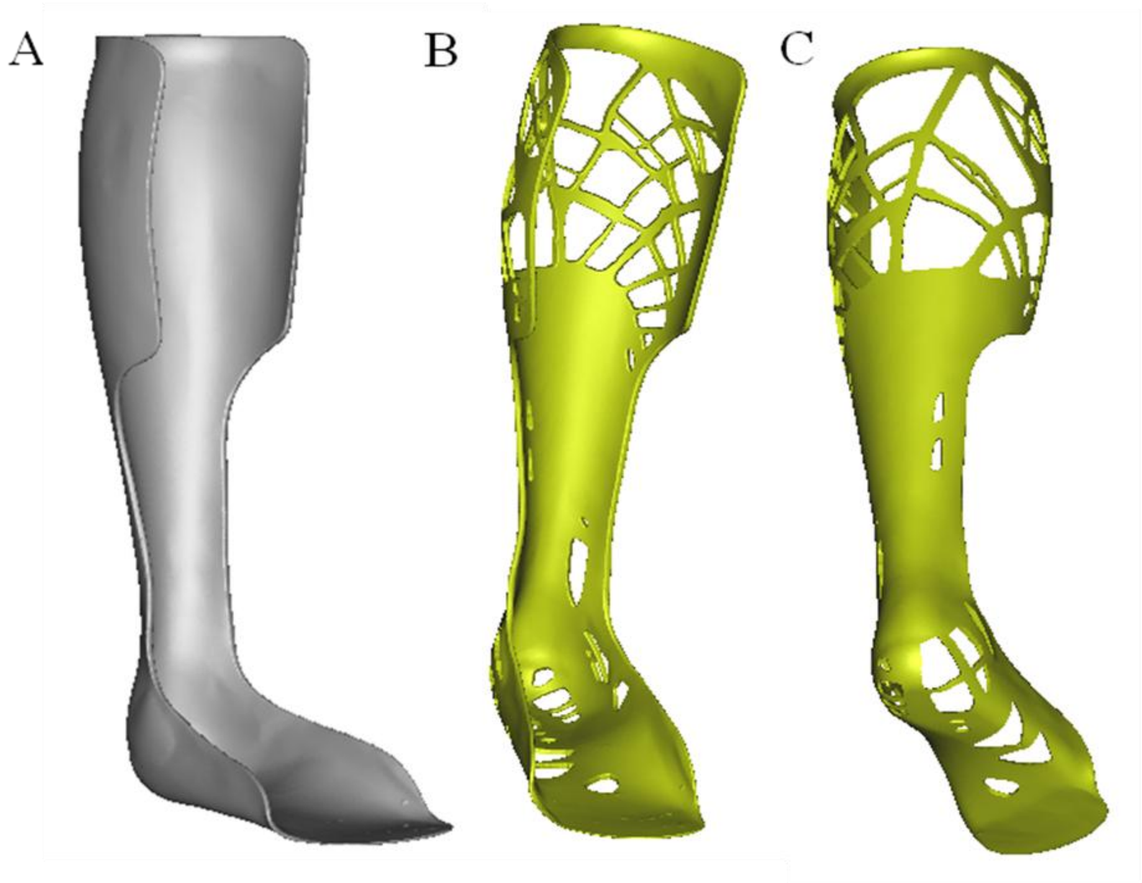

Figure 4. A custom made AFO (A) with material cut off according to the optimised solution. Anterior view in B and the posterior in C.

New approaches to the design and manufacture of foot and ankle-foot orthoses

Reproducing the performance of current state-of-the-art orthotics is an important step in investigating the viability of AF methods and prior to bringing them to the market. Beyond this however, there is potential to integrate functional features in the orthosis and to optimise their properties in ways not possible with traditional methods.

Some of these possibilities have been described in the literature, and further examples are presented here for FOs (Faustini 2004, Rogers et al., 2007, Faustini et al., 2008). For example, patterns of conforming beams, such as the ones presented in figure 5, can be integrated on the top surface of the orthoses. These beams will deform when placed under a load. They could perhaps be added to areas of the orthotic surface based on interface pressure measurements or visual observation of irritated areas on the foot surface. When combined with a thin cushioning layer which is traditionally adhered to the upper surface of the orthosis, they can be used to provide different cushioning properties for different areas of the foot.

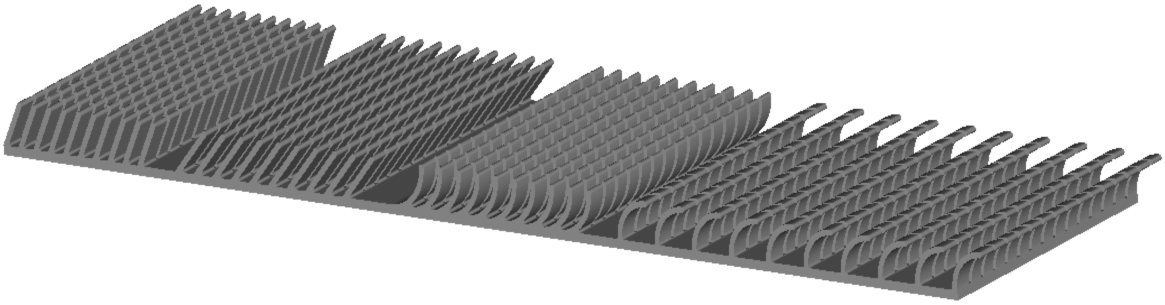

Figure 5. A conceptual drawing of different beam structures that can be integrated on the surface of an orthoses.

The beams could be linked to a pressure measurement as follows. The pressure measurement output, usually visualised in different colours and contours for the regions where different pressures were measured, as shown in figure 6.

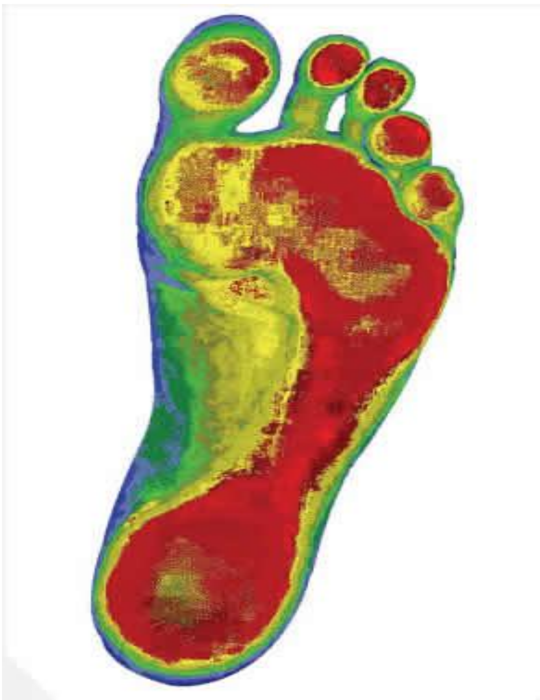

Figure 6. Different pressure regions from a pressure plate measurement projected onto the foot (Alba Chiropractic 2010).

This measurement data (specific surfaces or contour curves) can then be exported as greyscale bitmap images. These image files could then be imported into the orthotic CAD system and projected onto the relevant surface on the orthoses. Via preset threshold values, the cushioning beams could then be designed and patterned along the specified high pressure areas.

Other examples of functionality that have been built into foot orthoses (Pallari 2008):

- Rearfoot wedges. The function of a rearfoot wedge is to realign the foot during the gait cycle by rotating the rearfoot relative to the rest of the foot. The front part of the orthoses can be kept flat, while the heel part can be tilted and a rigid heel part designed accordingly. The “blending” of the frontfoot and the rearfoot parts of the orthoses can be seen in figure 7.

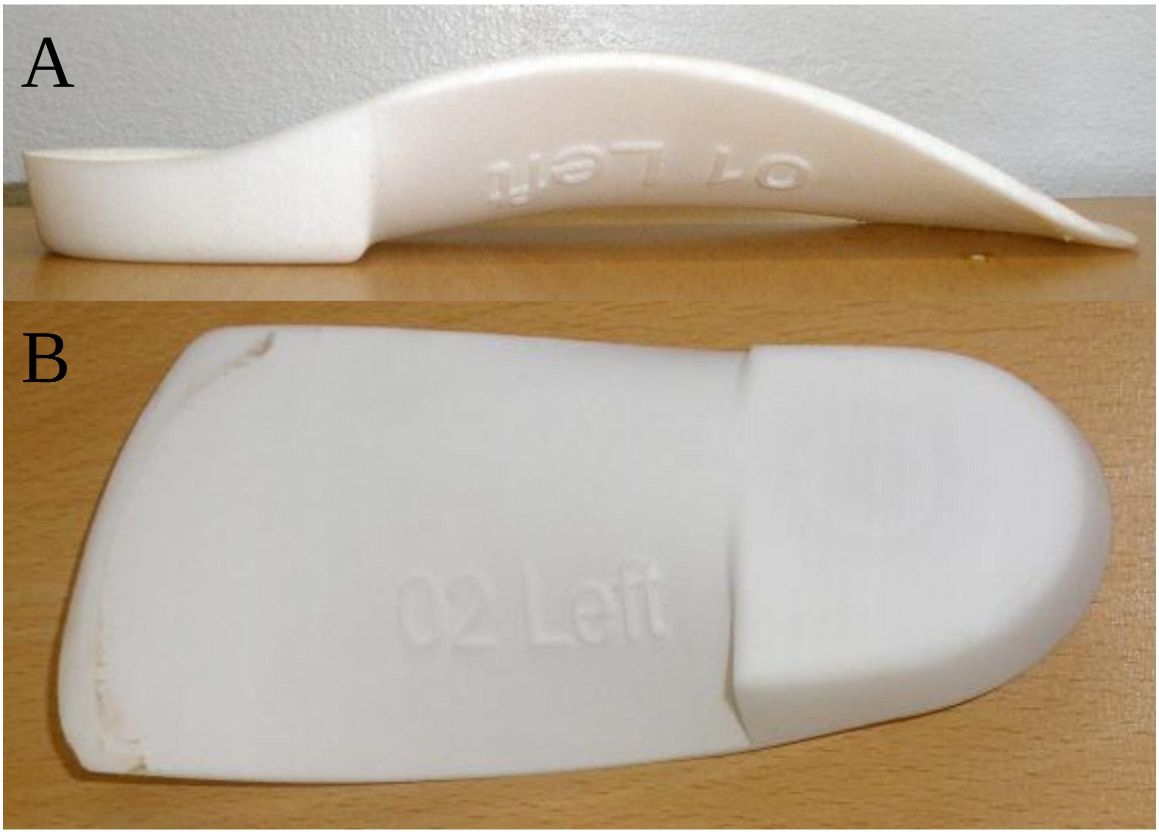

Figure 7. Foot orthoses with an integrated rearfoot wedge. Medial view in A and anterior view in B.

- Metatarsal pads, bars and cut-outs. These come in a variety of shapes and sizes and are used to redistribute the plantar pressure in the forefoot.

- Heel and arch supports. These define a “cup” in which the heel will be positioned and the arch support which normally prevents the foot arch from collapsing.

Sensor integration

A further opportunity resulting from the design freedom provided from AF is the potential to embed sensors into an orthosis. These could be used to collect data on a wide range of normal, day-to-day activities over an extended period of time. Data recorded by the embedded devices could provide valuable feedback to the patient or prescribing clinician if the desired treatment/rehabilitation effect intended by the clinician when prescribing a certain orthotic device is being achieved.

From a recent literature review on in-shoe sensing technologies covering pressure, temperature, shear, humidity, as well as additional biofeedback indicators the following key specifications have been observed:

- The measurements taken should be sufficiently accurate and repeatable under a large number of loading cycles and in the different environments (e.g. changing temperatures and humidity levels) that the orthotic will experience in-shoe.
- They should not affect the performance of the orthoses or cause any discomfort to the patient.
- The sensor should be reliable.
- Data should be stored with a high degree of fidelity and be easy to access, either through the implementation of wireless technology or with built in data loggers attached to the sensor.

Different attempts have been proposed to embed devices for biofeedback indicators into insoles, orthotics or even footwear, for example plantar pressure (Pataky et al., 2000), humidity (Morley et al., 2001) and plantar blood flow detectors (Cobb & Claremont, 2001). Rutkove et al. in 2007 for instance used the iButton, a low cost temperature sensor with built in data logger, to carry out a study comparing temperatures measured in-shoe on the dorsal surface of the foot with ambient levels over the course of two days. Activity was also monitored using accelerometers and a diary was kept by the subjects. The sensor was found to be robust and reliable and the authors recommended its use for clinical and research purposes. However, to date few sensing technologies are being applied to orthotics.

There is typically a lack of studies which describe long term continuous measurement using in-shoe devices. Researchers have attempted to measure a wide range of physiological factors regarding for instance the diabetic foot with generally high levels of success, however the majority of experiments were either non-ambulatory or set in a laboratory with only a relatively small number of steps being measured, with even the longest studies only lasting for a few hours.

Biofeedback type systems aimed at causing the patient to adjust their gait have been proven to be effective in a number of studies, however again these have generally only been over short time periods and with low numbers of subjects. There remains a great deal of potential in this area for more innovative uses of different types of feedback mechanisms, the range of physiological data collected, and the exploitation of the data.

AF technologies can enable the sensors to be placed very precisely in the correct place and an unobtrusive way. To do this in an operational setting, the placement has to be fast, easy and all the necessary wires etc need to be accommodated in the design. This is not currently feasible in any orthotics design system and would require a custom application to be developed.

Software design tools for orthosis design

Several different ways of utilising the design freedom of AF in FOs and AFOs have been described. To make these new types of devices in a production operation, suitable CAD systems are required. Existing orthotic CAD/CAM systems are not ideal for these new technologies because:

- The interventions enabled by the software focus in manipulating the positive cast (a duplicate of the patient’s foot or leg), not in creating the final orthotic product.

- The file input options are usually restricted to photographs and pressure measurement data. FE data for example cannot usually be imported.

- The file output options are usually restricted to those compatible with milling machines.

- AF is not considered as a manufacturing option for the end product or of the positive and complex surface manipulation operations are not possible.

- Automation possibilities, enabled by macro’s for example are not there.

Generally speaking, only FO CAD systems allow the design of the end product which is then milled from foam blocks. To make AF a viable, commercial option for orthotics manufacturing, software solutions are needed to utilise AF to its full potential.

Rogers et al. in 2007 summarise the same conclusion as follows: “While SFF will not replace conventional fabrication; it can be another tool in the prosthetist’s toolbox” and further “The cost of the software is the price of entry. The lack of availability of such software is the barrier.”

Conclusions

The latest literature indicates that the basic assumption of using AF to make FOs and AFOs is a feasible one. Further research illustrates how the shape of the orthotic device can be altered to save weight, to have more functional properties, and can be fitted with external sensors.

While orthoses can be engineered to a very high degree of user specific customisation through the incorporation of gait and surface pressure measurement analysis into the design process, this is not done in current clinical practice. This is mostly because of time, cost and manufacturing constraints. The orthotic and prosthetic industry does not have a tradition of engineering and expert designer familiar with finite element analysis for example are not common. Where the design work is done at a case-by-case basis, using current engineering software, the time it takes to make one design may increase the cost per product significantly.

These issues can be partially solved by developing specific software packages to enable the full potential of AF to be utilised in orthotic and prosthetic product design and in creating completely new kinds of products, changing the industry currently restricted by old and inefficient manufacturing methods.

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