Mass Matching
Customization, Configuration & Creativity

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Ref.
Rapid manufacturing of orthotics and prosthetics – is it a good idea?

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This research presents the possibilities of creating customised orthotic and prosthetic products using rapid manufacturing (RM) processes, which show potential in improving lead times, quality, consistency and patient care. Research addressing the various technical, clinical and commercial aspects of orthotic and prosthetic devices and their production and how RM could improve the state of the art is presented in this paper.

Limitations in the manufacturing technology and in associated materials and material properties research coupled with the conservative nature of the orthotics and prosthetics (O&P) industry has prevented these technologies from being adapted so far. Nevertheless, the right combination of RM technologies, new kinds of functional integration systematic design and engineering, proper clinical research and co-creation of the devices with the patient open up great possibilities to create a new generation of O&P devices that could have a major impact in the industry.

Keywords. Rapid manufacturing, Orthoses, Prosthesis, Functional integration, IDEF0.
Introduction

This paper aims to review the current state of research of using rapid manufacturing (RM) for the production of customised orthotic and prosthetic (O&P) products. An orthotic device supports or corrects a part of a person’s musculoskeletal system. A prosthetic device/limb replaces a missing part of the body, such as an arm or a leg.

Since each body is unique and not all patients can be treated with standard sized prosthesis and implants, there is a great need for customised products in this industry. Good fit and comfort is important and improved clinical effectiveness has been linked to customised products over mass-produced ones (Woodburn et al, 2002; Brncick, 2000 and Mundermann, 2001). In the perfect world, all O&P products would be customised.

The production of customised orthotic and prosthetic devices is currently a craft. The process is time-consuming and requires experienced craftsmen who generally make their decisions based on experience and trial and error rather than systematic engineering principles. This results in inconsistent designs and patient care.
A general description of the “traditional” process for making custom prosthetic sockets is presented in Figure 1. The process used to create orthotic devices also is very similar to this. Computer assisted design (CAD) systems have also been used to assist in creating the positive improving consistency and repeatability of this process, but the process remains slow and complex and it requires considerable input from experienced craftsmen. Furthermore, in these traditional processes the possibilities for innovation or product development are limited.

With CAD systems it has been observed that orthoses rejection ratio has been reduced combined with time reduction up to 50% and cost saving up to 25% to 50% (Staats and Kriechbaum, 1989).

A new family of manufacturing processes has emerged in the late eighties that could radically change this industry. Rapid manufacturing is known by several names, such as rapid prototyping, freeform fabrication and additive fabrication. It
generally refers to layered manufacturing methods that work by adding layers, one on top of each other, of usually liquid or powder material and selectively bonding or fusing them together, often with the aid of a laser. These processes are largely free from geometrical constraints and enable very complicated parts to be manufactured with varying material compositions.

These new technologies could be suitable for orthotic and prosthetic manufacturing, as they have been designed from the onset to handle one-off part production. In addition, because of the different nature of the manufacturing process, functional elements, such as locally adjusted stiffness or flexibility, can be built into the orthoses. The process for manufacturing and fitting an orthotic device would also be very similar to this.

Rapid manufacturing has the potential to offer significant advantages over traditional O&P production. Some of these are listed here (Pham and Dimov, 2003; Hague et al, 2003; Syrjälä 2003; Dickens and Fouchal 2000; Kulkani et al, 2000 and Hopkinson et al, 2005):

- Faster production over the traditional process and more consistent quality.
- A more comfortable experience for the patient as no messy plaster work is needed anymore.
- Fewer and less experienced technicians can be used as there is less need for manual work and experience “with your hands” is not as crucial.
- The orthoses/prosthesis can be tracked/archived/reproduced when needed.
- Less production management and simpler production processes.
- Less production equipment and stores needed.
- More possibilities in new product development.

The idea of using rapid manufacturing for prosthetic sockets is almost as old as the industry itself. Already in 1998 Cheng et al, investigated manufacturing of transtibial sockets using stereolithography (Cheng et al, 1998). Several other
groups and individuals have done further research on prosthetic sockets, different orthotic devices and even on complete prosthetic legs as in Figure 2.

![Prosthetic Leg Prototype](image)

Figure 2. A prosthetic leg prototype (Desk Engineering 2009).

This research will discuss material from relevant research and case studies to establish what kind of experimental evidence exists for and against using rapid manufacturing in the O&P industry.

**Clinical advantages from rapid manufacturing**

Most of the research in the field addresses prosthetic socket, foot orthoses (FO), or ankle-foot orthoses (AFO). A research group at the University of Texas – Austin has published several papers about engineering sockets for lower
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extremities – presented in Figure 3 – or ankle-foot orthoses (Rogers et al, 2008; Faustini et al, 2008; Faustini et al, 2006 and Faustini et al, 2005). An AFO is presented in Figure 4.

Figure 3. A prosthesis for below-the-knee amputees: I - socket, II - attachment fitting, III - pylon, and IV - prosthetic foot (Faustini et al, 2005).

Figure 4. Ankle foot orthoses (Twin city 2009).
In one research paper, a new type of AFO is described. It utilises one of the advantages of rapid manufacturing (Faustini et al, 2008). Complex structures added to the AFO shape can be built at the same cost and time as simple ones. In this case functional elastically deforming structures were integrated to the orthoses body as displayed in Figure 5 (Faustini et al, 2008). Faustini et al also mention that the structure can be scaled up or down to meet the demands of a particular patient (Faustini et al, 2008). Using finite element analysis the stiffness of the AFO can be modelled and the structure scaled up or down to customise the stiffness of the AFO for a particular patient. Their approach is not focused on creating a mass customization process but it is implied as the final goal for future development.

Figure 5. An AFO produced with the SLS process with integrated functional structures (Faustini et al, 2008).

Faustini compared a “traditional” transtibial socket made from Duraform PA with the SLS process with one with integrated compliant features optimised to
absorb local loads, such as in Figure 6 (Faustini 2004). Faustini measured how the different sockets affect the surface pressures the in the fibula head - with and without the compliant features – and observed the maximum pressures drop from 172 to 66.4 kPa with the compliant features (Faustini 2004). This is significant in terms of comfort as high peak pressures are generally linked with discomfort and pain.

Figure 6. A transtibial socket with compliant features (Faustini thesis).

Rogers et al further explored integrated compliant features with a patient trial and measured surface pressure changes in the fibular head and the distal tibia as presented in Figure 7 and Table 1 (Rogers et al, 2008). These reductions are significant in terms of user comfort especially during extended periods of use. This research further indicates that additive fabrication has the potential to
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improve orthotic and prosthetic treatment by enabling new possibilities in product development. Furthermore, in several papers, where SFF prosthetic sockets have been investigated for prosthesis, the results indicate that they have a better fit and stability over traditionally made ones, since the geometry of the residual limb can be reproduced very accurately (Ashley, 1993; Rogers et al, 2008 and Faustini et al, 2006).

Figure 7. Local pressures on the Distal Tibia (top) and the Fibula Head measured through the gait cycle (Rogers et al, 2008).

<table>
<thead>
<tr>
<th>Peak pressures measured</th>
<th>Distal Tibia (mid stance)</th>
<th>Fibula Head (terminal stance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional socket</td>
<td>177.8 kPa</td>
<td>97.4 kPa</td>
</tr>
<tr>
<td>Compliant socket 1</td>
<td>88.4 kPa</td>
<td>33.9 kPa</td>
</tr>
<tr>
<td>Compliant socket 2</td>
<td>97.9 kPa</td>
<td>25.9 kPa</td>
</tr>
</tbody>
</table>

Table 1. Localised peak pressures from the Distal Tibia and Fibula Head (Rogers et al, 2008).

In a major European Framework 7 project – CustomFit – transfemoral prosthetic sockets have also been investigated. Prototype sockets were
manufactured using the SLS and 3D printing processes and tried on by amputees. It was reported that not only would prosthetics production this way be feasible, but for each amputee the total cost of the treatment process could be reduced by 2000 Euro using additive fabrication (Martinez and Marin, 2009 and Shelley 2009).

More complex compliant structures that could be integrated to the orthotic or prosthetic structure as has been described in several publications by another research group at the University of Texas (Montgomery et al, 2009, Maheswaraa et al, 2007 and Gupta et al, 2006). They focus in the designing compliant structures such as those presented in Figure 8 and in the computational methods used for them. This further indicates the feasibility in functional integration of deforming structures made with layer manufacturing. There are also interesting possibilities with further customising the functional aspects of the AFO as the deforming structures properties can be quantified and liked to in-shoe pressure or pressure mat measurements.

Figure 8. A compliant structure that can be built to an orthotic or prosthetic shell (Gupta et al, 2006).
At the University of Leeds, Pallari investigated the feasibility of creating a mass customisation system for foot orthoses using rapid manufacturing (Pallari, 2008). Unlike in the majority of research described so far, the new mass-customisation principles and rapid manufacturing technology was applied to existing clinical processes. The clinical process development was straightforward and was built on existing, best clinical practice on the day.

This research demonstrated that the development of a mass customisation system for foot orthoses is possible. The personalised orthoses manufactured in Nylon using a selective laser sintering machine performed as well as currently available “traditional” personalised orthoses in patient trials. Also, external wedging under the heel – a feature needed in certain cases – was replaced by integrating the same function to the orthoses “shell”.

The new mass customised orthoses, presented in Figure 9, have been tested in a patient trial (7 patients), and the gait parameter measurements and fit and comfort assessment results indicate that the performance of layer manufactured orthoses was found to be sufficient with current materials (Duraform PE) for short, controlled trials (Pallari, 2008). The new orthoses achieved a similar effect to normal customised orthoses. This indicates that the mass customisation system can produce orthoses without any loss of clinical effectiveness (Pallari, 2008).
Changes in the clinical and manufacturing processes

In mass customisation processes, the fundamental functions identified by numerous authors are; acquiring customer requirements, processing the customer order, design of the product, plan for manufacturing, manufacturing the product, delivery of the product (McCarthy et al, 2003; Kumar et al, 2002; Piller and Stotko, 2002 and Cullinane et al, 1997). Based on the core functions in the customisation process, and on Cullinane et al’s generic IDEF0 process model (Cullinane et al, 1997), a more specific model was developed for orthotic and prosthetic products, in Figure 10, and a modified model with rapid manufacturing in mind, as in Figure 11 (Jumani and Dalgarno, 2008). The main objective of modelling the customisation system for O&P devices is to understand the existing situation and to analyse the present processes and operations in the system in order to improve the system.
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Figure 10. The generic IDEF0 process model developed for the customisation of medical devices (Jumani and Dalgarno, 2008).

Figure 11. Rapid manufacturing based IDEF0 process model for the mass customisation of medical devices (Jumani and Dalgarno, 2008).
Figures 10 and 11 show that the customisation process involves a core function of planning for manufacturing. This function involves time for the planning and scheduling of the various manufacturing activities such as, process scheduling, set-up time, quality control activities and inspection processes that increases the overall production lead-time. There are some fundamental similarities in the designed model with the context model in terms of core functions. Although both process models are designed to produce customised products, there are differences in the mechanisms, controls and other resources required which includes the policies, resources and technologies.

Manual work for designing the foot orthoses makes the overall process longer and requires high skill and increased labour work which ultimately increases the designing time and designing cost for the foot orthoses. Rapid manufacturing has the potential to change not only the products and processes, but also the way orthotic and prosthetic specialists operate. Research done by Wagner et al investigates the change in prosthetists and prosthetic technician’s roles and skills needed in the overall production process assuming “traditional” and with the adaptation of rapid manufacturing (Wagner et al, 2008). The differences between these two processes can be seen in Figures 12 and 13.
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This was evaluated using a “job characteristics model”, where the skills change and job satisfaction implications of applying new technology to traditional manufacturing processes are assessed. The research showed shown that the application of RM can cause major changes on the workshop level (Wagner et al, 2008).
2008). Computer skills will become more important but the traditional craft skills will not be needed as much and that the technicians involved face major changes in their work (Wagner et al, 2008). Furthermore, Wagner et al, comment that RM may enable technicians to become more productive and to decrease the time when a new technician becomes productive (Wagner et al, 2008). This can have a significant impact on the developing world where there are few trained and experienced O&P technicians.

Cost models

Investigation of foot orthoses and the cost of rapid manufacturing in comparison to traditional manufacturing methods has been carried out by the authors. In this research, the fused deposition modelling (FDM) and SLS processes have been evaluated in comparison to the traditional milling based manufacturing process for customised foot orthoses in order to evaluate the cost and time involved in each step of the design and fabrication. Table 2 shows the designing time and cost involved in the different foot orthoses design techniques. A CAD based design process is more effective, quicker, and more consistent between users.

<table>
<thead>
<tr>
<th>Orthoses designing techniques</th>
<th>Designing time</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand carving, moulding, casting</td>
<td>2 hours</td>
<td>£40/pair</td>
</tr>
<tr>
<td>CAD designing</td>
<td>20 minutes</td>
<td>£7/pair</td>
</tr>
</tbody>
</table>

Table 2. Orthoses designing time and cost by different techniques.
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Cost per pair through the CNC technique is £38, £51 using SLS and £64/pair using FDM. In addition to the costs in table 3 there is an estimated added clinical cost of £3-£5 to capture the geometry of the foot through digital scanning (Payne, 2007).

Table 3. Estimated annual design and fabrication cost.

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**Design and manufacturing cost for 3520 pairs/year by CNC machine**

<table>
<thead>
<tr>
<th>Cost</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design cost (CAD)</td>
<td>£7/pair</td>
</tr>
<tr>
<td>Cost of CNC machine</td>
<td>£1,000</td>
</tr>
<tr>
<td>Labour cost (Machine Operator)</td>
<td>£20/hour</td>
</tr>
<tr>
<td>Cost of Blanks</td>
<td>£10/pair</td>
</tr>
<tr>
<td>Labour cost (Finishing/tuning)</td>
<td>£20/hour</td>
</tr>
<tr>
<td><strong>Total manufacturing cost</strong></td>
<td>£135,240</td>
</tr>
</tbody>
</table>

**Design and fabrication cost of 3600 pairs/year through SLS system**

<table>
<thead>
<tr>
<th>Cost</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design cost</td>
<td>£7/pair</td>
</tr>
<tr>
<td>SLS system cost</td>
<td>£50,000</td>
</tr>
<tr>
<td>Material cost (Duraform PA)</td>
<td>£72,000</td>
</tr>
<tr>
<td>Labour cost (Technician)</td>
<td>£35,200</td>
</tr>
<tr>
<td><strong>Total fabrication cost</strong></td>
<td>£182,400</td>
</tr>
</tbody>
</table>

**Design and fabrication cost of 3600 pairs/year through Fused deposition modelling**

<table>
<thead>
<tr>
<th>Cost</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design cost (CAD based)</td>
<td>£7/pair</td>
</tr>
<tr>
<td>FDM system cost</td>
<td>£5,000</td>
</tr>
<tr>
<td>Material cost (ABS P400)</td>
<td>£165,000</td>
</tr>
<tr>
<td>Labour cost</td>
<td>£35,200</td>
</tr>
<tr>
<td><strong>Total fabrication cost</strong></td>
<td>£230,400</td>
</tr>
</tbody>
</table>

Typical retail costs for a pair of customised foot orthoses is between £50 and £200 (Pallari, 2008 and Woodburn et al, 2002), depending on supplier and lead time, and so that rapidly manufactured ones are competitive on cost and that a mass customisation system would aim to provide better lead times. Overall there is clear commercial potential.
Furher remarks were made concerning the applications of new techniques such as 3-D laser scanning. Combined with the applications of the CAD based design system and rapid manufacturing systems the orthoses design and fabrication process can be improved to be more effective, reliable, accurate and cost effective.

Why has rapid manufacturing not been adopted by the O&P industry

The research described above outlines the current state of science in RM with O&P. The technical and clinical research is limited in scope and definite conclusions are hard to make based on this evidence. Some general problems with RM technologies can also be highlighted here (Pham and Dimov, 2003; Hague et al, 2003; Syrjälä, 2003; Dickens and Fouchal, 2000; Kulkani et al, 2000 and Hopkinson et al, 2005):

- The surface finish of SFF manufactured parts is usually in the range of Ra 2-5 µm. Without sanding, this surface finish cannot match that of moulded- or thermoplastics. However, as some manual finishing work will be needed for all orthoses and prosthetics anyway, sanding the surface is not seen as being a major issue – especially comparing this amount of finishing work with the traditional manufacturing process.
- One of the limitations of RM technologies is the small number of different materials, their properties, and their relatively high cost. The main problem with the material properties is that they are not well known, rather than that they are not good enough.
- Public information on the material properties is limited – especially with longer term wear and fatigue. O&P products are used generally for several years and to guarantee the performance of on RM product, the practitioner would have to do their own materials testing as the RM materials and
systems providers do not currently (2009) provide this kind of information. Also, the traditional thermoplastics used currently are not brittle as RM materials can be (nylon for example) and their flexibility should be improved for O&P applications.

- The investment cost of purchasing RM machines is high and the material price also forms a major part of the end product cost. Traditional orthoses materials, such as plaster and sheets of thermoplastics are cheap in comparison. The transition to centralised fabrication can also be difficult for smaller practitioners who are accustomed to having control over every part of the manufacturing process.
- Lastly, scepticism and resistance to change is a great obstacle for the widespread use of rapid manufacturing technologies.

General development trends and particulars in the O&P industry – evolution, not revolution.

Change in the O&P industry is not usually fast apart from some specific high-tech applications, such as prosthetic knees or hands. One reason for this is the way patient’s orthoses are funded. Health insurance companies and state funding agencies are always looking to cut costs and experimental treatments are not usually compensated. It can be hard for any new technology or product to break through this obstacle (Otto, 2008).

Thomas Kirk, the CEO of Hanger Orthopedic Group, has recently raised concern about the state of the industry; "There are pockets of people out there who’d like to continue doing things that have always worked for them before. We have to make sure the profession understands that to survive and prosper, they're going to have to realize it's time to move forward. And it's going to take a commitment and willingness to change."(Otto, 2009). Inevitable changes are affecting the industry:
• The need for an evidence base is increasing and pressure is being applied from the funding agencies to provide this evidence (Jerrell, 2006; Otto, 2009 and Delander, B 2009).
• Further pressure is applied by the need to improve the standards for patient care and improved cooperation and collaboration between the industry, state/insurance healthcare agencies and the patients and patient organizations (Jerrell, 2006; Otto, 2009 and Delander, B. (2009).
• Currently, the use of CAD/CAM is increasing in the industry. However, there is a problem with not enough CAD/CAM experience and education in the industry – in 2008, even when CAD is an established tool in the industry for milling applications (Otto 2008A; Otto 2008B and Crownover , 2008). Many experienced professionals in the field are used to working with their hands and to change this way of working to a CAD/CAM system can be difficult if the pre-requisite computer skills are not there.

Further, the reluctance to change old practices and to hang on to tradition slows down progress. Those players that can adapt to this situation and can embrace change can succeed in the future despite increasing pressure to cut costs in healthcare as the population in western industrialised countries is aging (Otto, 2009).

How to break through

If there would be an easy answer to this question, we would already see commercial applications for rapid manufacturing in O&P. Based on this research; the following aspects can be seen as relevant:

• Material properties are one of the main issues. The materials themselves can be suitable for O&P applications but could be better in regards to flexibility and thermoformability. In some applications these issues may not be problems. The other big question is how well can the products last through extended periods of use? This is an open question and ideally it should be answered by the RM material and systems providers. For the moment, the end user will have to do the necessary testing in these properties. Material
and process research is progressing fast with RM technologies and the answers to these questions may surface eventually.

- **Cost issues** – the right applications need to be identified as will the right combination of partners (software and systems providers) who will take on the risk of “trying it out” for the first time. With high production costs, the benefit of using RM must be sought elsewhere. From better products with added value, better designs and faster delivery to fewer hospital visits or reduced costs at the workshop.

- There are numerous benefits in using CAD tools for the design work. All patient and product information can be stored, manipulated and measured digitally. Design rules and company-specific procedures and designs can be built into the system, allowing for less experienced users to create designs better and more consistently than they could otherwise. Parts of the design process could also be automated in the software. To fully utilise the possibilities RM could provide, the CAD system has to be tailored to this purpose rather than for milling applications.

- The productivity of the manufacturing processes is a key issue. Should one maximise the productivity of the machines or aim for a fast delivery time? Current high-end RM machines are expensive and a decrease in these prices is not in the immediate future even if their productivity and quality of parts is likely to improve. Collaboration with the RM process and materials providers is also crucial. The lower the production costs are, the more attractive the business case becomes.

- More information is also needed on how much precisely an O&P company could save by adopting RM over traditional manufacturing in different cases and business “environments”. For example, how much is the decrease of lead time from two weeks to two days worth? Also, success stories from other companies would lower the threshold of considering RM seriously.

- With RM it would be easy to realise new approaches with product design and customisation, such as the Colin Matsco designed prosthesis concept presented in Figure 14. If the whole design and manufacturing process can be digitised, products like this are completely feasible. This kind of design can of course be combined with functional integration to create a next generation of O&P products. In a recent article, Phil Newman from Touch Bionics suggests that future O&P products will be smaller, lighter and more stylish than today (Delander, 2009). This follows the example set by mobile personal audio players from the walkman to the iPods of today. He makes further predictions are made about different users wanting customised appearance in their products (Delander, 2009).
To push the O&P industry to the 21st century, a new mindset is needed. Rapid manufacturing technology that has the potential to disruptively change the products in this field, but to do this, the industry needs to begin to engineer and design their products, in a more systematic manner. A proven clinical and engineering base should be required to ensure and eventually improve patient health care for all new products. Out of the O&P products discussed in this paper some are more suitable economically for actual commercial operations than others. To succeed commercially, the right applications have to be found where RP technology is used to add value to the product and the tools developed to enable efficient custom product design. Later, as materials, processes and design software improves, more applications will emerge.
References


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