COST MODELLING OF RAPID MANUFACTURING BASED MASS CUSTOMISATION SYSTEM FOR FABRICATION OF CUSTOM FOOT ORTHOSES

By

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Submitted in accordance with the requirements for the degree of

Doctor of Philosophy

University of Newcastle

School of Mechanical and Systems Engineering

June 2013

DEDICATED TO ALL THE TEACHERS IN MY LIFE

ABSTRACT

Solid freeform fabrication (SFF) or Additive manufacturing (AM) techniques have emerged in recent years as advanced manufacturing techniques. These techniques have demonstrated advantages particularly in situations where the demands for unique geometrical structured customer-specific products are high and the time to market is very short. Applications of these techniques in the medical sector in combination with the latest medical digital imaging technologies are growing quickly. The techniques have inherent advantages of compatibility with the output information of medical digitising techniques.

Foot orthoses are medical devices used as shoe inserts in the treatment of foot disorders, injuries and diseases such as diabetes, rheumatoid arthritis, congenital defects and other foot related injuries. Currently custom foot orthoses are fabricated through manufacturing techniques which involve costly and based on lengthy trial and error manufacturing process. These techniques have limitations in terms of fabricating required geometries and incorporating complex design features in the custom-made orthoses.

The novelty of this research is to explore the commercial scale application of rapid manufacturing techniques and to assess a rapid manufacturing based design and fabrication system for production of custom foot orthoses. The developed system is aimed at delivering the custom made orthoses at mass scale with improved fit, consistency, accuracy and increased product quality.

The traditional design and fabrication process for production of custom foot orthoses was investigated and modelled with IDEF0 modelling methodology. The developed IDEF0 model was re-modelled and then the rapid manufacturing approach was integrated in the design and fabrication process. The main functions of foot geometry capture, orthoses design and manufacture of orthoses were modelled and evaluated individually with respect to time and cost and quality of the final product.

Different well-established rapid manufacturing techniques were integrated in the current design and fabrication process. The results showed that the techniques have significant impacts on the overall design and fabrication process in terms of increased process efficiency, low lead-time, increased productivity and improved quality of the final product.

An orthosis model was fabricated on an experimental basis using different well established rapid manufacturing techniques. The techniques were separately investigated and analysed in terms of orthoses fabrication cost and build time. The cost and lead-time in different techniques were modelled, analysed and evaluated for evaluation of commercial scale applications. The analysis and evaluation of the cost and lead-time modelled for different rapid manufacturing techniques showed that selective laser sintering technique is the better option for integrating the technique in fabrication of custom foot orthoses and that it has the potential to compete with conventional techniques.

AFFIRMATION

The work presented in this thesis is original in its contents, thus it can be said that barring the referenced knowledge given in the thesis, the unreferenced part of this thesis is my own work, which has not previously been submitted for any other degree.

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ACKNOWLEDGEMENT

Driven purely by four years of PhD training both as explicit as daylight and as implicit as the darkness of the night in absence of moonshine, its stress and strain and by unlocking the mind’s thinking capability store and getting to know about its application; the author of this thesis can’t be thankful enough to the ultimate creator The Almighty Allah, my ever-caretaking parents and my conscientious supervisor. While being here in Newcastle, UK, I am and will always be sincerely grateful to my supervisor, Prof. Dr. K W Dalgarno for his thought-provoking assistance in the form of clear directions that he provided during the discussions about the work and its progress, his useful and timely comments about my writing drafts and patience and logical hearing to my raw viewpoints. Thank you Prof. for valuable discussions about the PhD thesis and its structure I am thankful to Dr Javier Munguia Valenzuela (Research staff) and Dr. Jari H Pallari, Materialise HQ, Belgium. This leads me to thanking my colleagues for their help. I am particularly and will eternally be grateful to my family, who all have seen very little of me in these four years.

Abbreviations

CAD	Computer Aided Design
CIM	Computer Integrated Manufacturing
CODP	Customer Order Decoupling Point
FDM	Fused Deposition Modelling
FMS	Flexible Manufacturing System
LM	Layer Manufacturing
MCP	Mass Customisation
MRI	Magnetic Resonance Imaging
NC	Numerical Control
NBIC	National Bicycle Industrial Company
SFF	Solid Free Form
SLS	Selective Laser Sintering
SLA	Stereolithography Apparatus
3DP	Three Dimensional Printing
POS	Panasonic Order System

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Chapter 1 Introduction

1.1 Background

In view of worldwide increased competition in manufacturing business, companies are under pressure to adopt new manufacturing approaches and strategies in order to respond quickly to their customers for providing high variety, high quality and cost-effective personalised products (Piller and Stotko, 2002). This requires reorganisation and introduction of new manufacturing approaches combined with integration of information technology (IT) resources and efficient supply chains systems to meet the challenges of increased demand for product variety and personalisation to satisfy the changing customer demands without compromising the lead-time, cost and quality of products (Pine, 1993; Lebovitiz and Graban, 2001).

Recently in manufacturing engineering, applications of new approaches such as agile manufacturing, lean manufacturing, rapid manufacturing and mass customisation have received much attention in literature. Mass customisation is an approach which is believed to offer solutions for provision of individualisation and customisation in the products at a mass scale (Pine, 1993; Piller, 2003). This new approach of mass customisation can be widely observed across the manufacturing sectors in automotives, computers, telecommunication, electronics, textile, sports, consumer and medical products (Tseng and Piller, 2003; McCarthy and Brabazon, 2003; Selldurai, 2004**.** In medical sector production of custom-made devices, implants and tailored treatments have a long history and the need for custom-made products/devices and personalised rehabilitation aids are more explicit in this sector (Kumar et al., 1996; Dalgarno et al., 2006).

Solid free form fabrication (SFF) or Additive manufacturing (AM) techniques have emerged in recent years as advanced manufacturing techniques. These techniques have great advantages particularly in situations where the demands for unique geometrical structured customer-specific products and the time to market are very short. Additive manufacturing techniques are based on an additive approach where parts are built gradually by adding material layer by layer to create three dimensional geometrical parts specified by a computer aided design (CAD) system. There are many commercial rapid manufacturing techniques based systems available in the market such as selective laser sintering (SLS), stereolithography (SLA), fused deposition modelling (FDM) and 3D printing (3DP) systems (Noorani, 2006, Gibson et al., 2010).

Applications of rapid manufacturing techniques in the medical sector in combination with the latest medical digital imaging technologies such as computerised tomography (CT) and magnetic resonance imaging (MRI) are growing quickly. Rapid manufacturing techniques have the inherent advantages of increased design freedom, the ability to fabricate unique geometrical structures/parts and the compatibility of these techniques with the output information of medical digitising techniques. These factors have significantly increased the role of rapid manufacturing techniques for the fabrication of customised/tailored devices, implants and rehabilitation aids in the medical sector (Cormier et al., 2003; Kruth et al., 2005; Tukuru et al., 2008).

Foot orthoses are medical devices used as shoe inserts in the treatment of biomechanical foot disorders, injuries and diseases such as diabetes and rheumatoid arthritis. Foot orthoses are prescribed for the treatment of medical conditions developed in rheumatoid arthritis (Woodburn et al., 2002; Magalaheas et al., 2006; Bellamy, 2007), diabetes (Bus et al., 2004; Muller et al., 2006; Frykberg et al., 2006; Paton et al., 2007), congenital defects and numerous foot disorders and injuries to reduce stresses, provide comfort to painful areas, preventing deformity and disability and promoting improved gait in the patients (Pratt, 1994; Hunter et al., 1995; Nigg et al., 1999; Nicolopoulos et al., 2000)**.** The significant challenges in the foot related problems are growing deterioration in the pathological conditions such as increasing pain and joint destruction in rheumatoid arthritis (Helliwell et al., 2007) and progressing foot ulceration in diabetes which quickly changes the state of diseases (Paton et al., 2007). In order to prevent these progressing problems and conditions, custom foot orthoses are prescribed for correcting the foot alignment to support abnormal foot structure and transferring and redistributing the mechanical stresses and loads on the foot tissues in the affected parts of the foot (Obrovac et al., 2005). Figure 1:1 shows the images of the foot orthoses.

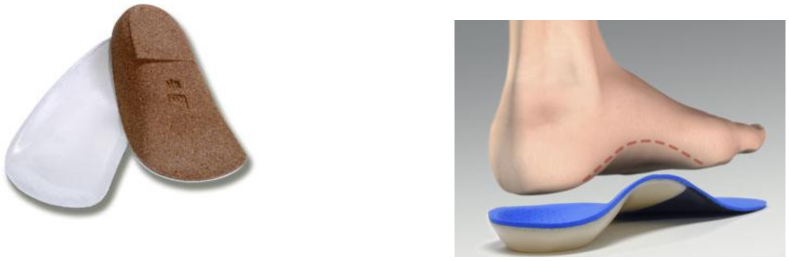


Figure 1:1 Foot orthoses

Literature reveals that fabrication of custom foot orthoses primarily is based on labour intensive craft based manual techniques involving lengthy design and fabrication process (Doxey, 1985; Pratt, 1995; Hunter et al., 1995; Lusardi and Nielsen, 2000; Obrovac et al., 2005). Computer based methods were introduced in 1960s in fabrication of custom foot orthoses using NC milling machines (Lusardi and Nielsen, 2000). The NC milling techniques require significant amount of set-up time and appropriate setting of process planning parameters such as fixture planning, tool path planning, tool selection and tool wear (Frank et al., 2003; Czajkiewicz, 2008).

With recent technological advancements, modern approaches such as computer aided design and computer aided manufacturing (CAD/CAM) were introduced in foot orthoses design and fabrication (Stattus and Kriechbaum, 1989). Currently, CAD/CAM orthoses fabrication systems ranges from office based manufacturing systems to factory-based manufacturing systems and have replaced the craft based practices in the orthotics and prosthetics manufacturing industry (Smith and Burgess, 2001). However, milling process limitations in CAD/CAM for fabrication of complex orthoses design features such as wedges, flanges and metatarsal dome and incorporation of functional elements such as local stiffness restricts the product range using these techniques (Pallari et al., 2010). Additionally, the experts in prosthetics and orthotics industry have raised significant training issues for applications and use of CAD/CAM in prosthetic and orthotics manufacturing industry (Otto, 2008, Pallari, et al, 2010).

1.2 Aims and objectives of research

The aim of this study is to assess the cost and lead-time of a rapid manufacturing based mass customisation system for fabrication of custom foot orthoses.
To achieve the aims of the study, the following objectives have been determined;

i. To summarise and evaluate existing research in the area of rapid manufacturing in the medical field, mass customisation, foot orthoses fabrication and process modelling.

ii. To develop a process model for rapid manufacturing based fabrication system for production of custom foot orthoses.

iii. To use the developed model to evaluate the set of mass customisation systems based on varying conditions and constraints for different rapid manufacturing techniques.

iv. To evaluate and compare the cost and lead-time of different rapid manufacturing based fabrication systems with conventional resources based fabrication system.

1.3 Hypothesis

In medical sector rapid prototyping (RP) and its more mature form rapid manufacturing (RM) techniques have revolutionised the way the parts are fabricated. These techniques have the advantages of creating the parts directly from 3D CAD information layer by layer without tooling and moulding and have greater design freedom in production of geometrically complex parts and components. This creates the viability of rapid manufacturing techniques in the medical sector for fabrication of custom-made devices, parts, rehabilitation aids, dental, prosthesis and orthotics. The RM techniques have shown successful commercial scale applications for mass customisation of in-the-ear canal hearing aids and custom-made dental braces.

Fabrication of custom-made foot orthoses involves traditional CAD/CAM techniques that have limitations in fabricating the required orthosis design features such as wedges, flanges and metatarsal dome. Additionally, CAD/CAM techniques have shown difficulties in incorporating the orthoses functional elements such as integration of local stiffness at specific sites in the orthoses shell. These limitations of CAD/AM techniques restrict the product range. Rapid manufacturing techniques have advantages over the conventional manufacturing techniques in terms of fabricating the complex geometrical design features with accuracy, consistency, low lead-time and overall improved quality product. Rapid manufacturing techniques combined with medical digitising technologies can generate a digital design and fabrication system for mass scale production of custom-made foot orthoses.

The integration of rapid manufacturing approach in the traditional orthoses design and fabrication process can improve the current process by replacing the traditional functions of manual foot geometry capture and orthoses design methods that involve longer time and increased cost in the process. The applications of rapid manufacturing techniques in design and fabrication system can generate effective solution for production of cost-effective custom-made foot orthoses with low lead-time at commercial scale.

1.4 Structure of the Thesis

The main part of this thesis begins with the Chapter 2 which introduces the areas of research from which this work is based. In this chapter an extensive literature review has been conducted which consists mass customisation, rapid manufacturing techniques, medical applications of rapid manufacturing, process modelling techniques and fabrication of custom foot orthoses. Further, the chapter discusses the medical applications of rapid manufacturing techniques for mass customisation in order to evaluate the applications of these techniques at commercial scale production of custom foot orthoses.

Chapter 3 covers modelling of design and fabrication process for custom foot orthoses and an initial process model was designed for rapid manufacturing based design and fabrication of custom foot orthoses. Chapter 4 presents the methods for foot geometry capture and orthoses design. Different foot geometry capture and orthoses design methods are analysed and evaluated in terms of cost, lead-time, accuracy and consistency.

Chapter 5 discusses orthoses fabrication methods and various rapid manufacturing techniques used for fabrication of orthoses are discussed. In chapter 6, analysis and evaluation of cost and lead-time is presented for fabrication of custom-made foot orthoses through different rapid manufacturing techniques. Chapter 7 presents the overall discussion with conclusions and recommendations and finally at the end of chapter future work is outlined.

Chapter 2 Literature survey

2.1 Introduction

The last two decades have remained periods of tremendous upheaval and rapid change in the field of manufacturing engineering. The applications of rapid prototyping (RP) and its more mature form, rapid manufacturing (RM) together with advancements in medical digital techniques have grown significantly in the production of customised products, implants and devices in the medical sector (Heiu et al., 2003; Brown et al., 2003; Gibson et al., 2004; Winder and Bibb, 2005). These techniques have shown successful commercial applications in mass customisation of personalised in-the-ear hearing aids and dental braces (Tongola et al., 2003; Gibson et al., 2010).

In this chapter, a literature survey is reported which has been conducted in the context of the aims and objectives of the research study. This addresses mass customisation, rapid manufacturing techniques and medical applications of rapid manufacturing techniques, custom foot orthoses design and fabrication process, process modelling methodologies and IDEF0 process modelling technique.

2.2 Mass customisation

Mass customisation (MC) was once considered a paradox to be resolved in the future but has become everyday reality for many companies because of applications of advanced manufacturing technologies (AMT) (Pine et al., 1993; Kotha, 1995; Lau, 1995; Eastwood, 1996), product modularity (Pine, 1993; McCutcheon et al., 1994; Baldwin and Clark, 1994; Pine et al., 1995) and extensive applications of information technologies (Piller et al., 2004) in manufacturing for customisation. Advanced manufacturing technologies such as computer-aided design (CAD), computer-aided manufacturing (CAM), flexible manufacturing systems (FMS) and computer integrated manufacturing (CIM) are considered as enabling technologies in manufacturing for mass customisation. Some researchers consider these technologies as fundamental enablers for mass customisation manufacturing; offering potential in reducing the tradeoffs between variety and productivity (Ahlstrom and Westbrook, 1999; Kotha, 1995). The flexibility of these technologies enables manufactures to produce quickly a variety of products cost-effectively and in lot sizes as small as one.

The term “Mass Customisation” was initially anticipated by Alvin Toffler in 1970 in his book “Future Shock” (Toffler, 1970) and later on coined by Stanley Davis in 1987 in his book “Future Perfect” (Davis, 1987). Later on in the year 1993, Joseph Pine has popularised mass customisation as new manufacturing strategy in his influential book “Mass Customisation” (Pine, 1993). The important objective of mass customisation is to achieve economies of scope that makes customised products as affordable as mass produced products (McCarthy et al., 2003).

2.2.1 Definition of mass customisation

There are many definitions for mass customisation in the literature. Three of which the author considers well founded are;

- Mass customisation can be defined as provision of customised products and services, using stable business and processes at a cost and fulfilment similar to standard or mass produced products (Ross, 1996).

- Mass customisation is a combination of producing customised products at a mass scale with the ability to provide customisation to satisfy the individual customers at reasonable cost with small lead-time (Pine et al., 1993).

- Mass customisation is the competitive manufacturing ability to produce customised products or services in high volume at reasonably low costs within short lead-time (Silveira et al., 2001).

2.2.2 Customisation approaches

In MC literature, a number of writers have presented the frameworks for customisation process. Coates and Wolf (Coates and Wolf, 1995) described customisation as a manufacturing practice and termed customisation as “soft” and “hard”. According to them, customisation is “soft” when the customers are not involved in the manufacturing process, while in the “hard” customisation, customers are involved in the manufacturing process.

Lampel and Mintzberg (Lampel and Mintzberg, 1996) have identified a continuum of five main strategies of customisation depending on the customer involvement in the value chain (design, fabrication, assembly and distribution) of the product creation process. These are standardisation, segmented standardisation, customised standardisation tailored customisation and pure customisation. The customisation strategies differ from each other depending on the occurrence of customisation in the value chain. Pure standardisation refers to production of complete standard products. In segmented customisation, customers are seen as cluster of buyers and products are customised during distribution stage, targeting different markets areas. In customised standardisation, the product is customised during the assembly phase using standard modules. In tailored customisation basic product design is tailored and the product is fabricated for the specific needs of customers. In pure customisation, the product is created from scratch for the customers. Pure customisation refers to the involvement of the customer in the entire production cycle where the complete product is created from scratch according to the needs and requirements of the customers. Figure 2:1 shows the customisation strategies during the value chain of the product creation process.

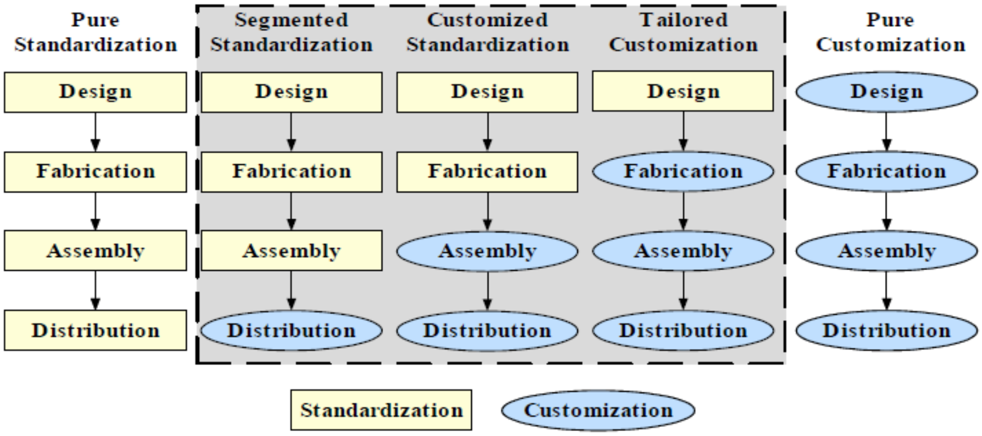


Figure 2:1 Customisation stratgies in the value chain (Lampel and Mintzberg, 1996)

Spira, (Spira, 1996) presented a customisation framework based on four types of customisation from customised packaging, customised services and additional custom work to a modular assembly for realisation of customisation.

Gilmore and Pine (Gilmore and Pine, 1997) have identified four distinct approaches for customisation based on the empirical observations. These are collaborative, adaptive, cosmetic, and transparent customisation. In collaborative customisation, the customers select from pre-determined product configuration options and interact with manufacturer before the product is customised. In adaptive customisation, the standard products are customisable during their use by the customer. In cosmetic customisation, the standard products are packed especially for the specific customers. In transparent customisation, standard products are customised to fulfil the need of individual customer.

Silveira and associates (Silveira et al., 2001) developed eight generic approaches of customisation ranging from pure customisation to pure standardisation based on different frameworks presented by the researchers.

Duray and colleagues (Duray et al., 2000) combined customisation approach developed by Lampel and Mintzberg with the type of product modularity and categorised the customising companies according to the way they achieve mass customisation (discussed in Section 2.2.3). They categorised the customising companies in groups of fabricators, involvers, modularisers and assemblers. Figure 2:2 represents the configuration model of customising companies developed by Duray and associates (Duray et al, 2000). The fabricators group involve the customer at an early stage of the product creation process for fabrication of unique products; which closely resemble pure customisation. The involvers group involve the customer in product design during the design and fabrication stage in which standard product modules are combined according to customer requirements. The modularisers group involve the customer during assembly and delivery and use modularity at an earlier stage in the manufacturing process which is used by the customer at product usage stage. The assemblers group offers to the customers a wide range of selectable options using modular components whilst offering a wide range of choices to the customers.

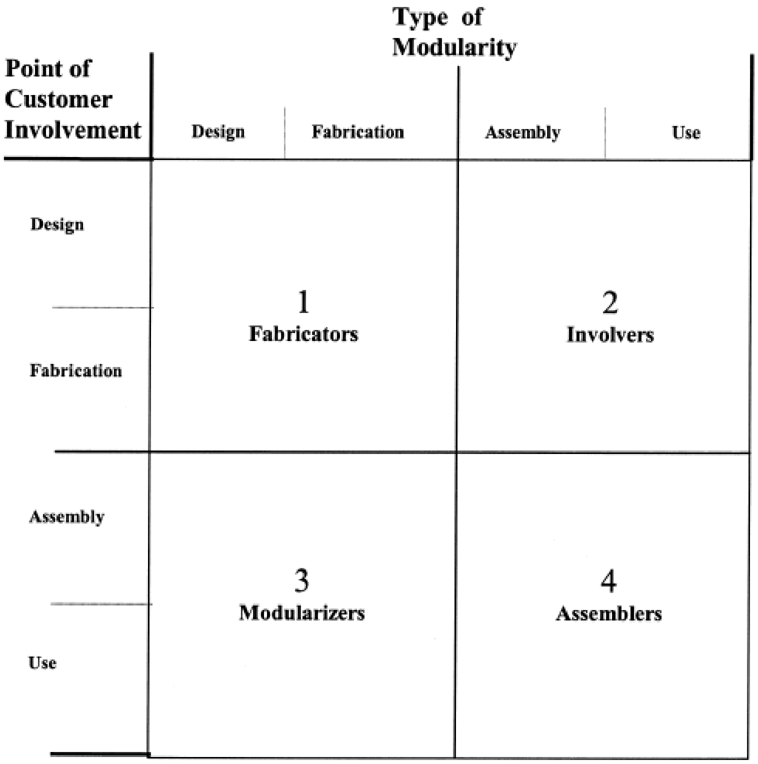


Figure 2:2 Operationalised configuration model (Duray et al., 2002)

2.2.3 Classification of customisation approaches

Customisation has many shades, which can be realised during the manufacturing process. For example the simple and basic form of customisation is somewhat providing cosmetic options which may involve offering a number of colours, surface finish and packaging etc (Ross, 1996; Pine and Gilmore, 1997). Beyond the cosmetic form of customisation another form of customisation in which a range of selectable options are offered in the products to customers according to their preferences. However, the most competitive and challenging form of customisation is providing core customisation (Ross, 1996). Core customisation is a form of customisation in which the product is fabricated from scratch and the customers are involved at the beginning of manufacturing process until the final product has been produced. The process of core customisation actually starts from identifying the needs of the customer for the specific product to be customised and involves all stages of the manufacturing cycle from design to a complete final product (Ross, 1996; Alford et al., 2000; Duray et al., 2000; Squire et al., 2006).

2.2.4 Levels of customisation

Customisation level is mainly determined by two factors; product modularity and point of customer involvement.

i. Product modularity

To achieve mass customisation, product modularity is often applied to create product variety. Modularity is seen as key for the realisation of mass customisation (Pine, 1993; Pine et al., 1995). Modularity is the process of enabling a product to be manufactured from standardised plug and play modules or components which are capable of being assembled to a final product bringing high product variety. Ulrich and Tung (Ulrich and Tung, 1991) developed the typology of modularity which can be applied in the manufacturing cycle for bringing customisation into practice. These are cut-to-fit modularity, bus modularity, component swapping modularity, mixed modularity, sectional modularity and component sharing modularity.

Example of production of lower limb prosthesis shown in Figure 2.15 in Section 2.3.4 is an example of customisation in the products achieved through product modularity. The lower limb prosthesis is based on product modular structure comprise of residual limb socket and other parts of the leg. The socket for residual limb is fabricated individually and customised according to required size and measurements of the residual limb of the patients whereas all the other components and parts are included from product modular structure.

ii. Point of customer involvement

The point of customer involvement is the point in customisation process where customers interact during the manufacturing cycle of a product. This is achieved through established forms of communications with the customers in order to change, alter or modify the product according to their requirements and preferences (Duray et al., 1999; Duray, et al., 2000; Duray, 2002). This is a very important step in the mass customisation process and termed as “value creation” process during manufacturing cycle. Customers take part during the value chain of manufacturing activities such as design, fabrication, assembly and distribution and eventually become co-producer or prosumer (Toffler, 1970).

As the product or service during manufacturing has to pass through several transforming stages from design stage to a finished customised product, customisation can occur at any point in the value chain (Lampel and Mintzberg, 1996). The point of customer involvement also known as Customer Order Decoupling Point (CODP) determines the degree of customisation level in the products (Skipworth and Harrison, 2004). Figure 2:3 represents the levels of customisation in the product creation value chain and the types of modularity applied in the customisation process. Early customer involvement in the manufacturing cycle using component sharing and cut-to-fit modularity results in a higher level or degree of customisation in the products. Customer involvement at the later stage in the production cycle using component swapping, mix, bus and sectional modularity result in lower degree of customisation in the products (Duray et al., 2000).

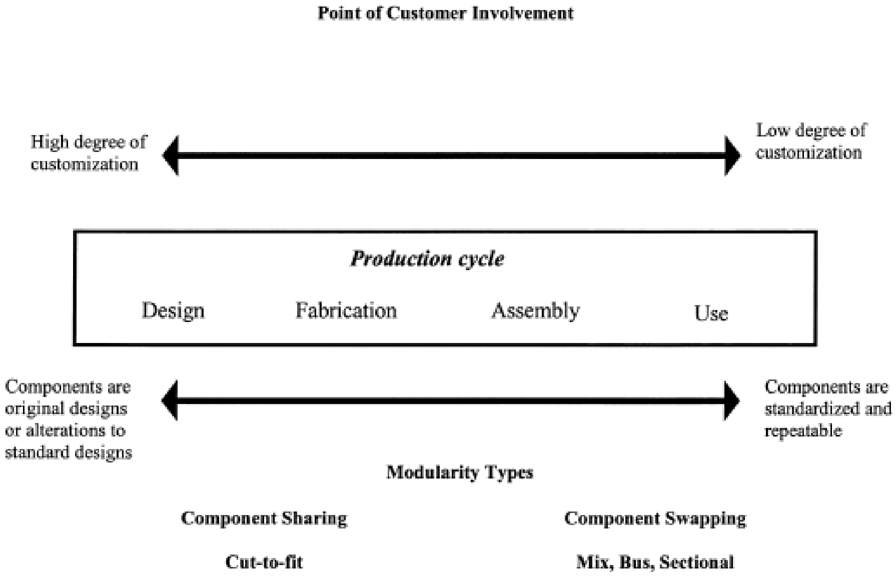


Figure 2:3 Customer involvement and modularity in production cycle (Duray et al., 2000)

2.2.5 Commercial examples of mass customisation

i. Dell mass customisation

Dell is one of the most recognised brands of computers in the world. Dell produce and distribute servers, storage devices, printing and imaging systems, workstations, notebooks and desktop personal computers, networking products as well as PDAs, software and peripheral products. In year 1996, Dell began selling computers via its website (www.dell.com), offering a customisation option in their products (Lebovitz and Graban, 2001). This strategy was successful and by the year 1997, Dell was one of the top five computer manufacturer/supplier in the world using the build-to-order manufacturing strategy. The company now ships more than ten million systems every quarter.

The Dell mass customisation system works through the strategy of establishing a direct contact with customer. Direct relationship with customers is the main successful factor and creates “valuable information” for the company regarding customer choices and preferences (Kraemer et al., 2000). Customers are able to customise the products through the Dell website according to their requirements and preferences within range of selectable options and choices offered by company. In Dell, the product is manufactured only after the customer has placed the order. Once the order for the product is placed, a highly flexible manufacturing system supported with efficient supply chain is used to customise and provide the custom made product within short period of time (Pollard, 2008).

ii. mi-adidas shoes mass customisation

Adidas Saloman AG (Adidas) company started mass customisation in their products by the year 2001 under the name of “mi-adidas” for providing customised athletic sports shoes. The program is for customisation of running shoes to be fitter, high performance, choice of colours and designs; all services which were once only available to top athletes (Berger, 2003). By providing custom shoes the company has established “mi-adidas” sales points either within the selected stores or in mobile units which travel between top sports events. The customisation process in “mi-adidas” involves three steps in customisation process. In the first step a profile of the customer is created which includes the information including the type of sports he/she play, nature of ground surface (hard or soft), type of socks and required degree of grip of the shoes.

In the next step dynamic scanning of the foot measurements are taken which includes the measurement of the foot, pressure points distribution and some other unique physical attributes. In the third and last step the customers are able to select different design variations and colour combinations for the shoes. Once this process is completed the order is transferred to the manufacturing facility for final production of customised shoes. An extensive supply chain system is used in order to deliver the customised products within minimum delivery time to the customers (Moser et al., 2006).

iii. National Bicycle Industrial Company (NBIC)

Panasonic is also a famous name in bicycles along with other consumer electronics in Japan. The company provides customised bicycles to the customers in Japan with a two week delivery time. This delivery time is expanded to three weeks for provision of customised bicycles worldwide. In the year 1987, company started the customisation of bicycles by establishing a new plant near to its mass production plant and introduced a new production system named "Panasonic Order System" (POS).

In (POS) customisation process customers can customise the bicycle by visiting a nearby dealer where they can choose from eight million different combinations comprising the type, colour, frame sizes, and other features of bicycle. At the shop various measurements of the customer are taken in terms of torso length, leg length, arm length and style of riding such as racing, touring, or off-road riding. This requires different frame angles, frame dimensions, and tube gauges for optimum performance. The customer has further options to select from the range of bicycle components such as gears, pedals, brakes, handle bars and accessories according to their requirements and preferences. Once the order is completed, it is then transferred to the factory having highly flexible manufacturing system for production of the final customised bicycle (Kotha, 1996).

The examples of product customisation showed that customisation is mainly achieved through modular structure of the products and with the customer involvement during the production cycle. As previously discussed in Section 2.2.4 modularity in the product structure facilitates manufacturing of the products with some degree of distinctiveness and differentiation which is achieved through combination of different plug and play product modules (Ulrich, 1995; Pine, 1993; Pine et al., 1995). Thus, modularity is used as a key feature for achieving higher scale in mass customisation; as the modular approach offers increased range of end products (Pine, 1993; Baldwin and Clark, 1994). However, in its actual concept pure customisation is to provide the products which accommodate all the requirements made by individual customer where the each product is created entirely from scratch. This concept of customisation is really challenging and most competitive. The manufacturing companies offering customisation must have ability to understand the customer requirements and must have the capability of providing the pure customised products (Ross, 1996).

The important point in the customisation process is that there must be customer involvement in the product customisation process that distinguishes the customised products from mass produced products. Early or later stage involvement by the customer during the product production cycle shows the level or degree of the customisation in the product whereas product modularity contributes to alleviate the customisation responsiveness, speed and shortened lead-times (McCutcheon et al., 1994).

2.3 Introduction to rapid manufacturing (RM)

Rapid Manufacturing (RM) is natural extension of rapid prototyping (RP) and has evolved from the rapid prototyping technologies which have emerged over last two decades (Hague et al, 2003). Rapid manufacturing is defined as the direct creation of parts or components using parts designs created in a CAD system through a layer by layer or additive manufacturing process. Rapid manufacturing processes require no tooling or moulding and offer a greater design freedom in fabrication of highly complex parts (Phillip and Wendell, 1997; Kruth et al., 1998; Levy et al., 2002).

In rapid manufacturing a virtual model of the part is designed through computer aided design (CAD) and is converted to .stl file format which is *de-facto* industry standard file format for rapid manufacturing systems (Pham and Dimnov, 2001; Gibson, 2005, Cee Kai, 2003; Noorani, 2006; Hopkinson et al., 2006). The designed data is then sent to rapid manufacturing systems for the creation of the parts.

Rapid manufacturing techniques have profound impacts on design and manufacturing with the advantages of creating complex geometrical parts, tool less manufacturing and digital manufacturing process. The development of rapid manufacturing techniques is closely related with developments and advancements in computer technologies and wider applications of computers in the manufacturing industry.

2.3.1 Basic working process of rapid manufacturing

There are five basic steps involved in a rapid manufacturing process.

- Creating a CAD based model of design.
- Converting the CAD model into .stl file format.
- Slicing the .stl file into thin cross-sectional layers.
- Fabrication of the model layer by layer on rapid manufacturing system.
- Clean and finish the fabricated model or part (post processing).

There are many rapid manufacturing techniques commercially available and these techniques are called solid freeform fabrication (SFF), additive manufacturing (AM) or layer manufacturing (LM). For small production runs or one-off products with complicated and complex geometrical designs features application of rapid manufacturing techniques can be the quick and cost effective manufacturing processes (Pham and Dimnov, 2001; Hopkinson and Dickens, 2003).

2.3.2 Rapid manufacturing (RM) techniques

Rapid manufacturing techniques can be categorised in different ways depending on the nature of the fabrication process such as laser, printer technology and extrusion technology (Gibson et al., 2010) or type of materials used (Kruth et al., 1998; Pham and

Dimnov, 2001; Noorani, 2006). According to the type of material used, rapid manufacturing (RM) techniques are divided into three categories which are;

- Liquid-based rapid manufacturing systems
- Powder-based rapid manufacturing systems
- Solid-based rapid manufacturing systems

i. Stereolithography SLA (Liquid-based system)

Stereolithography is widely considered as the founding process in RP and was patented in 1984. The first commercial implementation of system introduced by 3D systems Inc, USA in 1986 (Pham and Dimov, 2001; Cee Kai, 2003; Hopkinson et al., 2006; Wohlers, 2006). Figure 2:4 represents the schematic process of SLA technique. This technique gradually builds up a three-dimensional (3D) part from liquid photosensitive polymers (C) contained in vat (B); layer by layer (Noorani, 2006). Computer aided design (CAD) is used to drive the laser beam (D) to strike at the selected spots of the surface of liquid polymer that turns it into solid state forming a solid layer (Kruth et al., 1998). The model or part is built on a platform and once the first layer is adhered to the platform, the platform is then lowered and a fresh layer of liquid polymer is swept over the previous layer. The CAD guided laser beam again strikes on the newly deposited liquid polymer making another solid layer over the previous made layer. This process is performed and repeated continuously to construct layer by layer addition until the final model or part is completed (Yan and Gu, 1996; Rosochowski and Matuszak, 2000). The self adhesive property of the material causes layers to bond to one another to form a complete 3D part or object. Afterwards the fabricated solid model or part is removed from the system.

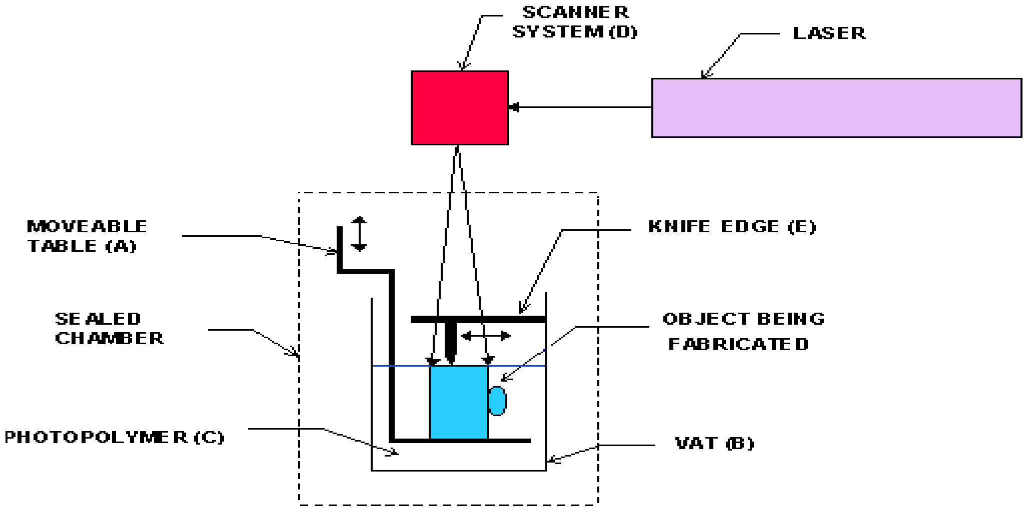


Figure 2:4 Schematic of Stereolithography (SLA) technique (additive3d.com, 2010)

ii. 3D printing (liquid-based system)

Figure 2:5 represents the schematic of 3D liquid based printing process. In 3D liquid based printing technique parts are created using CAD design by selectively deposition of photopolymer resin through a jetting head on to a build tray. Once the material is jetted on the build platform it is cured by ultra violet lights that turn the resin into solid layer. This process is one of the recent 3D printing techniques introduced by an Israel based company named Objet Geometries (Vaupotic et al., 2006; Czajkiewicz, 2008).

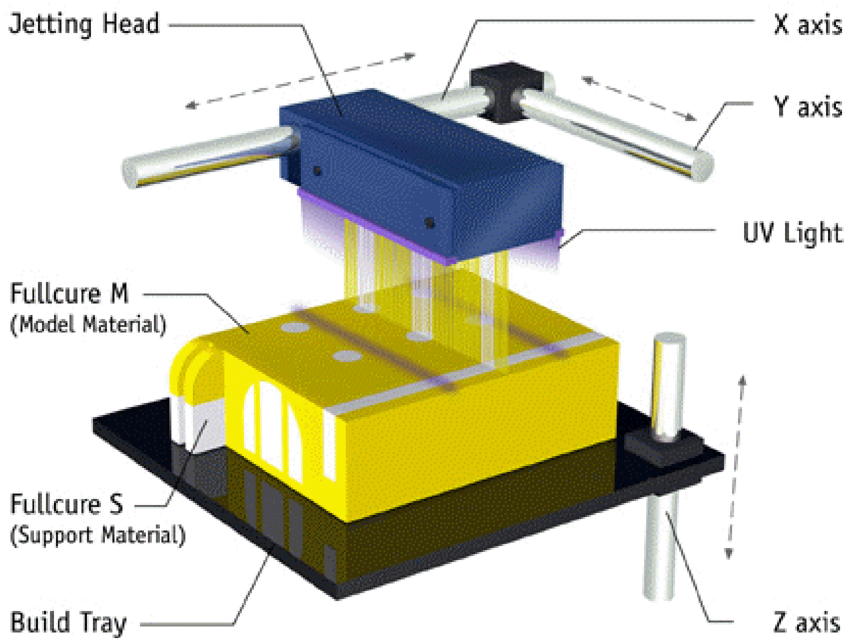


Figure 2:5 Schematic of 3D liquid based printing (3DP) technique (Objet geometries Ltd, 2010)

iii. Selective laser sintering SLS (Powder-based system)

Selective laser sintering was first invented and patented by Ross Householder in 1979 and later on it received much attention and was commercialised following the work of Carl Deckard at the University of Texas at Austin. The first SLS system was introduced by DTM Corporation (now a part of 3D systems) in 1992 (Wohlers, 2010).

Selective laser sintering (SLS) creates three-dimensional solid objects or parts by selectively fusing powder material with CO2 laser, turning powder material into solid objects. Figure 2:6 represents the schematic of the SLS process. The powdered material is spread on the bed (A) by a roller (B) over the surface of build cylinder (C). Powdered material is then sintered or melted by CAD guided laser beam (F) that selectively scan the surface of the powder bed, melting the powder and creating a two dimensional solid layer. When the first layer is completed, the fabrication piston (D) moves down and another layer of powder material is deposited on the fabrication bed (A) from the powder delivery system (E) by roller on the top of previously formed layer. The process is repeated until the part or object is completely formed (Yan and Gu, 1996). In this process the fabrication chamber is maintained at a temperature just below the melting point of the powder material so that heat from laser only needs to raise the temperature slightly to cause sintering (Pham and Gault, 1998; Pham and Dimov, 2001). This makes the process of fabrication of the part or object quicker. After completion of fabrication process the part is removed from the building chamber of the machine.

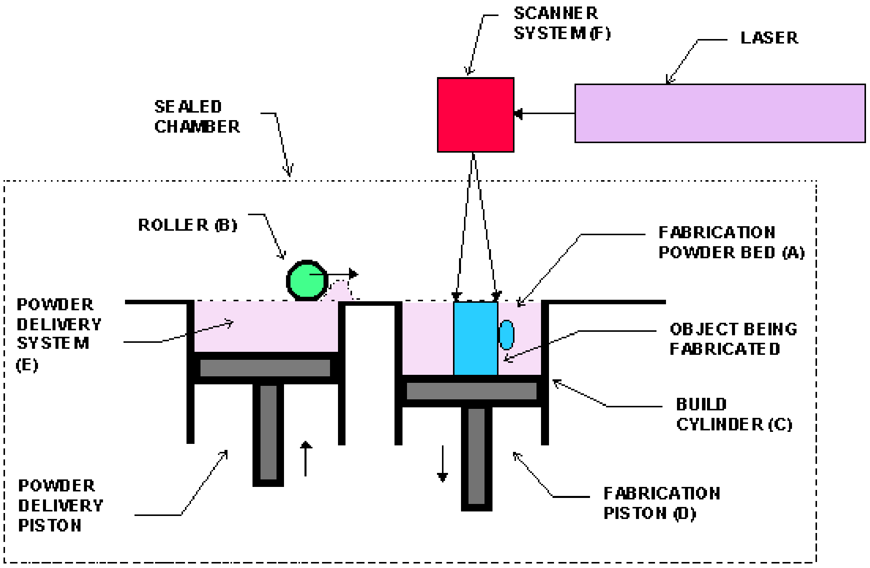


Figure 2:6 Schematic of Selective Laser Sintering (SLS) technique (additive3d.com, 2010)

iv. 3D printing (powder-based system)

Three dimensional printing (3DP) is a quick and low cost layer manufacturing technique. This technique was developed at Massachusetts Institute of Technology (MIT) USA and is used for rapid production of prototype parts and tools directly from three dimensional computer aided design CAD based model. Figure 2:7 represents the schematic of 3D printing technique. The technique has greater design freedom and can create parts of any geometry from a variety of materials, including ceramics, metals, polymers and composites. In three dimensional printing, the process starts by depositing a layer of powder at the top of a fabrication chamber (B). A measured quantity of powder is deposited from a powder supply chamber (E) through a roller (D) by moving a piston upward incrementally. The moving roller then distributes and compresses the powder at the top of the fabrication chamber. After that a multi-channel jetting head (A) subsequently deposits a liquid adhesive in a two dimensional pattern onto the layer of the powder which becomes bonded in the areas where the adhesive is deposited in order to form a layer of the part. Once a layer is completed the fabrication piston (C) moves down by the thickness of a layer and the process is repeated until the part is formed on the build cylinder. This process offers the advantages of speedy fabrication, significantly lower system and material cost than other processes (Wohlers, 2006).

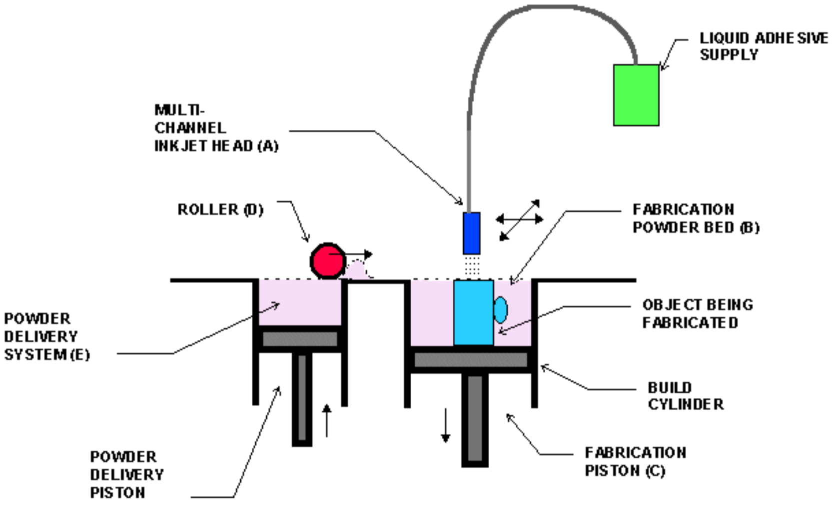


Figure 2:7 Schematic of (3DP) powder based printing technique (additive3d.com, 2010)

v. Fused deposition modelling FDM (Solid-based system)

Fused deposition modelling (FDM) is widely used rapid prototyping technology. It was first commercialised by Stratasys Inc, in 1991 and patented in 1992. Figure 2:8 represents the schematic of the FDM process. In this process the thermoplastic polymers are used as raw material and the objects are formed by extruding the thermoplastic polymer supplied through a coil (A) by a temperature controlled extrusion nozzle (B) that travels in X, Y and Z directions (C) to create a two dimensional layer (Hopkinson et al., 2006). The build platform (D) is maintained at lower temperature in order to make thermoplastic quickly harden. After the platform lowers, the nozzle deposits another layer upon the previous layer and this process is repeated until completion of the part.

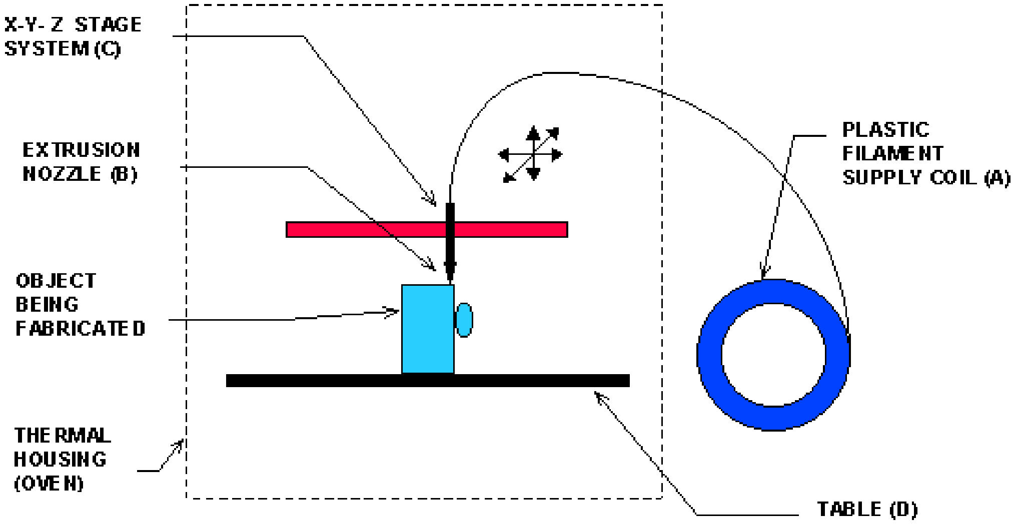


Figure 2:8 Schematic of Fused Deposition Modelling (FDM) technique (additive3d.com, 2010)

2.3.3 Applications of rapid manufacturing in various manufacturing sectors

There are a wide range of applications of rapid manufacturing techniques as the technology has been introduced successfully in the manufacturing sectors including automotive, aerospace, computer, marine and shipbuilding, toys making, architecture modelling, textile and garments designing, medical and consumer products (Pham and Dimov, 2001; Hopkinson et al., 2006; Wohlers, 2010; Gibson et al., 2010).

i. Applications in aerospace

Aerospace industry has the demand from clients with different features in the aircrafts and aero industry has to manufacture hundreds of parts in small volume as the spare parts for the aircrafts. Walter and associates (Walter et al., 2002) have studied the effects of rapid manufacturing on the supply of spare parts to commercial air craft industry. The uncertainty factor for need of spare parts requires maintaining huge inventory of the parts in advance to avoid delay in repair of the air craft. Rapid manufacturing can produce spare parts on demand thus reducing the inventory and parts can be supplied within time that has significant impacts on profits in the industry.

One of the additional advantages of rapid manufacturing is part consolidation which greatly reduces the time and labour in fabrication of the parts for the industry (Gibson et al., 2010; Wohlers, 2010). The part consolidation example in Figure 2:9 shows the traditionally produced part (a) has 16 small designed parts where as the rapid manufacturing can built the same part directly without tooling with integrated assembly and consolidated in a single build saving the tooling, assembly, labour, time and cost. One of the other examples is Paramount Industries, USA which supply the unmanned air vehicles (UAVs) for USA government. Many of the complex parts for UAVs were produced through selective laser sintering technique by the company (Wohlers, 2010).


(a) (b)

Figure 2:9 Aircraft duct (a) original design with 16 parts (b) consolidated design (Gibson et al, 2010)

ii. Applications in automotive

The rapid manufacturing approach is used in the fabrication of concept cars and models in automotive industry. BMW, Hyundai and Bentley car manufacturers are using FDM and SLS techniques in the fabrication of parts, fixtures and tooling for automotive assembly (Gibson et al., 2010). Formula 1 racing cars also use the rapid manufacturing techniques in fabrication of electrical housing, camera mounts, and other aerodynamics parts for the racing cars (Wohlers, 2010).

iii. Applications in architectural models and building components

There is an increasing trend of applications of rapid manufacturing for the fabrication of architectural models and buildings components. Traditional methods for constructing architectural models and building components are time consuming and labour intensive. Rapid manufacturing with architectural CAD techniques are in progress for bringing these techniques in quickly producing architectural models with improved aesthetic appearance and forms. Figure 2:10 shows the fabricated building panels by 3D printing for minimising thermal conductivity (Buswell et al., 2007), model of Library building using 3D printing (Gibson et al, 2002) and 3D model of a house (Maslowski and Heise, 2002).

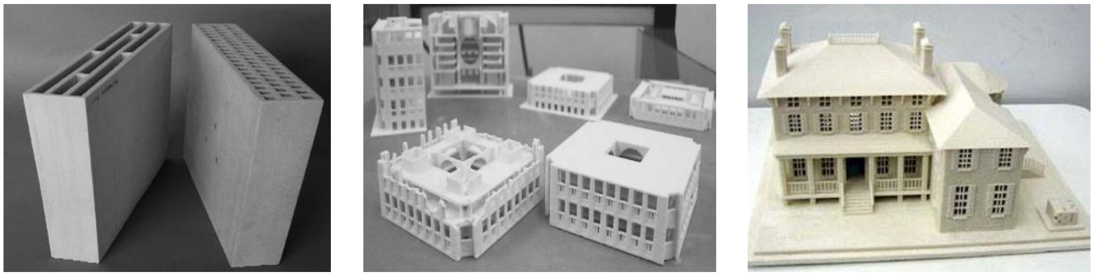

(a) (b) (c)

Figure 2:10 (a) Building construction panels (Buswell et al, 2007), (b) library building models (Gibson et al., 2002) and (d) 3D model of a house (Maslowski and Heise, 2002)

iv. Applications in consumer products

Application of rapid manufacturing techniques in the fabrication of consumer products is another growing sector in the manufacturing field. Custom headphones, case for apple iphone, custom-made dolls and action figures, toys manufacturing and personalized model making are the few examples of rapid manufacturing use in the production of consumer products (Wohlers, 2010; Gibson et al., 2010). Shapeways (shapways.com) is another internet based company offering fabrication of personalized parts and products. They offer fabrication of art, jewelry, gadgets, home decor and many more types of personalised products using rapid manufacturing technologies.

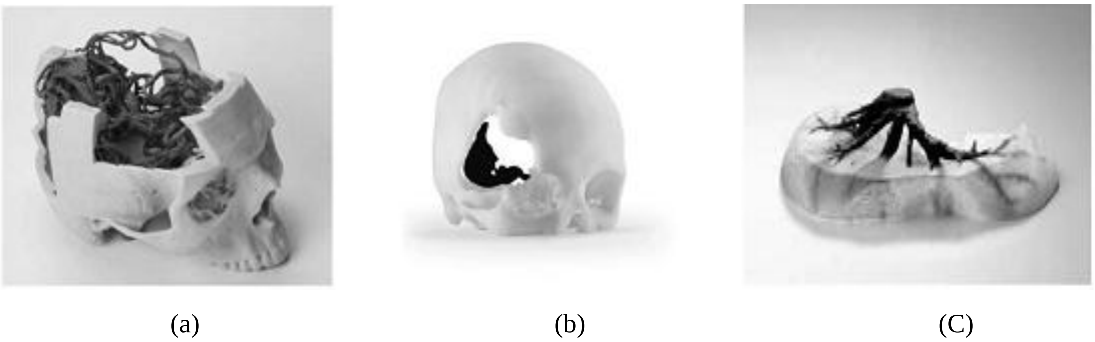
2.3.4 Rapid manufacturing applications in the medical sector

The development of rapid prototyping techniques were primarily aimed at facilitating and speeding up new product development process in various manufacturing sectors. However, its users quickly realised the benefits of applications of these techniques in the medical sector (Gibson, 2006). The need for highly individualised medical products and parts to fit with unique individual anatomical structures embarked researchers to exploit the rapid manufacturing capabilities of fabricating the complex geometrical parts and structures (Wohlers, 2010). In literature, numbers of researchers have documented the applications of rapid manufacturing in the medical sector. The rapid manufacturing applications in medical sectors can be categorised as;

i. Diagnostic and visualising tools and pre-surgical models
ii. Scaffolds and tissue engineering
iii. Dental implants and dental prosthesis
iv. Orthotics and prosthetics

i. Applications in diagnostic, visualising tools and pre-surgical models

Applications of rapid manufacturing are used in fabrication of physical models of human anatomy and parts; which are used prior to surgery planning and communication before going into actual complex surgery process. The models are used in understanding the complex anatomical structures and can be used in planning for pre-operative surgical procedures and simulations and predictions of outcomes by the surgeons (Noorani, 2006) and for the training and educational purposes in the medical field (Milovanovic and Trajanovic, 2007; Peltola et al., 2008; Giannatsis and Dedoussis, 2009). Figure 2:11 shows (a) 3D printed skull model with the interior vascular structure in different colour than the skull colour which can be used in planning specific problem surgery and teaching purpose, (b) fused deposition modelling produced skull showing tumour with different colour and (c) human organ vascularity shown with different colour produced on Objet Connex system (Gibson et al., 2010).



(a) (b) (C)

Figure 2:11 Images of medical parts using different colored RM systems. (a) 3DP based skull with vascular tracks in a darker color. (b) A bone tumor highlighted using ABS material. (c) Human organ fabricated through polyjet technique showing vascularity inside the organ (Gibson et al., 2010).

ii. Applications in scaffolds and tissue engineering

The ability of creating the complex structures with internal geometrical details such as scaffolds used for re-generation of bony tissues requires porous structure (Gibson et al., 2010). The porous supporting structure is used for re-growth of tissue cells in the damaged or defective bones. Rapid manufacturing techniques offer an efficient way to control, design and fabricate the structures like scaffolds where customisation is primary requirement (Peltola et al., 2008). The different rapid manufacturing techniques such as FDM, SLS, SLA and 3D printing have been demonstrated by numerous researchers (Yang et al., 2002; Lee et al., 2004; Hutmacher et al., 2004; Hollister, 2005; Leong et al., 2006; Armillota et al., 2007) as viable cost effective fabrication methods for creating customised scaffolds. Figure 2:12 shows the SLS based fabricated scaffolds.

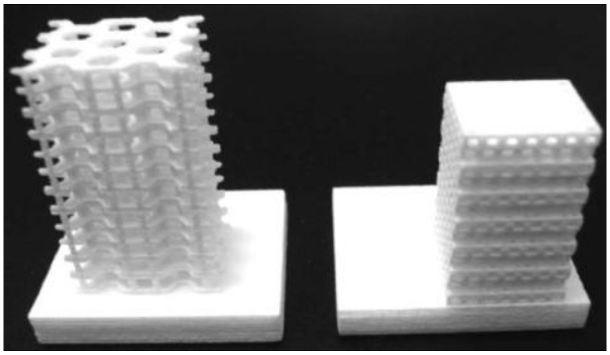


Figure 2:12 Scaffolds fabricated using SLS technique (Gibson et al., 2002)

iii. Applications in dental implants and dental prosthesis

Dental implants, prostheses, devices and parts such as crown, bridge, fixtures etc require customisation because of individual geometry, complexity in design and wide range of sizes for the individuals (Wohlers, 2010). Conventional methods for manufacturing dental prostheses and implants involve a number of activities to be performed manually such as; impression taking, wax casting, making assembly of biting, tooth preparation and other different steps to be performed before fabrication. The process involve increased time and requires high skills for fabrication of individual custom-made dental products (Kruth et al., 2005). The rapid manufacturing approach for fabrication of dental prostheses and dental devices starts by taking three-dimensional images and geometrical measurements of the patients and modelling and designing it in CAD-based software. The designed information is then transferred through .stl file format to a rapid manufacturing system for fabrication of final product (Qingbin et al., 2006). Figure 2:13

shows a stereolithography based fabricated jawbone.

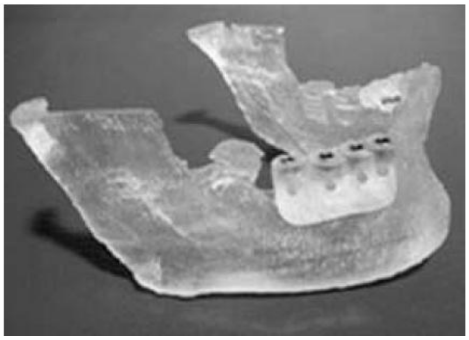


Figure 2:13 Jawbone with drill guides fabricated using SLA technique (Qingbin, et al., 2006)

iv. Applications in orthotics and prosthetics

Fitting of lower limb prosthesis in amputees is another application of rapid manufacturing techniques for customisation in medical sector. Laser scanning technology is used to measure and adopt the three-dimensional geometry of the residual limb of the patient and a virtual model of lower limb socket is produced in CAD design system. Finally, the designed information is sent to a rapid manufacturing system in .stl file format to fabricate the socket in which the residual limb of patient is to fit. The other parts of prosthesis remain same except the limb socket and its length. The shoe size depends on the other foot size of the patient and selected from the shoe stock (Ashley, 1993; Roger et al., 2007).

Various studies have shown the advantages of applications of rapid manufacturing techniques, computer aided design (CAD) combined with medical scanning technologies. The combinations of these techniques have shortened the fabrication process and have reduced manual labour work in various stages of manufacturing the parts. Number of researchers has demonstrated the rapid manufacturing based fabrication of lower limb prosthesis. Custom lower limb prosthesis was fabricated on the experimental basis at National University of Singapore by Cheng et al (Cheng et al., 1998; Ng et al., 2002; Tay et al., 2002). They used a fused deposition modelling technique in the fabrication of lower limb prosthesis and showed that the fabrication of prosthetic socket with functional characteristics is viable using fused deposition modelling technique. During the investigation, a long building time and high manufacture cost were observed in using the FDM technique.

Freeman and Wontrocik (Freeman and Wontrocik, 1998) used the stereolithography technique in the fabrication of custom-fit lower limb prosthesis. They conducted a cost benefit analysis using stereolithography apparatus (SLA) for manufacture of prosthetic sockets. The technique remove the traditional casting process for mould making in socket manufacturing and the sockets were designed using a CAD system and fabricated directly from the designed data. The study demonstrated that the technique can build sockets with varying wall thickness with improved fitting and accuracy. However, the production time and cost on sockets were higher than the traditional fabrication techniques.

Recently, Colombo and associates (Colombo et al., 2010) have fabricated the lower limb prosthesis using stereolithography technique. They find better quality results, increased fit and improved functionalities in the prosthesis. Herbert and colleagues (Herbert et al., 2005) investigated the applications of 3D printing technique for fabrication of prosthetic socket. This technique also eliminates the casting process of mould making for the socket and fabricates it directly from CAD by using a 3D printing technique. In their investigations however, they have mentioned observations regarding the material properties and durability of the parts produced through this technique which need further research specifically for suitability and functional requirements of the prosthetic sockets.

Faustini and associates (Faustini et al., 2005) at University of Austin Texas, USA demonstrated the fabrication of a prosthetic socket using the selective laser sintering (SLS) technique. As rapid manufacturing technique fabricates the prosthesis according to the dimensions and geometry of the residual limb of the patient captured through scanning technique; their investigations resulted in increased fit, comfort and stability with comparison to traditionally manufactured prosthesis. Figure 2:14 shows SLS base fabricated lower limb prosthesis socket and its components.

Figure 2:14 Lower limb prosthesis socket fabricated using SLS technique (Faustuni et al., 2007)

2.3.5 Mass customisation of medical devices using rapid manufacturing

The applications of rapid manufacturing in the medical sector are driven by the need of the patient-specific products requiring unique shapes and individual geometries and functionalities in the parts fabricated (Wohlers, 2010). There are an increasing number of practical applications of mass customisation projects in the medical sector which are using rapid manufacturing technologies for customised products because of the ability to fabricate the complex geometrical parts without tooling and fixtures (Webb, 2000). Some of the recent examples are; in-the-ear hearing aids and dental aligners (Dotchev et al., 2009; Wong and Eyers, 2010; Gibson et al., 2010).

i. In-the-ear hearing customised devices

Conventionally, in-the-ear hearing devices are produced by taking an impression of the ear canal and making its replica by developing mould casts according to measurements and geometry of the impression. The next step involves manufacturing of the shell for the device. After this, the amplification system is adjusted and fitted in the shell and finally assembly of all the parts of the device is done manually (Anon, 2003; Tognola et al., 2003). This requires high skill and time to produce the device and at the end fit, performance and quality of the product depends on the skill and craftsmanship of the individual technician (Cortex et al., 2004).

The same device is fabricated much quicker through rapid manufacturing approach and can be customised according to individual requirements and individual ear geometry. An in-the-ear hearing device customisation process uses digital technology to capture the geometry and impression of the ear and then design of device is made using a CAD-based design system. A virtual model of the product is produced whilst retaining space for an amplification system to fit inside the device. The final design information in the CAD file is converted into stl file format and then the device is fabricated using a rapid manufacturing system (Dalgarno et al., 2006). The commercial example of mass customisation using rapid manufacturing is the fabrication of customised in-the-ear hearing aid devices by Siemens and Phonak (www.phonak.com & www.hearing.siemens.com). Siemens is using selective laser sintering (SLS) and stereolithography apparatus (SLA) and Phonak are using selective laser sintering (SLS) technique for the fabrication of customised in-the-ear hearing aids. Figure 2:15 shows rapid manufacturing based in-the-ear hearing devices.

Figure 2:15 In-the-ear hearing aids, Phonak.com and Siemens.com; (Gibson et al., 2010)

ii. Dental aligners/braces

Dental alignment involves a procedure of fixing the traditional metal wire based fixed braces, which is done manually by an experienced dentist. The alignment takes a long time and it needs re-setting of fixed braces after approximately six weeks to re-apply the force, which cause some pain and discomfort. One of the disadvantages of fixed braces is the cosmetic appearance and the patients cannot remove them during eating and cleaning. Align technologies Inc USA; offering customised dental braces (www.invisalign.com). The teeth alignment is carried out through changing the series of dental braces until the required alignment for the teeth is achieved. These dental braces improve cosmetic dental appearance.

Invisalign use stereolithography (SLA) in the fabrication of customised dental braces. The design and fabrication process for the aligner begin by taking an impression and x-ray of the patient's teeth by a dentist. The captured data and information is then sent to the manufacturing facility where the scanned data is processed according to the dentist's recommendations and the detailed treatment is planned to match the objectives. Finally, a series of dental braces are fabricated using the SLA technique (Hopkinson and Dikens, 2006). The customised fabricated braces are then used by the patient according to planned treatment process until the desired cosmetic results are achieved. Figure 2:16 shows SLA base fabricated dental braces.

Figure 2:16 Transparent dental aligners (Invisalign.com, 2010)

iii. Custom shoe fabrication using rapid manufacturing

In 2008, Prior 2 Lever (P2L) retailed the world's first rapid manufacturing based soccer shoe for professional athletes; fabricated using selective laser sintering techniques. The shoe model named "Assassin" is shown in Figure 2:17 which is uniquely designed and fabricated for improving and enhancing the individual athlete's performance (Wohlers, 2008; Gibson et al., 2010). In the customisation process, the athlete makes appointment with P2L where a series of orthopaedic tests are performed and the player's feet are scanned using a 3D digital scanner. The scanned information is then used to fabricate the outsole of the shoe using laser sintering and the upper is made from exclusively sourced calfskin from Italy.

There is a commonality in the "assassin" outsole and in the insoles used as the orthoses in this research; the only difference being in the purpose. Whilst the P2L outsole is aimed at improving the athlete's performance by providing the exact shoe fit; here the insole is used as an orthoses and is mainly aimed at addressing and treating the foot related problems and diseases.

Figure 2:17 “assassin” fully customised soccer shoe (New Scientist, 2008)

Examples of in the ear-hearing-aids and lower limb prosthesis devices are good examples of application of modular approach for realising customisation at mass scale; where modular structure of the product plays important role in bringing customisation into practice at mass scale. Custom dental aligners and “assassin” shoe are the good examples of providing the core customisation at mass scale, where the product is fabricated from the scratch; realising pure customisation at mass scale.

The applications of rapid manufacturing techniques in the medical sector and commercial examples of mass customisation have shown increased advantages and benefits over the traditional manufacturing techniques. The compatibility of the rapid manufacturing techniques with the output data of medical digitising techniques has enabled the direct fabrication of complex individualised medical parts and devices with improved fit and comfort and adding value to the overall final product (Gibson, 2005). The commercial examples of in-the-ear-hearing aids and dental braces show that the shape complexity and individualisation in the products is not a limitation factor for production of customer-specific products on a mass scale. Align technologies, between 1997 to 2009 have produced over 44 million teeth aligner braces (www.aligntech.com); providing patients with truly individualised and customised teeth aligners with varying geometries to match each individual needs according to planned treatment. Siemens are currently producing 250,000 customised hearing aids annually using rapid manufacturing techniques (Gibson et al., 2010). Fabrication of these devices at this scale shows the customisation of individualised products on a mass scale.

The ability of rapid manufacturing techniques for building complex geometrical custom-specific devices, automated fabrication process, tool less operations and minimum requirement of labour content in the fabrication process are the major benefits of applications of these techniques in medical sector for mass customisation of personalised products. These factors significantly contribute for increasing the business volumes, sales and profits for the manufacturers.

2.4 Foot orthoses

The medical field concerned with the application of externally applied devices which support or correct the function of a limb or torso is called orthotics. Foot orthoses are shoe inserts which are used for correcting abnormal or irregular biomechanics of the foot. These are externally applied devices used to modify or adjust the structural or functional characteristics of the neuromuscoskeletal system (Hunter et al., 1995; Redford et al., 1995). The purpose of an orthosis is to improve function by redistributing the forces from the body in a controlled manner to protect and give relief to the body part. The need for foot orthoses arises due to biomechanical foot disorders, congenital defects, sports injuries, diabetes, and rheumatoid arthritis diseases (Hunter et al., 1995; Redford et al., 1995; Obrovac et al., 2005). Figure 2:18 shows the fabricated foot orthoses.

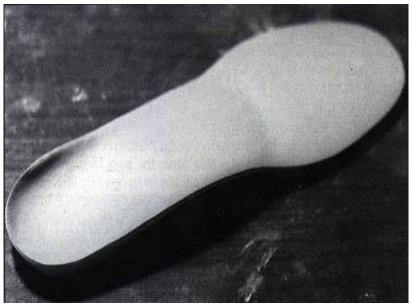


Figure 2:18 Foot orthosis (Staats and Kriechbaum, 1989)

2.4.1 Functions of foot orthoses

The primary function of the foot orthosis is to reduce and redistribute the weight bearing stress, control alignment and functions of the foot in order to treat or prevent injury causing forces on foot bones, joints, tendons and ligaments. It is applied to improve the joint functions of the foot and redistribute the body pressure to give relief in the pain and prevent further deformation in foot and to promote corrective gait.

2.4.2 Types of foot orthoses

Foot orthoses are classified into three main categories according to materials used in the manufacture of foot orthoses (Schwartz, 1991; Hunter et al., 1995). Various professionals engaged in design and manufacturing and orthotic materials supplier catalogues broadly classify the types of orthoses in the following categories; rigid, semi rigid and soft orthoses (Lockard, 1988).

i. Rigid orthoses

Rigid or “functional” foot orthoses are primarily aimed at correcting the abnormal foot function combined with corrections in lower extremity providing joint stability, controlling motion and improving foot function (Root et al., 1997; Steven et al., 2002). Rigid orthoses are made from materials that provide maximum correction and biomechanical control of structural deformities and integrity of joints by resisting the ground reaction forces which can cause abnormal gait (Anthony, 1991; Hunter et al., 1995; Lasurdi and Neilson, 2000).

ii. Semi-rigid orthoses

Semi-rigid orthoses are aimed at providing softness, relief form pressure sensitive areas, balancing the foot in neutral position, reducing the abnormal and excessive motion and improving lower extremity motion. Semi-rigid orthoses generally are combination of the properties of soft and rigid orthoses (Hunter et al., 1995).

iii. Soft orthoses

Soft or “accommodative” orthoses are aimed at cushioning, supporting and relieving the pain from injured or affected areas of the foot. The soft orthoses cannot realign the foot to correct any deformities in the foot, however, they are aimed at supporting and providing cushion, weight distribution; relieve pressure to painful areas, shock absorption and improving the mobility of the patient (Hunter et al., 1995; Steven et al., 2002). Soft orthoses are made from soft materials such as polyurethane foams (Lockard, 1988; Goodman, 2004).

2.4.3 Foot orthoses design features

Foot orthoses have several design and correction features in order to address specific problems, symptoms and pathologies of the patient. The various design features are prescribed by the orthotist based on a careful thorough examination of the foot and its associated problems and the treatment objectives. Some of the most common orthoses features are described as follows.

- **Arch support**

Arch support is a foot orthoses design feature incorporated for addressing the foot arch related problems. The arch support re-aligns the foot and increases the contact area under the arch of the foot distributing the pressure from pain full areas. Figure 2:19 shows the rear foot wedge and arch support (a) adopted from by Algeos, 2007 and simple arch support (b) adapted from Pedag, 2010.

(a) (b)

Figure 2:19 Orthoses with arch support (a) and (b) Schematice of arch support (Pedag, 2010)

- **Heel lift/heel cupping/heel cushion**

Heel supports are generally used to cushion the heel area by increasing the heel support thickness. A deep heel cup is created for optimal function of the foot control and greater stability and shock absorption. The height and thickness depend upon the problem and symptom in the foot and its treatment requirements (Chalmers, 2000). Figure 2:20 shows the wedges and post (a), deep heel cup (b) and heel cushion (c) in the orthoses design.

(a) (b) (c)

Figure 2:20 Heel lift/cupping/cushion in the orthoses shell (theorthoticgroup.com, 2010)

- **Medial flange**

A medial flange is an orthoses feature designed to support the severely pronated foot motions. This design feature is prescribed when the patient has slight or significant inward tilt during walking. Figure 2:21 shows the schematic of pronation (a) and (b) medial flange designed in the orthoses. The structure of the medial flange increases in the medial side of the foot starting from medial towards the heel and extending distally with required increase in height to control the tilt or severe poronation problem (Steven et al., 2002).

(a) (b)

Figure 2:21 Schematic of foot poronation (a) (orthoticshop.com, 2010) and (b) orthoses with medial flange (theorthoticgroup.com, 2010)

- **Wedges**

Wedges or posts are the support that is added under the heel or forefoot in order to overcome imbalances and realign and support the foot during walking or gait cycle.

Wedges can be placed through design modifications over or under the main body of the orthoses shell (Steven et al., 2002). However, in some cases if large corrections are required, these features can create a problem in fitting the orthoses shell in the shoe (Lasurdi and Nielson, 2000). Figure 2:22 shows the (a) over post and (b) underside post in the orthoses shell.

(a) (b)

Figure 2:22 Posts or wedges in orthoses shell (theorthoticgroup.com, 2010)

- **Metatarsal bars and pads**

Metatarsal pads and bars are used to redistribute the plantar pressure in the forefoot structures. The pads and bars sizes and shapes depend on the orthotist prescription mainly treating the forefoot and transverse arch problems. Figure 2:23 shows the metatarsal pad designed in the orthosis shell.

Figure 2:23 Metatarsal pad/dome in orthosis shell (theorthoticgroup.com, 2010)

2.4.4 Foot orthoses materials

The selection of materials for orthoses construction primarily depends on the nature of diseases and associated pathological conditions of the foot along with other factors such as weight and activity level of the patient (Buonomo et al., 2001, Kennedy, 2008). Foot pathology and type of diseases plays a vital role in selection of material for orthoses construction and their applications (Lockard, 1998). Diseases such as rheumatoid arthritis require rigid foot orthoses for controlling and improving the movements and functionality of the foot with comparison to diabetes related ulceration and early Charcot joint disease which requires accommodative orthoses for cushioning and redistributing the pressure from painful areas (Kennedy, 2008).

The materials used in fabrication of foot orthoses are broadly classified into two categories (i) natural and (ii) synthetic materials. Traditionally, the natural materials such as leather, cork, rubber and metal were used in orthoses construction (Lockard, 1988). With the technological advancements, modern materials such as carbon composites, plastics and acrylics are currently in use and are replacing the traditional materials in orthoses construction (Rome, 1991). Current materials are generally grouped as plastics, acrylics, composites, foams and rubber, leather and cork (Nicolopaulous et al., 2000; Steven et al., 2002; Caselli, 2004). The material for foot orthoses fabrication must combine physical and mechanical properties and characteristics including elasticity, density, durability, flexibility, compressibility, resilience, strength and stiffness (Rome, 1990; Nicolopoulos et al., 2000). The type of orthoses prescribed has a significant role in selection of combinations of above mentioned properties and characteristics in the orthoses material; as during the service phase the orthoses have to carry and withstand the whole body weight of the patient in parallel with serving and addressing specific treatment objectives for the user. The range and types of the current materials used for the orthoses fabrication are presented in following section.

- **Leather**

Leather is natural material traditionally used for construction of orthoses. Basically leather orthoses shell is made of lamination of layers of leather added over one and another to form a shape of positive cast of the foot that is inserted in to the shoe (Lockard 1988; Steven et al., 2002; Kennedy, 2008). Leather is combined with other material such as liquid latex binders and named as “rubber butter” (Steven et al., 2002; Caselli, 2004). The leather orthoses can be accommodative or functional depending on the material combination and fabrication techniques (Caselli, 2004).

- **Cork**

Cork is another natural material traditionally used in the orthoses construction (Hunter et al., 1995). Cork is combined with rubber binders such as liquid latex forming a sheet which is then sanded to the required shape to fit in the shoe (Kennedy, 2008). Cushion Cork^{TM}, Korex ^{TM}, Ortho cork ^{TM} and Brickcork are the examples of Cork based orthoses material used (Nicolopoulos et al, 2000).

- **Carbon composites**

Carbon composites are carbon fibber and acrylic composites materials used to construct strong, thin and light weight orthoses shells. Thin layers of carbon graphite fibre cloths are laminated using liquid resin to form and rigid carbon graphite orthoses shell. The number of layers laminated effect the strength of the constructed orthoses shell (Steven et al, 2004). TL-2100^{R} is a good example of graphite composite material by RX-orthotics materials.

- **Acrylic and thermoplastic polymers**

The acrylic and thermoplastics materials are rigid materials having ability to alter shape when heated (Nicolopolus, 2000; Caselli, 2004). These materials are used in accommodative orthoses which are aimed at improving the functions of the foot. Polymethyle methacrylate (PMMA) is regarded as rigid material commonly used in the orthoses fabrication (Rome, 1991). Polyethylene and polypropylene thermoplastics are also common material used in construction of rigid orthoses. These materials are light weight, flexible and come into different densities ranging from low to high density (Steven et al., 2002).

- **Rubber and foams**

The term rubber refers to group of compounds which are natural or synthetically produced substance having elastic, shock absorbing and resilient properties. This group is commonly known as elastomers including EVAs, sponge, latex and expanded rubber (Nicolopoulos et al., 2000). EVA is a heat mouldable material having better shock absorbing propertiesc ommonly used foot orthoses constructing materials. Spenco^{TM} and Lynco^{TM} are rubber based examples of materials for orthoses use. Another example of material used for orthoses is polyethylene thermoplastics under the name of

Plastazote^{TM}, Aliplast^{TM}, Evazote^{TM}, Dermaplast^{R} (Leber & Evanski, 1986; Kennedy, 2008).

2.4.5 Foot orthoses fabrication

The traditional process of fabrication of custom foot orthosis begins with capturing the geometry and measurements of the foot using plaster of Paris. The next step is to develop a positive mould of the foot impression using plaster of Paris or fibre resin tape. Once the mould is developed it is modified manually by adding and dressing with additional materials to incorporate the required features such as filling gaps or deformed spots or adding wedging angles and other orthoses features (Pratt, 2000). The orthosis is then created around the corrected and developed mould by draping a heated plastic sheet over it or using a vacuum pressing process (Doxey, 1995; Hunter et al., 1995; Pratt, 1995). Finally the fabricated orthosis is fitted to the patient (Lusardi and Neilsen, 2000).

With the technological developments in manufacturing engineering custom foot orthoses were manufactured through computer based applications. It started in 1960 with the application of stereo-photography and numerically controlled (NC) milling machines in the fabrication process (Lusardi and Neilsen, 2000). Computer-aided-design (CAD) and computer-aided-manufacturing (CAM) has now replaced most of the conventional manufacturing methods for foot orthoses fabrication (Staats and Kriechbaum, 1989). The CAD/CAM based orthosis manufacturing process starts with taking an impression of foot geometry, transferring the impression information into a CAD-based software system where the data is expanded and corrected using a special computer program developed specifically for foot orthosis. After that orthoses is milled from a blank using CNC milling machine (Staats and Kriechbaum, 1989; Davis, 1993).

2.4.6 Foot orthoses fabrication process

Fabrication of custom foot orthoses involve following main steps;

i. **Foot geometry capture**
ii. **Foot orthoses design**
iii. **Foot orthoses fabrication**

i. Foot geometry capture

In order to produce an effective and comfortable orthoses which fit properly and accurately with the patient, provide relief in pain and improve foot function; an accurate foot impression is a fundamental and important step in custom orthoses fabrication process. Presently various approaches and methods are applied for casting foot impressions.

The foot impression capturing techniques classified into two categories (i) plaster based impression capturing techniques and (ii) Digital based impression capturing techniques. In the following sections both categories are discussed starting with plaster based impression capturing techniques followed by the digital impression capturing techniques.

i. Plaster of Paris geometry capturing technique

Plaster of Paris impression casting is a well-established and widely applied technique for capturing foot impressions in the custom foot orthoses manufacturing. The technique is based on manual process of capturing foot impression requiring high skills and need considerable training and practice in order to obtain consistent impression casts. The steps involved in the foot impression capture are;

i. The patient is properly and comfortably positioned with knee extended. The foot and lower extremity is aligned in a neutral position as shown in Figure 2.25 (a) and (b).

ii. Applying carefully the gauze strip dampened in the plaster of Paris starting from lateral aspect of the foot covering the ankle and heel of the foot extending towards metatarsal and leaving some space to facilitate the removal of the cast as shown in the Figure 2.25 (c), (d) and (e) (Hunter et al., 1995).

iii. Next step is to apply another gauze strip on the foot from the anterior surface of the toe in the same position. With the back of the hand the applied strip is smoothed to ensure the total contact with the surface of the foot as shown in Figure 2.25 (f) and (g) (Hunter et al., 1995)

iv. The applied plaster of Paris is left for almost 30 minutes for drying process keeping the foot in the same position.

v. Final step is the removal of the cast from the foot. In this step the cast is carefully removed and then inspected and evaluated for errors and accuracy as shown in Figure 2:24 (h).

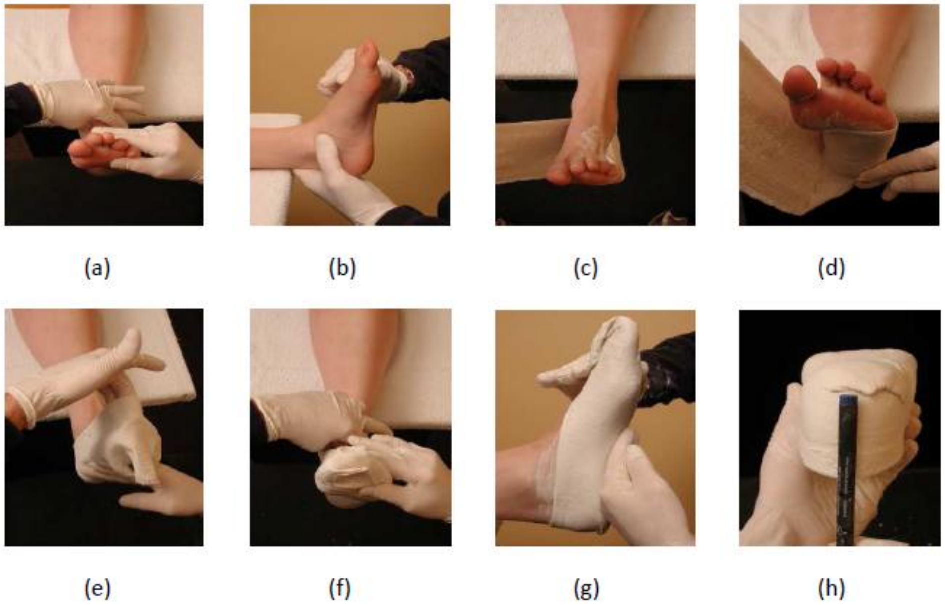


Figure 2:24 Foot geometry capturing in plaster of Paris based process

This technique has some in-built reliability issues such as occurrence of geometrical deviations which are mainly caused by drying process of plaster of Paris, variations in the uniformity of the thickness of the material, long cure time and physical handling and storage of the plaster casts. Labour is another major issue in the plaster of Paris casting technique. The impression taking process requires a highly experienced podiatrist and a technician to assist the podiatrist during and after the casting process.

ii. Plaster slipper geometry capture technique

This technique is relatively less messy and quicker than the traditional plaster of Paris casting technique. In this technique a slipper sock which is impregnated with quick drying resin is used for capturing foot impression. The resin sets quickly reducing the casting time as well as reducing labour work. The steps in capturing foot geometry using a plaster slipper sock are;

i. Proper seating and positioning of the patient foot with knee extended.

ii. A transparent plastic bag is wrapped around the foot before applying slipper sock. The plastic bag is used to avoid sticking of the resin in the plaster slipper socks as shown in the Figure 2.26 (a).

iii. In the next step plaster slipper sock; soaked in water is applied on the foot and elastic band is tied with clips over the foot in order to confirm the contact of the sock with the planter arch and foot contour shown in Figure 2.26 (b), (c) and (d).

iv. Next step is holding the foot in a neutral or desired position until the resin dries as shown in the Figure 2.26 (d) and (e).

v. Final step is removal of the cast as shown in Figure 2:25 (f), (g) and (h).

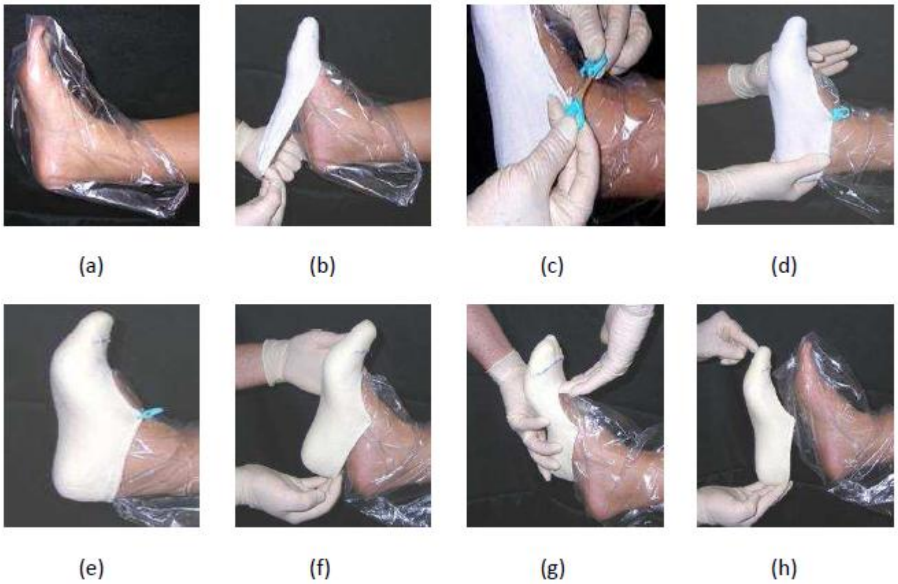


Figure 2:25 Foot geometry capturing in plaster slipper sock based process (stssox.com, 2010)

Plaster slipper casting is a quick process for capturing foot impressions when compared to the plaster of Paris casting technique. However, the process requires a highly skilled podiatrist to get an accurate impression of the foot. This technique also involves the time required for curing of the cast and also involves the cost for the required material in the impression capturing, handling and storage costs.

iii. Foam box impression geometry capture technique

In foam box impression casting technique, a low density foam block contained in a box is used for capturing the foot impression. The use of foam impression box eliminates the drying process required in plaster of Paris casting technique (Laughton et al., 2002). The patient foot is pressed in the foam block in a neutral position in order to capture the foot impression and geometry. This technique also requires high skills and involves manual work to get the correct foot impression. The steps in the capturing foot impression and geometry using foam impression box are;

i. Proper adjustment in the seating of the patient with hip and knee positioned at 90^0 angle, prior to process of the casting which is carefully managed as shown in Figure 2.27 (a) in order to generate accuracy in the impression (Laughton, et al., 2002).

ii. The Patient’s foot is pressed into the foam box in neutral position of the foot in non-weight bearing position as shown in Figure 2.27 (b) (Hunter, et al., 1995).

iii. Podiatrist carefully presses the foot into the foam box maintaining the neutral position as shown in Figure 2:26 (c) (Laughton et al., 2002).

iv. Podiatrist carefully checks that the foot is properly pressed according to required position of the casting shown in Figure 2.27 (d) and (e).

v. Patient foot is pulled back carefully from the box in the same direction avoiding deformation in the impression foam as shown in Figure 2.27 (g).

vi. After capturing the impression, the cast is filled either with the plaster of Paris to get the positive foot impression mould shown in Figure 2.27 (h) or the impression is scanned through 3D scanner to get the final measurements and foot geometry.

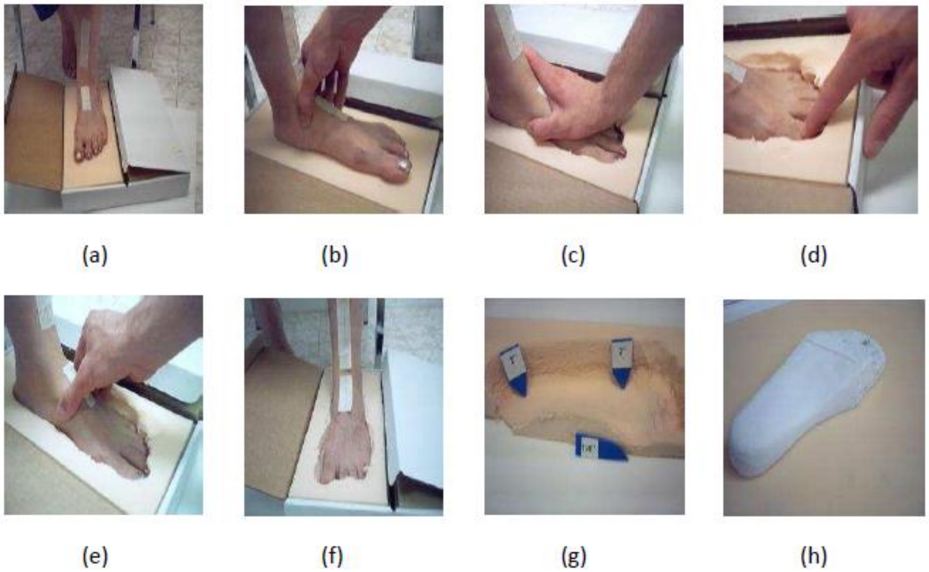


Figure 2:26 Foot geometry capturing in foam impression box based process

iv. Digital foot geometry capture

The applications of computers were introduced in 1970s for the design and fabrication of foot orthoses. Digitising technology was applied for capturing the foot geometry and foot impression. The impression of the foot which is either taken through plaster of Paris cast shown in Figure 2.28 (a) or by foam box impression shown in Figure 2.28 (b) is digitised through contacting the surface of the impression cast with a sensor probe shown in Figure 2.28 (c) and (d). The digitiser system technique works on magnetic resonance principle which sends the signals to the computer when a sensor probe is contacted with surface of the cast which reads and records the details of the impression shown in Figure 2.28 (e). The details of impression cast are captured and recorded in the digital format. The scanned information of the impression cast is then expanded and corrected by incorporation of required modifications and corrections using specific software developed for designing the foot orthoses shown in Figure 2.28 (f) (Staats and Kriechbaum, 1989).

Figure 2:27 shows the digitising process of foot impression casts captured through both techniques (Foam impression box (a) and plaster of Paris (b)) with the CAD based corrected orthoses model in the electronic format (c). The CAD based model is ready to be sent to the NC milling machine where the block of blank is milled for fabrication of orthoses.

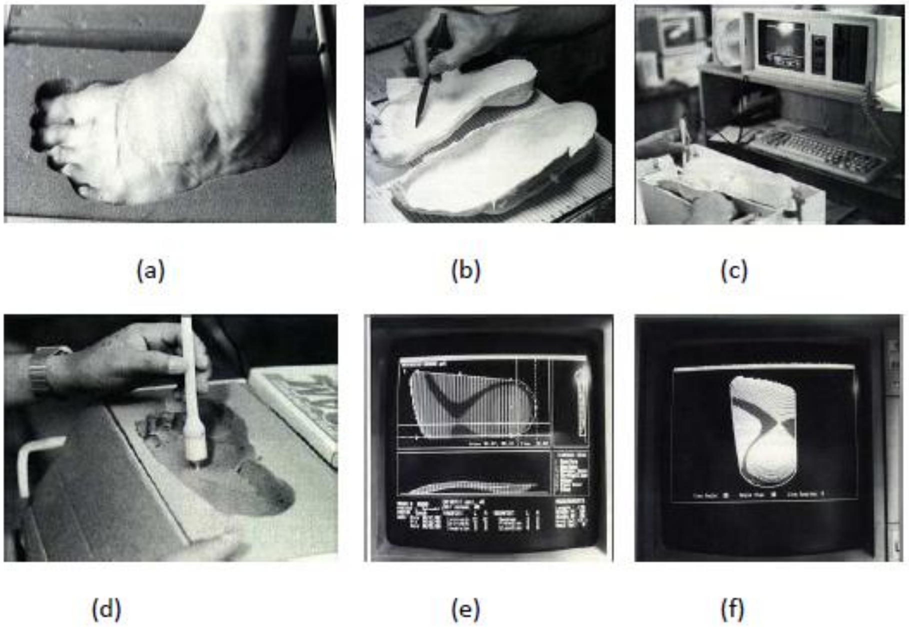


Figure 2:27 CAD/CAM orthosis fabrication (Staats and Kriechbaum, 1989)

v. Foot contour geometry capture using contact digitiser

Foot contour measurement technique is a foot impression capturing technique used for capturing the foot geometry through a contour measurement system. The system employs mechanical placement of sensitive pins which mechanically move upward when the foot is placed over the scanning area as shown in Figure 2:28 (c). In this process, sensitive pins contact the foot contour and capture the details of the plantar surface of the foot. The system captures foot geometry and shape of the foot and generates foot impression (Hunter et al., 1995; Boardman, 2007). The foot impression can be taken either in full, semi and non weight bearing positions. One of the advantages of contact digitiser is the speed and accuracy in capturing the foot impression. Figure 2.29 shows the foot digitising system (a) and setting of the digitiser (b) before the impression capturing process and (c) placement of foot for contour measurement. Once the contour surface of the foot is captured, the information is transferred to the CAD based design system for correction and modification for generating CAD based orthosis model (Davis, 1993).

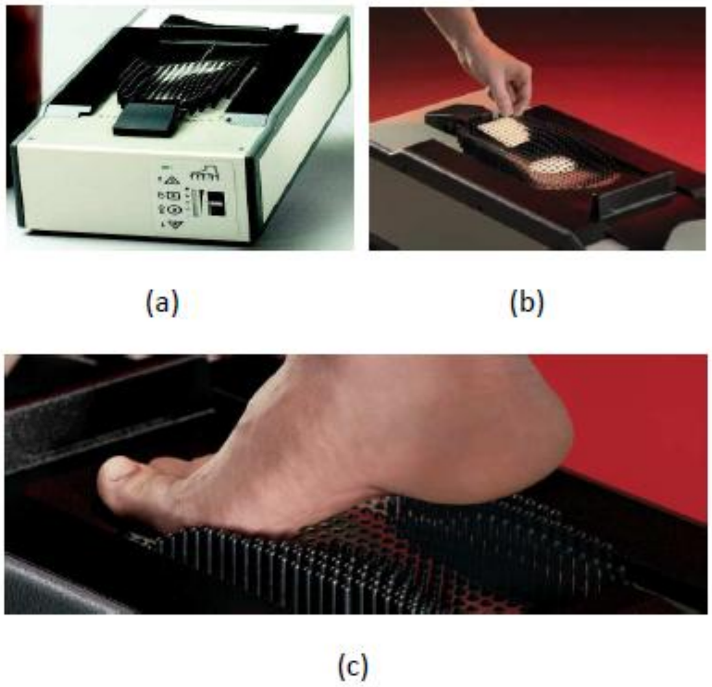


Figure 2:28 Foot impression capturing technique by contact digitiser (www.amfit.com, 2010)

vi. Scanning of foam box/plaster casts using impress scanner

Impress scanning is another technique in which a scanner tool shown in Figure 2.30 (b) used for capturing the foot impression. The scanning system (b) is capable of scanning foam box impressions, plaster of Paris and plaster slipper casts. Impress scanners use laser scanning technique to capture the foot impression and generates the 3-D foot information of the foot in digital format. The corrections and modifications in the foot impression can be incorporated through the CAD design system before the orthoses fabrication. One of the advantages of the impress scanner is the ability to scan positive or negative moulds including foam impression boxes and plaster positives. Figure 2:29 shows the foam impression box (a) and impress scanner system (b) for capturing foot impression.

Figure 2:29 Foam impression box cast (a) and (b) impress scanner (www.amfit.com, 2010)

vii. Foot geometry capture using 3D laser foot scanner

In this process, the foot is placed on the digital scanner shown in the Figure 2.31 (a) and (b) which scans 3-D image of the foot. The digital information is then transferred to CAD designing system. The main advantage of the direct foot scanning system is reduced labour work and increased degree of accuracy and precision in the foot impression capturing process. The Figure 2:30 shows the 3D digital laser foot scanner used for capturing foot impression.

Figure 2:30 Impression capturing technique in 3D digital scanner (www.londonorthotics.co.uk, 2010)

ii. Foot orthoses design

Foot orthoses is designed through traditional methods involving manual activities in the design process. The design process is mainly based on addressing the requirements of patient specific problems in the foot. The design process depends on the skills and expertises of individual podiatrist.

- **Traditional foot orthoses design methods**

The traditional method of designing foot orthoses is craft based which begins with development of a positive mould from the negative foot impression cast obtained through plaster or foam impression box casting. The positive mould is developed by filling the negative impression cast using plaster of Paris mixture. The positive mould cast is dried for several hours and then negative impression cast is torn away from the positive mould (Doxey, 1995; Hunter et al., 1995). The next step is manual dressing, modification and smoothing of the positive mould with additional material as shown in the Figure 2.32.

The modification of a positive mould is a time-consuming and demanding task which can only be completed with proper expertise and equipment (Hunter et al., 1995). In the modification process, required design features such as wedges, arch height, ramps, heel lift/cupping, met pads; prescribed by the orthotist at the time of impression casting are incorporated in the positive mould (Staats and Kriechbaum, 1989; Madazhy, 2004; Leung et al., 2004). The final step is the fabrication of the orthoses over the corrected model (Lasurdi and Nielson, 2000). Figure 2:31 shows the manual corrections in the positive mould of the cost (a) and (b) corrected positive moulds showing arch fill.


(a) (b)

Figure 2:31 Manual corrections process in positive mould (a) and (b) corrected positive mould with arch fill design feature (footcraft.com.au, 2010)

- **Computer aided (CAD) foot orthoses design methods**

With the technological developments, digital based techniques were introduced in designing the foot orthoses. The techniques use CAD systems in designing the foot orthoses using specific orthoses designing software. A number of foot orthoses design softwares are currently present in the market offered by different companies.

The orthoses design software such as “correct and conform” from Amfit Inc; USA, allows number of modifications and corrections in the foot impression information based on pre-specified design features or can be altered individually using menu driven commands and tools (Davis, 1993). This has replaced the manual activities in orthoses designing process by making the design process much quicker and efficient and cost effective (Staats and Kriechbaum, 1989; Boardman, 2007) with having the additional advantages for the orthoses designers for advance determination of how the orthoses will turn out after manufacturing (Williams, 2010). Figure 2:32 shows the CAD based designed orthoses model and orthoses design software.

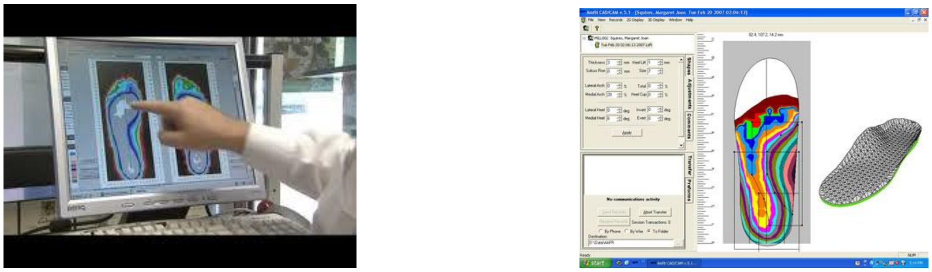

(a) (b)

Figure 2:32 “Correct & confirm” design software (a) and (b) CAD designed model (Amfit Inc;USA, 2010)

iii. Foot orthoses fabrication

- **Traditional foot orthoses fabrication**

Fabrication of foot custom orthoses traditionally is based on manual activities and craft based processes. Figure 2.30 shows the thermoplastic piece (a) and (b) orthoses draped over the positive mould of the foot impression cast. The fabrication process begins with placing the thermoplastic sheet which is slightly larger than anticipated orthoses measurements and dimensions in a pre-heated convection oven (Hunter et al., 1995). The sheet of plastic is placed in the oven for five minutes in a correct temperature until the plastic become pliable.

In the next step, heated plastic sheet from the oven is taken out and draped it over the developed positive mould and then manually smoothed and pressed to get full contact with the positive mould. In the next step cutting lines are marked on the draped plastic as shown in Figure 2:33 (b). The last step is cutting of the shell according to drawn lines and smoothing the edges of the orthoses with grinder to get accuracy in measurements and finishing in the final product (Pratt, 1995; Doxey, 1995).

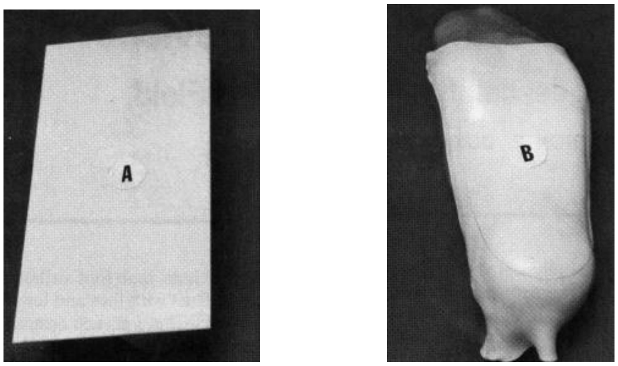


Figure 2:33 Thermoplastic piece (a) and (b) heated sheet draped over positive mould (Doxey, 1995)

Another way of fabricating the custom orthoses is use of vacuum press or vacuum former instead of manually pressing the heated plastic sheet over the positive mould to get the orthoses shell fabricated. It has been recognised by many authors that vacuum press fabrication of orthoses shell bring more uniform and better results compared with manual draping for orthoses shell fabrication (Pratt, 1995; Doxey, 1995). The process requires high skill and expertise in this type of orthoses fabrication to get the accuracy in measurements in final product (Hunter et al., 1995). Figure 2:34 shows the vacuum press and the formed orthosis shell.

Figure 2:34 Vacuum press and moulded orthoses shell (Pratt, 1995)

- **CAD/CAM orthoses fabrication**

Since its beginning in 1960s computer based custom orthoses fabrication with applications of stereophotography and NC milling machines has progressed well over the time. The technological advancements and computer designing techniques CAD presently widely used in custom orthoses fabrication (Lasurdi and Nielson, 2000). The modern system for fabrication of custom foot orthoses are comprised of digital foot geometry capturing equipments (Davis 1993; Smith et al., 2001), CAD based orthoses design system with specific software developed for orthoses designing (Davis, 1993) and automated CNC machine for milling the orthoses (Lasurdi and Nielson, 2000).

The first commercial CAD/CAM system for production of custom foot orthoses was “Orthoscan system” introduced by American Digital Technology in the year 1988. The second system was introduced by the “Ammon Production system” through Ammon Corporation and was manufactured by the Bergmann Orthotic Laboratory. The both systems were using digital technology for capturing foot geometry (Grumbine, 1993).

Presently, there are several foot orthoses manufacturers and suppliers from different parts of the world such as KLM Laboratories, Inc Canada (www.klmlabs.com), Amfit Inc, USA, (www.amfit.com), Foot Dynamics USA (www.footdynamics.com), AliMed Inc, USA (www.alimed.com), insole Pro, UK (www.insolepro.co.uk), London orthotics consultancy, Ltd, UK (www.londonorthotics.co.uk) in the orthoses industry using CAD/CAM applications in fabrication of custom foot orthoses (Pallari, 2008) . Amfit Inc, USA is one of them, currently fabricating the custom foot orthoses at their facility in USA and also provides the CAD/CAM orthoses fabrication systems for the market (Davis, 1993). Figure 2:35 shows the Amfit foot contour digitizer and Amfit custom insole fabrication system (www.amfit.com).

Figure 2:35 Foot contour digitiser (a) and (b) insole fabrication system (www.amfit.com, 2010)

2.5 Process modelling

Models are constructed to represent and describe the processes, existing systems or proposed new systems in order to evaluate the feasibility, practicality and anticipated performance from the processes or systems. A model is a representation of a process, an object or a system aiming at providing an understanding of the process (Yousuf and Smith, 1996). The purpose of a model is to derive a framework for applying logic and mathematics which can be independently tested and evaluated and applied for reasoning in a range of situations. A well designed model gives a comprehensive understanding of a process or a system (Saven, 2004).

Process models are composed of interdependent and interfacing inputs or elements that are combined together to perform a task or serve a purpose as an output (Hammer and Champy, 1993). A well organised and structured process model provides a clear understanding of the process, its input and output, functions, resources and performance.

2.5.1 Process modelling methodologies

There are several methodologies which exist for process modelling such as Data Flow Diagram (DFD), Structured System Analysis and Design Methodology (SSADM), Structured System Analysis and Design (SSAD), Integration DEFinition methodology (IDEF), Structured Analysis and Design Techniques (SDAT), Computer Integrated Manufacturing Open System Architecture (CIMOSA) (Ang et al., 1997; Ang et al., 1999). Although these methodologies vary in scope, appearance and theoretical foundations; the basic applications of these methodologies are to improve the structure and design, increase productivity and aid communication in a process.

The most influential and popular process modelling methodology is IDEF0 methodology (Saven, 2004). An IDEF0 is a methodology designed to model the decisions, actions, functions and activities of a process or system (Cullinane et al., 1997). An IDEF0 modelling methodology represents the actions, activities and functions of a process in a systematic manner identifying the functional relationships in activities and functions and flow of information and objectives of the process (Smart et al., 1995).

2.5.2 IDEF0 modelling methodology

There are sixteen IDEF methods/versions starting from IDEF0 to IDEF14. All IDEF methods are designed for specific purpose to accumulate information and develop understanding of the system through modelling processes. An IDEF0 model is comprised of graphical representation of series of related diagrams organised in a hierarchy, showing graphically the complex functional relationships and identifying the information and objects that are interrelated (Saven, 2004). IDEF0 has four important characteristics which make it a powerful modelling tool; differentiation between organisation and functions, simple graphics, data abstraction and preciseness (Mandel, 1990; Hunt, 1996). An IDEF0 model consists of four elements which are abbreviated as ICOMs (Input, Controls, Output and Mechanisms) and these are;

1. Inputs: represented by arrows flowing into the left side of the box.
2. Outputs: represented by arrows flowing out from right hand side of the box.
3. Controls: represented by the arrows flowing inwards from top side of the box.
4. Mechanisms: represented by the arrows flowing into bottom side of the box.

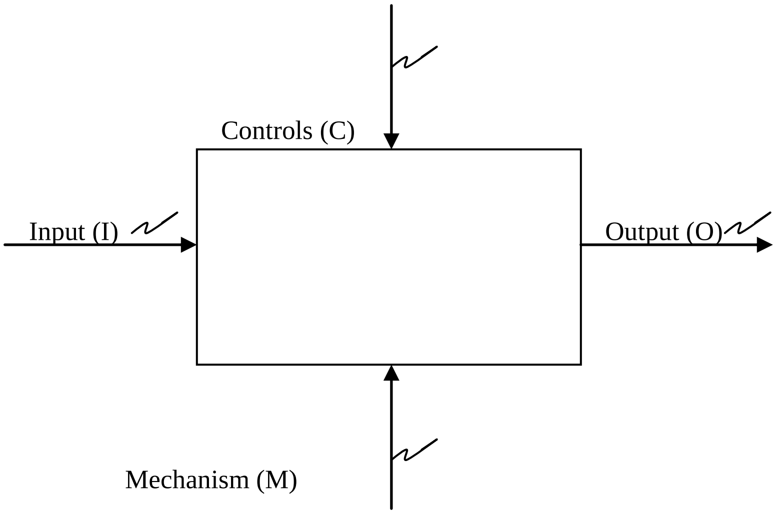


Figure 2:36 IDEF0 basic digram

Figure 2:36 shows a schematic of IDEF0 diagram. The above mentioned elements (ICOMs) of the IDEF0 consist of inputs and outputs which may be the information or physical objects used in system, controls which are used for activating or regulating the function inside the boxes and mechanisms which are the resources that perform or carry out the functions in a system. A well structured IDEF0 model of a system identifies activities and functions in a systematic manner representing the relationship between functions and objectives required.

The main objectives of the IDEF0 modelling methodology are;

i. To represent and provide functional modelling of a system and the functional relationships and information flow in the system.
ii. To provide generic, rigorous and precise modelling characteristics.

2.5.3 History and background of IDEF0

The origins of systematic and structured approaches for modelling and analysis of systems dates late to 1960s and early 1970s. In 1979 DeMacro introduced the term structured analysis; a methodology for creating information flow in models (DeMacro, 1979). Initially, DFD (Data Flow Diagram) was used to represent entire system with other additional levels of DFD for additional information in a system. Later on, some deficiencies were observed in DFD approach and the need for capturing control flow and control processing information became apparent for modelling real- time systems (Ward and Mellor, 1985).

For this purpose in 1977 SDAT was developed by Ross and Schoman. SDAT is a graphical language consists of boxes and arrows that represent system components and interfaces and capture multiple levels of details in hierarchical manner. In mid 70s Soft Tech, Inc introduced this well established graphical language to overcome and improve some of shortcomings of modelling and analysis methods. The United States Air Force in late 1970s used SDAT as a language to develop the functional modelling method to support its Integrated Computer Aided Manufacturing (ICAM). IDEF0 was derived from the SDAT. Since the use and application of SDAT and IDEF0 in aero space industry in United States air force, IDEF0 modelling methodology has been widely applied in organisations and industries (Ross, 1985).

2.5.4 IDEF0 modelling methodology working principles

IDEF0 modelling methodology works on hierarchical principles where the modelling process starts with construction of the highest level diagram showing the purpose or context of the model; generally called context or reference model and marked as “A-0” diagram/model. The “A-0” is a one box diagram which determines the subject of the model and defines the scope of analysis to be included in the model (O’Sullivan, 1991; IEEE Xplore, 1998).

The developed context or reference model is then decomposed to generate the details of the model at the required level marked as “as-is” A0 model. The “as-is” A0 model contains three to six boxes, representing the activities in the system (Yousuf and Smith, 1996). The justification of recommendation of limits of the boxes, in case of less than three boxes is given that model does not constitute sufficient details for useful decomposition; whereas the boxes more than six contain details that should be suppressed within the diagram and unpacked in the decomposition. The relationship between reference model A-0 and “as-is” A0 model is called parent and child diagrams. The “as-is” A0 models are analysed and evaluated in order to improve the models or systems from where the new “as-to” be models are created; aiming at modifying or improving the systems or models efficiency (Ang et al., 1994).

Ross (Ross, 1995) described a structured modelling technique that has become synonymous with the design and manufacturing systems is the ICAM definition zero language. IDEF0 is widely used technique for modelling the design and manufacturing systems. Following section presents some of the examples of IDEF0 modelling in design and manufacturing systems. Before presenting the IDEF0 examples in design and manufacturing systems in the context of this research, firstly; introduction to new manufacturing systems named mass customisation production (MCP) systems is presented.

2.5.5 Mass customisation production (MCP) systems

Production systems which can deliver one-of-a-kind products or customised products to individual customers on large or mass scale are named as mass customisation production (MCP) systems. These systems apply advanced information technologies resources, highly flexible integrated manufacturing systems and efficient supply chain management systems (Chinnaiah et al., 1995). From the strategic point of view mass customisation is the process of differentiation through adding value into the product for the customers. The value creation process in the realisation of the products differentiates the mass customised production systems from mass production systems (Cullinane et al., 1997).

2.5.6 Fundamental process of mass customisation production (MCP) systems

The main objective of the mass customisation system is to realise the customised products at mass scale within minimum time and at cost near to mass production systems. These production systems involve complex manufacturing activities in order to generate a high variety of customised products. These systems involve extensive applications of the information technology resources, flexible integrated manufacturing systems and efficient supply chain management systems establishing the direct link between the key components of the system for realisation of the customised products

(Chinnaiah et al., 1995; Cullinane et al., 1997).

In mass customisation production systems, the customisation process starts from acquiring the customer order towards efficiently delivering the customised products. Implementation of mass customisation needs to understand and evaluate key components, various operations and multifaceted manufacturing activities involved in the customisation process. In mass customisation production systems the key components or fundamental functions identified by numerous authors in the literature (Kumar et al., 1996; Cullinane et al., 1997; Piller, 2002; McCarthy et al., 2003) are;

- Acquiring customer requirements
- Processing customer order
- Design of the product
- Plan for manufacturing
- Manufacturing the product
- Delivery of the product

These key components or elements in the mass customisation process are integrated through efficient information management systems and are regarded as the important elements for success of mass customisation systems.

2.5.7 Process modelling of mass customisation production (MCP) systems

In mass customisation production systems the core processes and activities are complex, interrelated and involve high variations in the operations for manufacturing variety of products. This requires developing a process model to support the dynamic nature of the operations, processes and activities in the mass customisation systems. These systems require effective process modelling in order to streamline the various operations and processes for the quick and efficient realisation of mass customisation production.

As mentioned earlier, IDEF0 is a powerful tool for functional modelling of complex manufacturing systems. It represents the descriptions of relationship of functions and activities involved in the systems (Nookabadi and Middle, 1996). IDEF0 modelling methodology represents the detailed functional description of various functions and activities, their relationship, information flow and evaluates the performance and consistency of the operations and processes in the systems. The main strength of the IDEF0 based models is the simplicity and ability of clearly representing the components of the system. In the following section an IDEF0 model for the mass customisation systems is presented from the literature developed by Cullinane and associates (Cullinane et al., 1997).

2.5.8 Generic model of mass customisation production (MCP) systems

The design of the IDEF0 process model for various systems starts generally form constructing the reference or base model which represents the existing or current situation of the systems and the purpose of the model.

An IDEF0 reference model of a mass customisation production system is presented from literature developed by (Cullinane et al., 1997) shown in the Figure 2:37. The box represents the purpose of the model which is a generic mass customisation production system. The arrows from left side of the box are inputs which are various entities such as customer information, business objectives, industry data, raw materials and other resources which will be consumed or transformed by MCP system. The arrows at the top of the box represent the controls which are resources, organisational policies, available technologies and guidelines that guide the MCP system, while the arrows at the bottom of the box are the mechanisms which are the people and systems that carryout and accomplish the operations in the MCP system. The arrows at the right side of the boxes show the output from the generic MCP system. This reference model is further decomposed into “generic operational based IDEF0 model” for mass customisation systems which shows more levels of details of the model shown in the Figure 2:38.

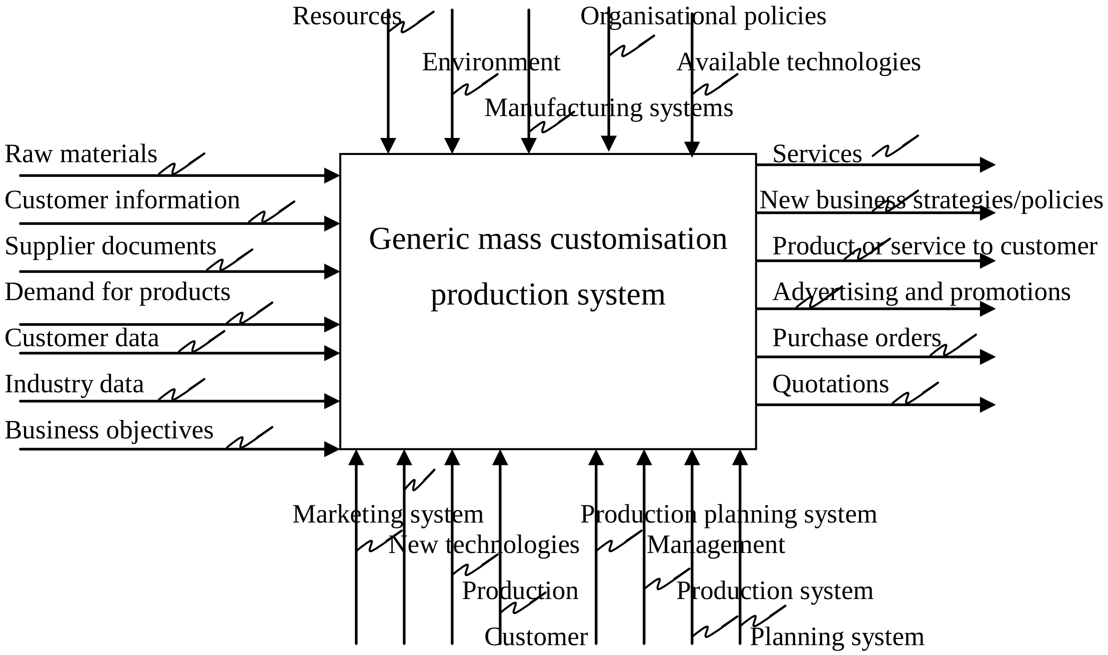


Figure 2:37 IDEF0 reference diagram of mass customisation system (Cullinane et al., 1997)

2.5.9 Generic operational IDEF0 model for mass customisation systems

From the base or context model of mass customisation production system presented in the Figure 2.38, a detailed operational IDEF0 model is developed by (Cullinane et al., 1997). The developed model shows the details of various operations involved in the systems and facilitates in understanding the complexities in mass customisation systems; showing the relationship between various functions of subsystems in the overall system.

The generic operational IDEF0 model presents a detailed description of various processes and activities of the individual subsystems in terms of performance and outputs from the systems. The model provides more details regarding the order of sequence of subsystems, inputs and outputs, relationship and information flow in the overall system. It represents individual functions, controls and mechanisms required to perform the operations for generating output from the subsystems.

The model represents a clear logical relationship, impacts of the subsystems on each other and on the overall system. The model shows that various functions and operations are interrelated in a systematic hierarchy based on the IDEF0 modelling principles. From operational aspects for mass customisation production systems; the key operations and activities in the generic operational IDEF0 model are explained individually according to hierarchy of the operations involved in the mass customisation manufacturing systems. The key functions are;

i. Capturing customer requirements

The first step in the customisation process is to capture the needs, requirements and preferences of the customer for customisation in order to understand, evaluate and generate the details for the product to be customised. This step differentiates customisation production from mass production by incorporation of the customer preferences into the products (McCarthy et al., 2003).

The main objective of representing the activities individually is to evaluate and assess the required resources such as inputs, controls and mechanisms for performing the activity. Figure 2.39 shows the activity of capturing customer requirements “A1”. The function of this activity is to receive, gather and interpret the various inputs and transforming them into outputs. The inputs such as demand for the product, customer requirements and preferences, customer data and business objectives which are transformed into the outputs such as customer order for the product. The mechanisms are management and other subsystems to carry out the task of analysing the inputs such as understanding carefully the requirements of the customer for the products and all other associated information. This activity generates accurate details, attributes and specifications for the product under guidelines of the controls for the organisation which are company policy, available resources and available technologies.

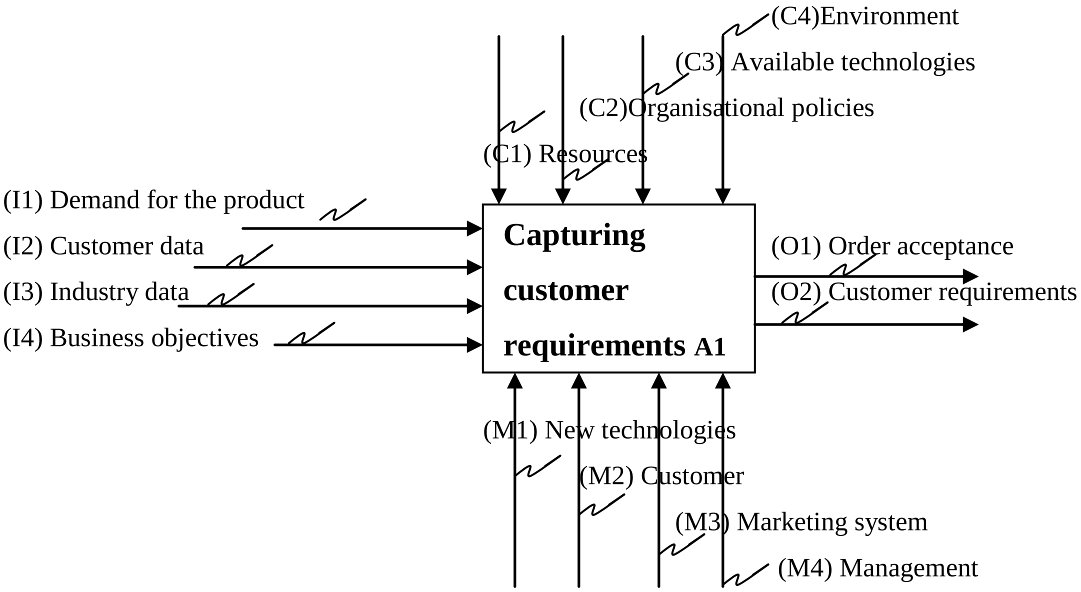


Figure 2:38 Individual subsystem for capturing customer requirement in MCP system

ii. Processing the customer order

After the customer order is evaluated and generated for the product, the next step is modelling the activity of processing the customer order “A2” shown in the Figure 2:39. The activity involves mechanisms including management and marketing systems which perform the functions in this activity under the guidelines of the controls including company resources and organisational policies. This activity generates a production order as an output that contains the complete information details regarding the customer order such as; assigning an order number, customer profile, product information, date of completion and delivery date. The properly completed documentation of the product order is then communicated to design and development section of the company.

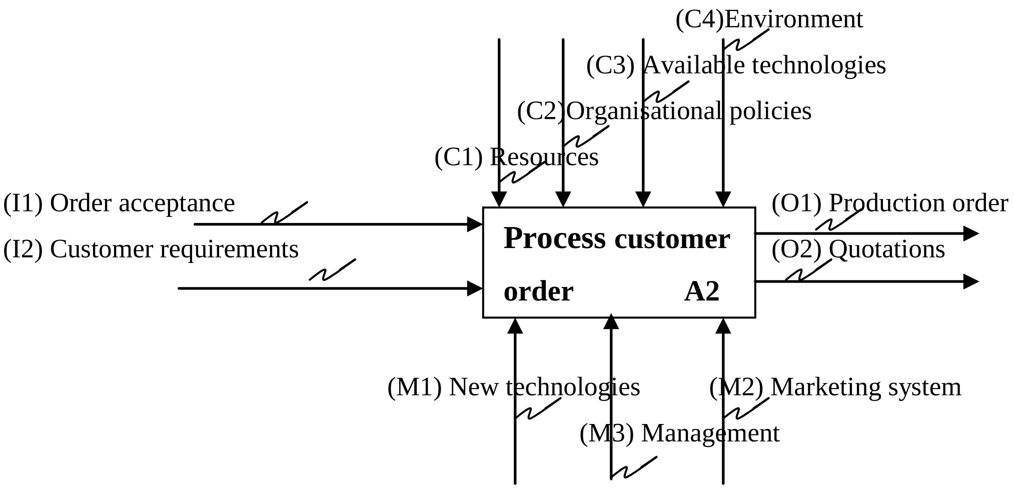


Figure 2:39 Individual subsystem for processing customer order in MCP system

iii. Design of the product

Once the production order is completed it is used as an input for the activity of designing and developing the product activity “A3” shown in the Figure 2:40. Modelling this activity represents design and development system and other resources which work as the mechanisms to carry out the design function for creating a product design using the controls and tools such as computer aided design CAD systems. The product design is generally configured from the designed templates or master design model from which different product designs are developed. If required, different designs can be altered, changed or made cut-to-fit for the final design according to customer requirements and then sent to the manufacturing department for fabrication of the product.

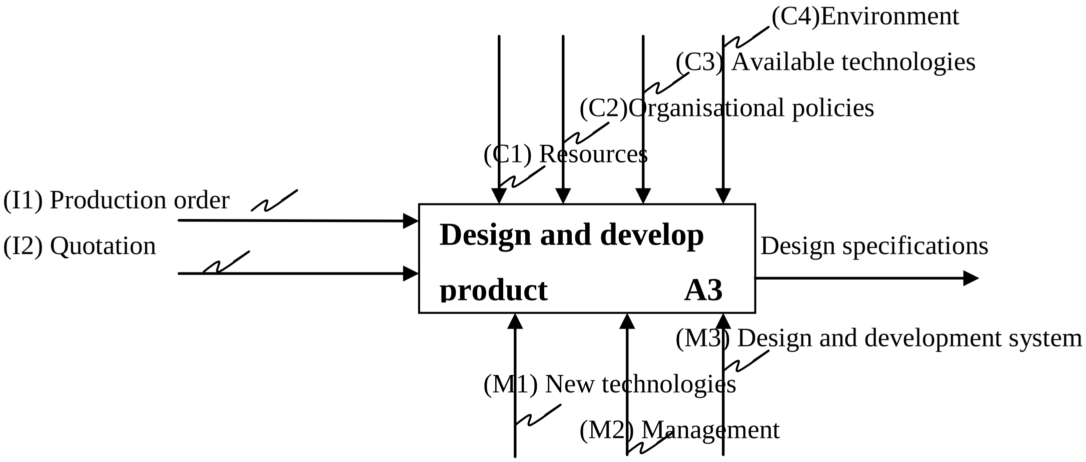


Figure 2:40 Individual subsystem for generating design of product in MCP system

iv. Plan for manufacturing

The next step is the function of generating the plan for manufacture. This activity “A4” shown in Figure 2:41 is performed through production planning systems which work as the mechanism. In this activity design specifications are used as inputs. This function generates the plan for the manufacturing under the guidelines of controls such as existing manufacturing system and other resources. It generates the detailed information regarding the process plan, production schedules, quality controls and inspections, supply of raw material for the product and set the quality standards for the product.

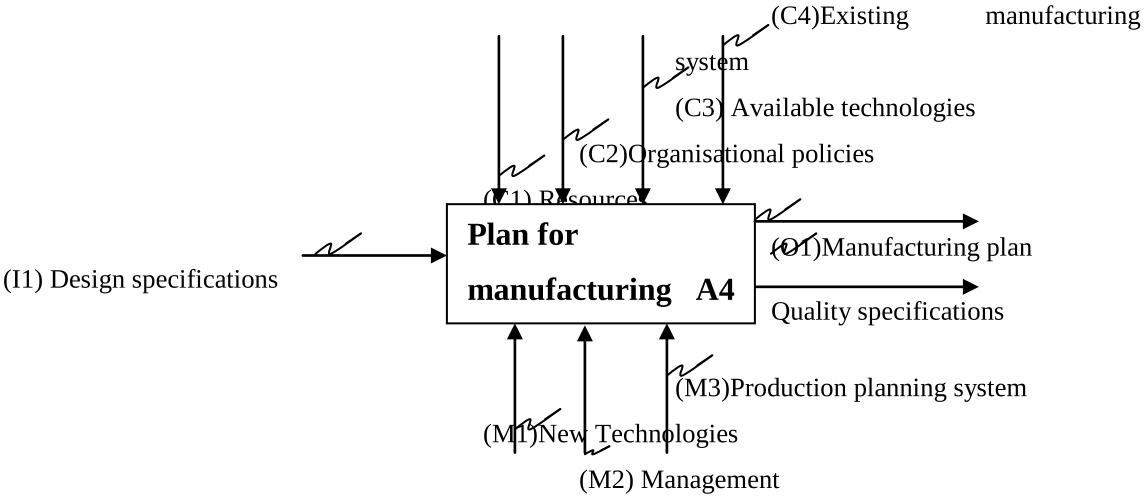


Figure 2:41 Individual subsystem for generating plan for manufacturing in MCP system

v. Executing manufacturing

Manufacture of the product is the next activity in the model after plan for manufacturing activity completed. The activity of executing the manufacturing “A5” is shown in the Figure 2:42. Production system which acts as mechanism performs the operations in the activity according to the design specification which is used as input to manufacturing the final product. The advanced manufacturing techniques such as, flexible manufacturing systems (FMS), computer integrated manufacturing (CIM) and computer aided manufacturing (CAM) are used for manufacturing the final product.

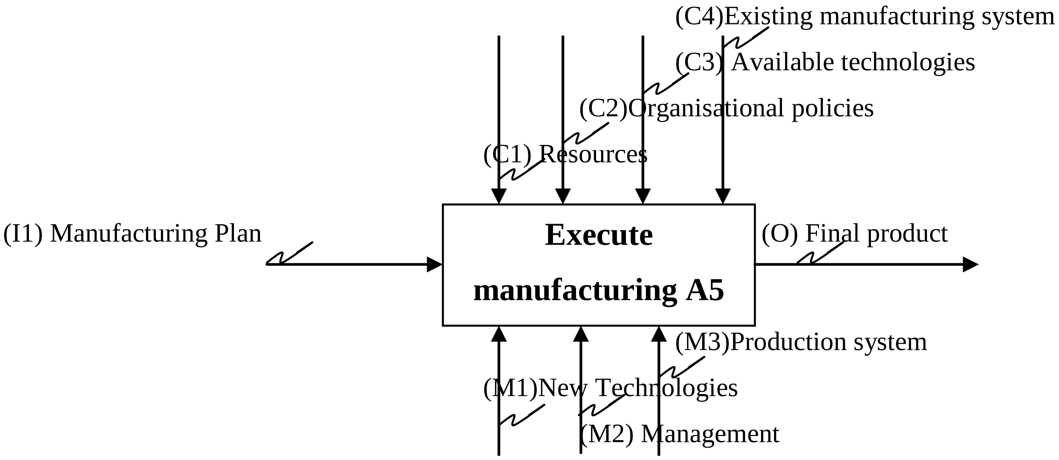


Figure 2:42 Individual subsystem for production of final product in MCP system.

vi. Delivery of the product

Delivering the custom-made product is the last activity “A6” in the process shown in the Figure 2:43. An efficient delivery system which acts as a mechanism performs the process of delivering the finished product in mass customisation systems. The delivery system may have its own resources to deliver the product or the system can use third party for delivering the product to the customer.

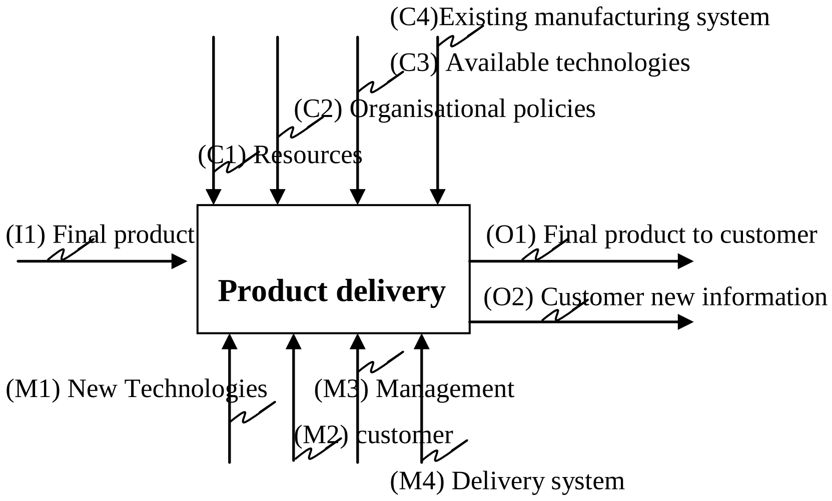


Figure 2:43 Individual subsystem for delivering final product in MCP system

All the above modelled functions are combined and a generic IDEF0 operational based model for mass customisation systems is developed. Figure 2:44 shows the generic operational IDEF0 based process model combined with all the main functions described above, for mass customisation system.

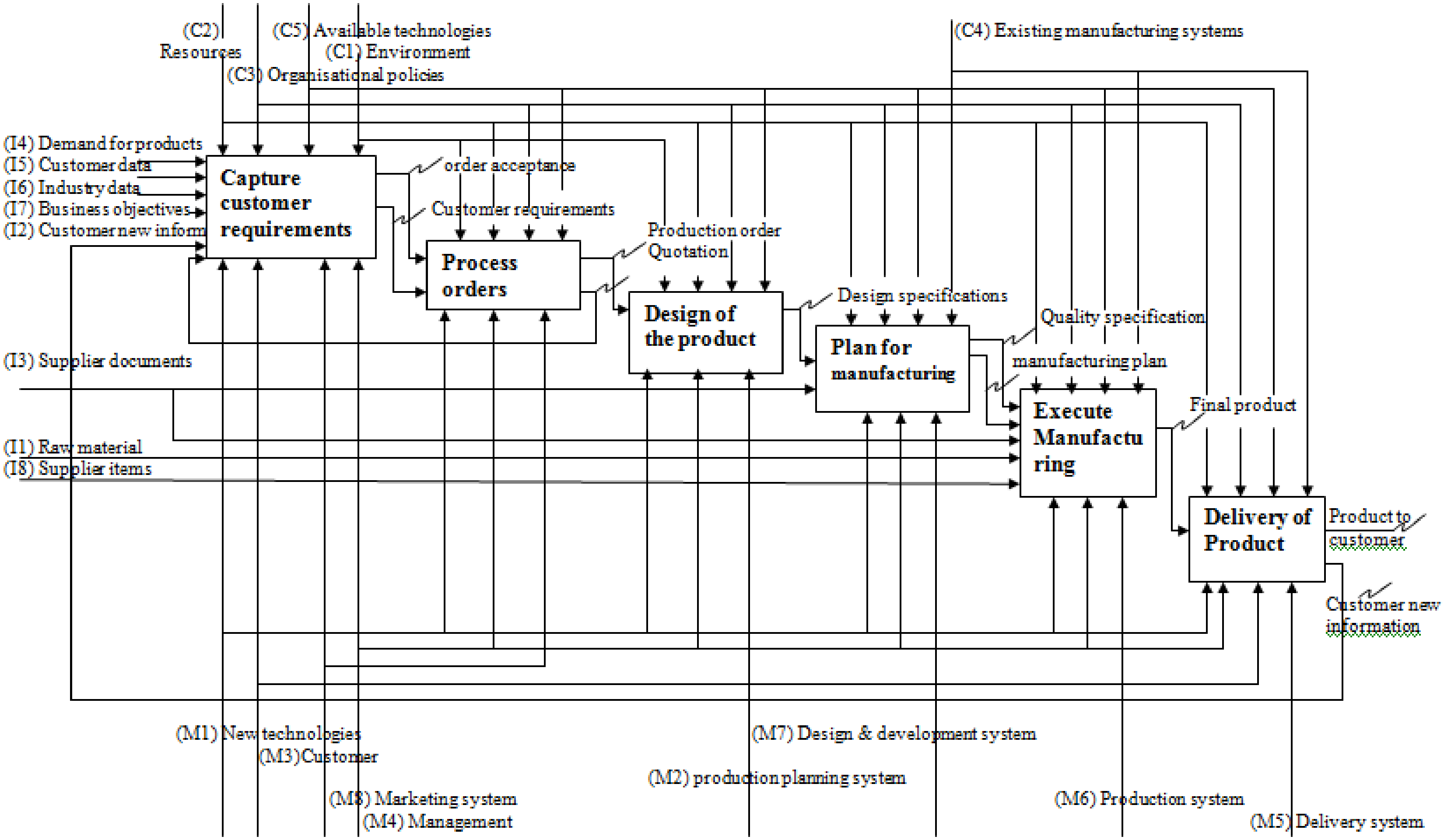


Figure 2:44 Generic operational IDEF0 model for mass customisation systems (Cullinane et al., 1997)

2.5.10 Applications of IDEF0 process modelling: examples in manufacturing

IDEF0 modelling methodology can be used for modelling the different manufacturing systems and in redesigning and improving the productivities and competitiveness in the systems (Yousuf and Smith, 1996). According to Godwin and colleagues (Godwin et al., 1989) IDEF0 modelling technique is applicable to all kind of organisational and manufacturing systems regardless of their size and complexities. Some of the IDEF0 process models for different purposes are presented.

i. IDEF0 business process model NAPS in Finland

The Finland based company NAPS is involved in selling the photovoltaic and solar power products to private households and companies in the Finland. The sales order process was modelled using the IDEF0 modelling technique by Rajala and Savolainen (Rajala and Savolainen, 1996). The company's sale order process is based on three main activities; which are (i) A1: enter order, (ii) A2: process order and (iii) A3: ship order shown in the Figure 2:45. The company receive the orders from the customers in the activity A1; where the marketing and sales assistant receive and carryout the assessment of the order along with other related information. The activity generates the output from which giving offer or answer to enquiry or to check with inventory and give a delivery date for the order. Similarly the other two activities of A2 and A3 are performed in the model. According to survey conducted company received a positive response from the customer in terms of quick order processing time and service (Rajala and Savolainen, 1996).

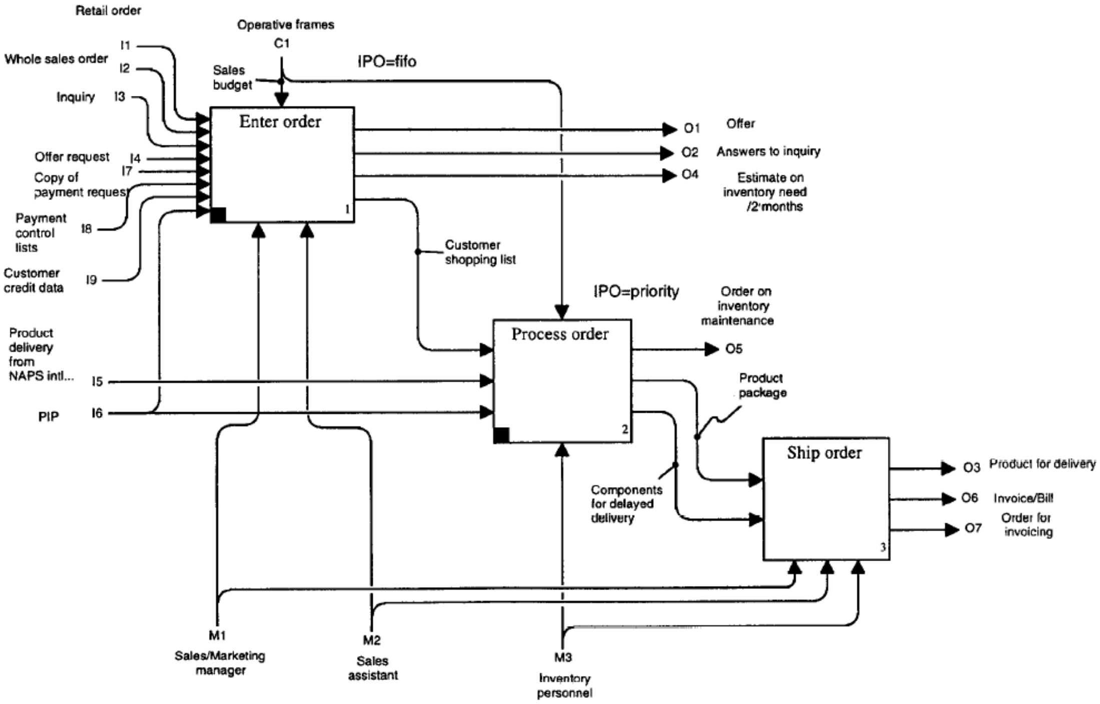


Figure 2:45 NAPS business process model in IDEF0 diagram (Rajala and Savolainen, 1996)

ii. IDEF0 based order fulfilment process model in steel industry

Yousuf and Smith (Yousuf and Smith, 1996) modelled the order fulfilment process model using IDEF0 modelling technique in a steel industry. According to them the main purpose of designing the IDEF0 model to identify the main activities and provide understanding of the nature of different operations and processes involved in the system. They modelled “order to fulfilment” process in the steel industry shown in Figure 2:46. The process involves the main activities of mange the order A1 to erection of the steel A5. The first activity of the managing the order A1 involve the input of order from the customer that is assessed by personal and equipment; working as mechanism under the guidelines of contact documents. The output from this activity is construction and erection of the steel structure which work as input for the following activity. Similarly all the activities are modelled in the model. The order fulfilment model developed provides the knowledge acquisition of required activities and presents a flow of information regarding the process of fulfilling the order in steel industry.

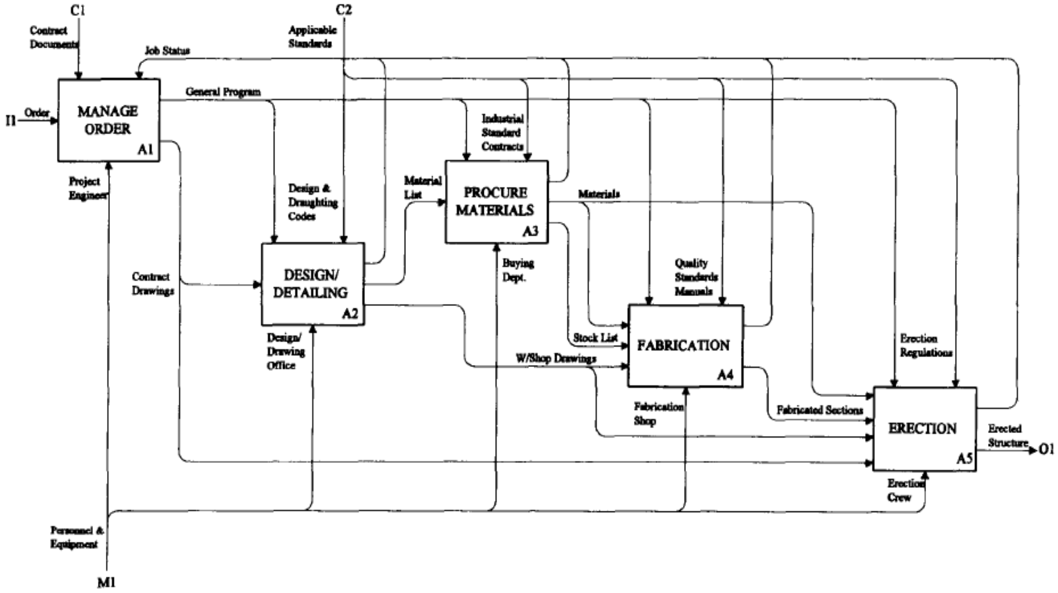


Figure 2:46 Order fulfilment model in steel industry (Yousuf and Smith, 1996)

iii. IDEF0 process model for production of personalised bicycles

Cullinane and associates (Cullinane et al., 1997) developed the IDEF0 process model for production of the personalised bicycles at NBIC Japan based on generic operational IDEF0 process model for mass customisation production systems. The developed model is shown in Figure 2:47. The process model is based on four main activities for production of personalised bicycle. The activities are capturing customer requirements A1, design product A2, manufacture the product A3 and deliver the product A4. The process model starts with the activity of capturing the customer order A1. Customer requirements for the bicycle are working as inputs for the activity and the sales representative use the ergonomics tools and work as mechanism to capture the required information under the guidelines of company policy and limitations of the technologies. The output from the activity is specifications for the personalised bicycle which work as input for the following activity of design of the product A2. Similarly the other activities are performed until the delivery of the product (Cullinane et al., 1997).

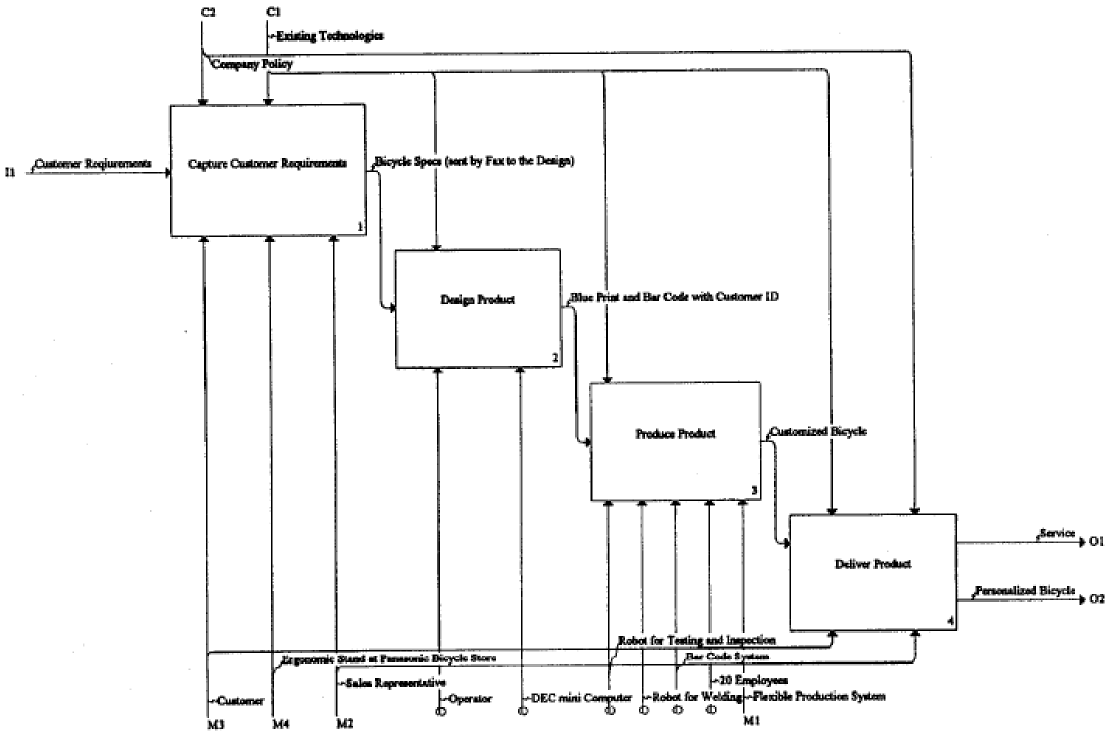


Figure 2:47 IDEF0 process model for personalised bicycles at NBIC Japan (Cullinane et al., 1997)

iv. IDEF0 process model for generation of 3D conformal products

Tuck and associates (Tuck et al., 2008) used IDEF0 process modelling in designing a process model for design and fabrication of custom-specific conformal products using rapid manufacturing. The process model of design and manufacturing of conformal products is based on four main activities of geometry capture A1, data manipulation A2; design the product A3 and manufacturing the product A4 in the system. The activity of geometry capture A1 is modelled in the process model shown in Figure 2:48 generates the scanned measurement of the individual geometry as an output from the activity under the controls of design rule guidelines and reverse engineering equipment which are used as mechanism for capturing the geometrical measurements. Similarly the other activities A2, A3 and A4 are modelled in the process model in a hierarchical manner for production of custom specific conformal products.

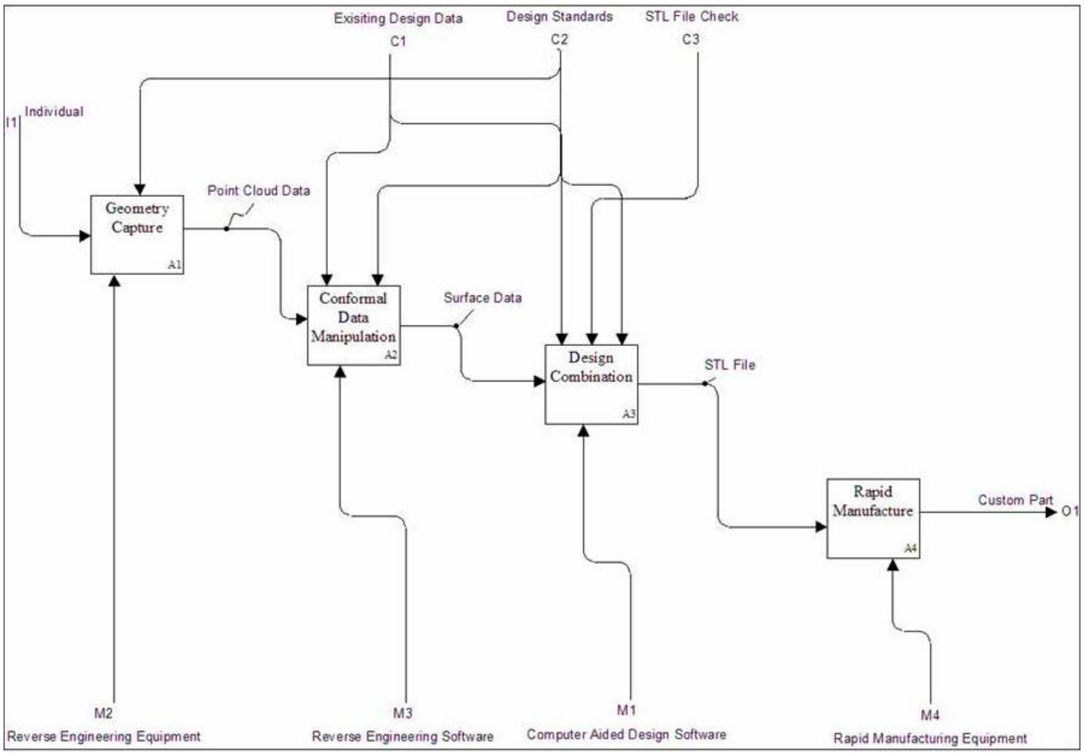


Figure 2:48 Process model for design and fabrication of custom-specific products (Tuck et al., 2008)

v. IDEF0 process model for manufacture of custom-fit prosthesis socket

Colombo and colleagues (Colombo et al, 2010) modelled the design and fabrication process for custom-fit socket for lower limb prosthesis. The process model is shown in Figure 2:49. The design and fabrication process is based on five main activities from the activity of geometry capture A1 to the activity of constructing the socket A5. The activity of geometry capture A1 is modelled; where patient work as input and the technician captures the geometry of the lower limb of the patient using the tools under the guidelines of the geometry capture methods. The activity generates the stump data as an output for the next activity of creating stump CAD model in the system. Similarly all other activities are modelled in the system using the IDEF0 modelling methodology.

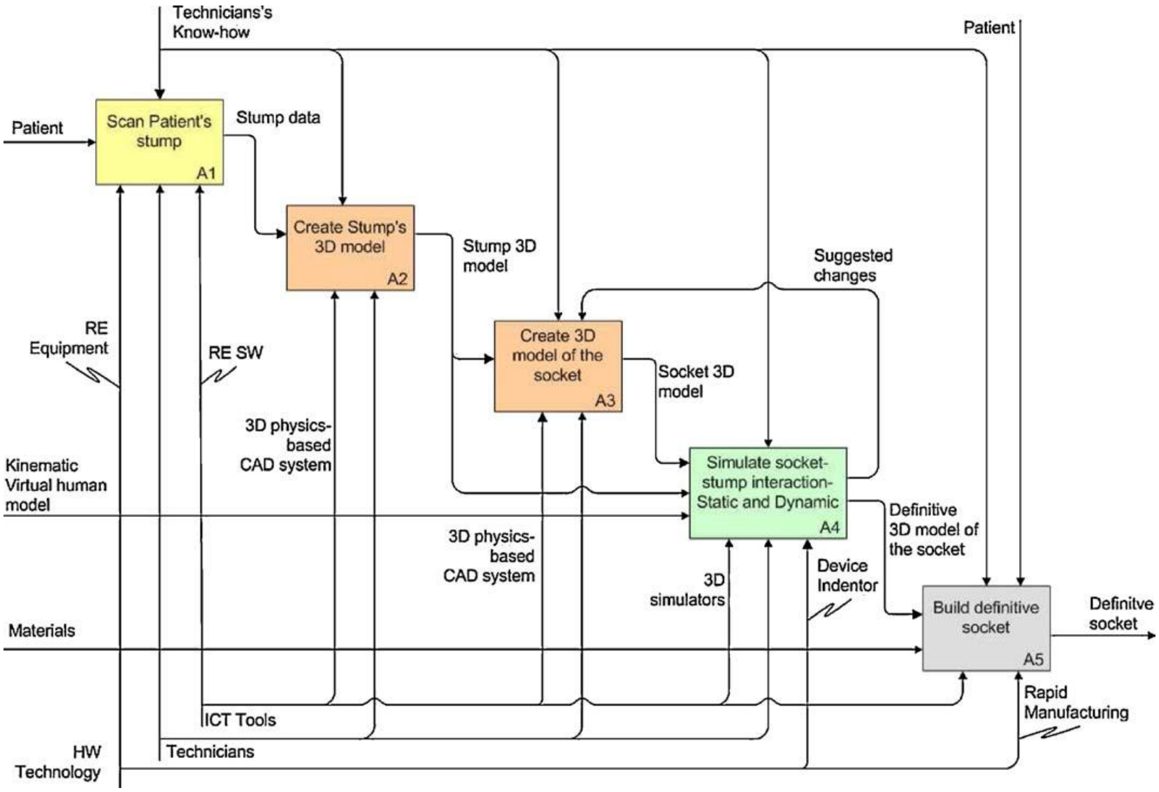


Figure 2:49 Process model for fabrication of custom made lower limb prosthesis (Colombo et al., 2010)

The examples of IDEF0 process modelling technique in design and manufacturing systems shows that it provide graphical structure of the processes and functions in the design and manufacturing systems. The modelling methodology presents explicitly subsystems, required controls, mechanisms, inputs and outputs with showing the functional relationship and information flow in the systems. It provides a clear understanding of the different activities and functions by modelling the individual activities and the output from the functions and activities in the systems.

2.6 Summary, context, aims and objectives of research

2.6.1 Summary of the literature review.

Custom foot orthoses are recognised and established as a non-invasive treatment in foot related problems and diseases including rheumatoid arthritis, diabetes and associated pathological complications of these diseases. The main characteristic of the custom orthoses fabrication and provision is the ability of providing the orthoses with prescribed required features and functional elements. The literature review has explored that conventional design and manufacturing practices and techniques are applied in the custom orthoses manufacturing. These techniques have limitations in incorporating the functional elements such as integration of local stiffness and complex design features including metatarsal pads and domes discussed in Section 2.4.2. These factors limit the range of product using the conventional techniques in the fabrication process.

Rapid manufacturing techniques have greater design freedom and ability in creating the complex geometrical structures with required design features and functional elements. These factors indicate that this approach has increased potential in production of custom made parts and products. The commercial examples of in-the- ear hearing aids and dental braces along with other medical applications examples have shown the advantages of these techniques. The developments in fabrication of prosthesis sockets using rapid manufacturing techniques have shown advantages of these techniques in creation of custom-specific parts with increased accuracy and improved fit.

The novelty of this research is the integration of rapid manufacturing techniques in design and fabrication process of custom foot orthoses. The main objectives are; the assessment of the rapid manufacturing approach in design and fabrication system which delivers improved quality orthoses with reduced lead-time and enables the production and delivery of custom-made orthoses at mass scale. The research addresses the issues in applications of rapid manufacturing techniques in design and manufacturing process for custom foot orthoses. The design and manufacturing costs and lead-time associated with the applications of different rapid manufacturing techniques are investigated and evaluated. The research establishes the platform in evaluation of different commercially available rapid manufacturing techniques in custom foot orthoses fabrication at commercial scale.

2.6.2 Structure of the work

The research is structured as follows;

1. Current design and manufacturing processes for custom foot orthoses is modelled and described. The modelling is based on the main activities and functions involved in the system. IDEF0 is used in modelling the activities and functions in the process. The main purpose of modelling the activities was to understand the functions and activities in current design and manufacturing process. In the next step rapid manufacturing approach was integrated in the process of design and fabrication for custom-made foot orthoses. A new process model based on IDEF0 was developed with integration of rapid manufacturing techniques in fabrication process. The developed model showed the impacts of rapid manufacturing techniques in the upstream and downstream activities in the design and fabrication process; representing the relationships in the functions and activities and overall improvements in the process.

2. The main functions including foot geometry capture and orthoses design were evaluated and analysed in the developed rapid manufacturing based IDEF0 process model in terms of cost, lead time, efficiency and overall productivity.

3. Different commercially established rapid manufacturing techniques were used in the experimental work for fabrication of the foot orthosis model. The cost and lead-time in different rapid manufacturing techniques were analysed and evaluated.

4. Based on the varying initial conditions and constraints, a set of mass customisation systems are proposed.

Chapter 3 Initial process modelling

3.1 Introduction.

In this chapter, analysis of the functions and activities involved in the design and fabrication of custom foot orthoses is carried out in order to understand and evaluate the design and manufacture process. IDEF0 process modelling methodology was used in the construction of a function based process model to illustrate the structured representations of the individual functions and activities in the system. The main objective was to assess and characterise the existing functions and carryout a functional analysis of the activities in the process of design and fabrication of custom foot orthoses.

3.2 System for design and manufacturing of custom foot orthoses.

Manufacturing systems have a value chain in the production cycle based on a set of generic functions. In conventional production systems the value chain of a production system starts from the generic functions of design, fabrication, assembly and distribution (Alford et al., 2000). However, in production systems aimed at customisation, the value chain starts from function of capturing the customer requirements. All the other functions in value chain are driven by this function in production of custom made products (Cullinane et al., 1997).

3.3 Functions in the system for design and manufacture of foot orthoses.

A value chain is developed based on the core functions involved in the system for design and fabrication of custom foot orthoses (Obrovac et al., 2005; Pallari et al., 2010). The developed value chain is based on the main functions in the production systems for mass customisation described in Section 2.5.6. A series of core functions identified in the value chain of custom foot orthoses fabrication are; (i) initial consultation and foot assessment, (ii) diagnosis, (iii) design of orthoses, (iv) plan for manufacture, (v) fabrication of orthoses and (vi) delivery of orthoses. In the following section, the core functions in the system are modelled in IDEF0 diagrams which will be used in constructing the IDEF0 process model of the existing system.

3.4 Controls and mechanisms in the system.

The controls and mechanisms in the system are the elements which facilitate and ensure the smooth running of the process of design and fabrication of custom foot orthoses. Controls are the specific guidelines that direct and regulate the activities to produce correct output from the function in the system. The mechanisms are the sub-systems, machines and people that carryout the activities of the functions in the system. Table 3.1 presents the identified controls and mechanisms in the system.

Controls	Mechanisms
Clinical practices (c1)	Orthotist (m1)
Resources (c2)	Diagnostic systems (m2)
Diagnostic methods (c3)	Foot geometry capture tools (m3)
Foot geometry capture methods (c4)	Orthoses designing system/tools (m4)
Orthoses design methods (c5)	Orthoses designer (m5)
Manufacturing planning methods (c6)	Manufacturing planning system (m6)
Manufacturing techniques (c7)	Manufacturing techniques (m7)
--------------	Operator (m8)
--------------	Delivery system (m9)

Table 3.1 Controls and mechanisms in the system

3.5 Description of the core functions in the system.

The main functions and activities that turn inputs into output through specified controls and mechanisms are presented and described according to their order of sequence in the system.

- **Initial consultation and assessment (A1).**

Figure 3:1 represents the function of initial consultation and assessment (A1) in the IDEF0 diagram. The activities in this function involve collection and recording of basic information of the patient including anthropometric information (gender, age, weight and daily activities), medical history and the details about foot problem and complaint. The input for this function is the patient (i1). The orthotist (m1) works as the mechanism and carryout the initial consultation and foot assessment functions. The clinical practices (c1) and the resources of the company (c2) respectively work as the controls in the function. The clinical practices (c1) are a set of specified clinical guidelines and procedures that guide step by step carry out foot assessment function. Clinical guidelines require a basic clinical assessment to be conducted which includes primary diagnosis of the foot and reviewing the past and current medical history. The primary diagnosis involve an initial physical examination of the foot in which the clinician/orthotist (m1) examine the state and range of motions/movements, alignments, muscle functions and the apparent deformities in the foot. The resources (c2) control and regulate the consumption of resources including orthotist time for assessment, use of instruments/equipment during primary diagnoses and recording of the initial information collected.

Based on the observations and findings in the initial consultation and assessment and from the results of primary diagnoses, a prescription/recommendation report is generated as an output (o1) from the function. In the prescription report, the orthotist recommends a more detailed diagnoses and clinical tests.

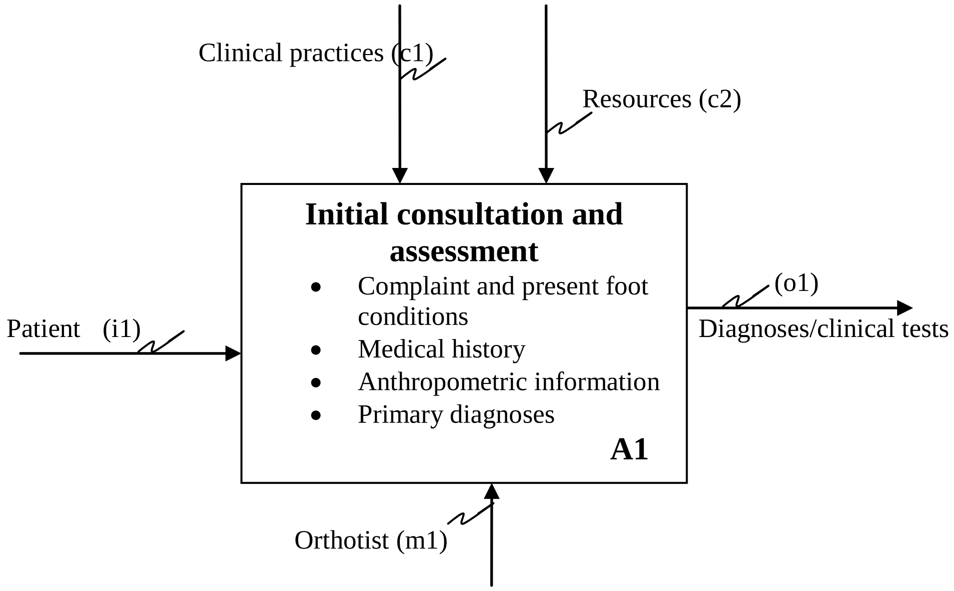


Figure 3:1 IDEF0 diagram of initial consultation and foot assessment function

- **Diagnosis (A2).**

Diagnosis is the next function in the system. Figure 3:2 represents the IDEF0 diagram of diagnosis function (A2). The function involves the activities to conduct the pathological tests, x-rays and relevant clinical tests. The recommendations for the clinical tests and detailed diagnosis (i2) work as input for this function. The function is carried out by orthotist (m1) using the diagnostic systems (m2) which work as the mechanisms in the process. The clinical practices (c1), resources (c2) and diagnosis methods (c3) works as the controls in the function. The clinical practices (c1) guide to perform the diagnosis function according to specified clinical procedures. The resources (c2) regulate the consumption of resources such as clinician time, time in diagnosis and use of instruments/equipments. The diagnosis (c3) process involves the set of standard clinical methods and practices which regulate and guide to carry out this function. The results and findings from diagnosis form a base which assists the orthotist in making the decision for surgical or non-surgical treatment. In case of non-surgical treatment, prescription for the foot orthoses (o2) is generated as an output from this function.

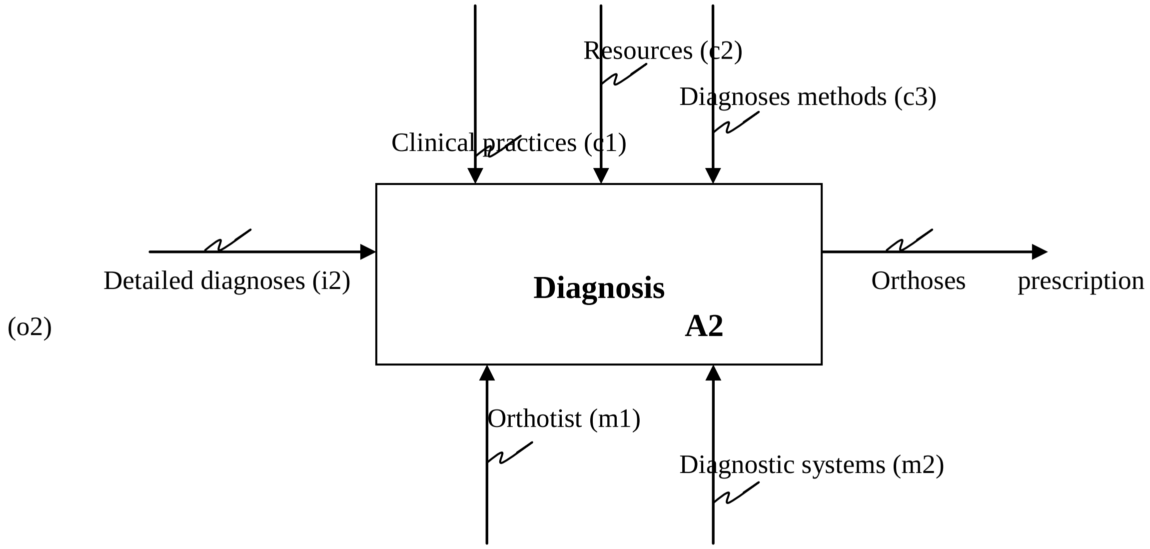


Figure 3:2 IDEF0 diagram of diagnoses function

- **Design of orthoses (A3).**

Figure 3:3 represents the function of designing the orthoses (A3) in the IDEF0 diagram. The activities in the function are foot geometry capture and design of orthoses. The prescription for the orthoses works as the input (i3) for this function. In the first step, foot geometry is captured. The orthotist works as mechanism (m1) and captures the foot geometry using the geometry capturing equipment and tools (m3) under specified foot geometry capturing methods (c4). In the next step, the designer (m5) designs the orthoses according to guidelines of design methods (c5) using the designing tools and equipment (m4) as the mechanism. The geometry capturing methods (c4) guides step by step foot geometry capturing process. The available resources (c2) regulate the consumption of resources including orthotist time in foot geometry capture process, designer time in designing foot orthoses and equipments, tools and consumables in geometry capture and design processes. The designer (m6) incorporates the prescribed design features in the captured foot geometry impression cast using the design equipments and tools (m5) as the mechanism. After incorporation of design features, the designer develops and rectifies the positive model of the orthoses. The orthoses design methods (c5) regulate and guide the methods for designing the orthoses. The output from this function is final design of the orthoses (o3).

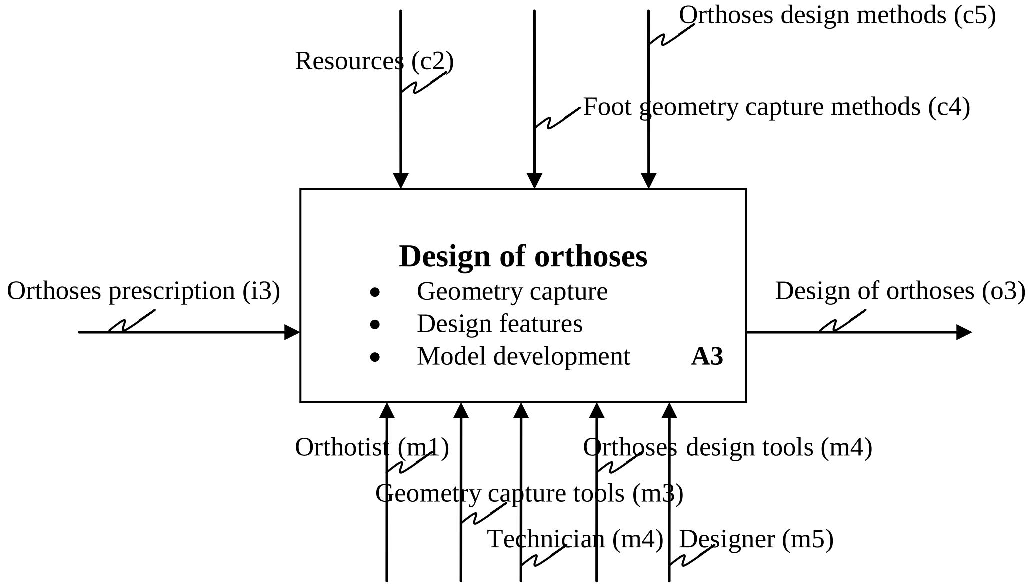


Figure 3:3 IDEF0 diagram of function of design of orthoses

- **Planning for manufacturing (A4).**

Figure 3:4 represents the function of planning for manufacturing the orthoses (A4) in IDEF0 diagram. The function involves generation of process plans, scheduling of production plans and establishment of quality control and inspection activities. The final design of the orthoses is used as input (i4) for this function. The function is carried out through manufacturing planning systems (m6) which comprise the systems and people involved in planning and organising the manufacturing activities under the specified manufacturing planning methods (c6) by using the resources of the company (c2). The output from this function is production order (o4) for the orthoses.

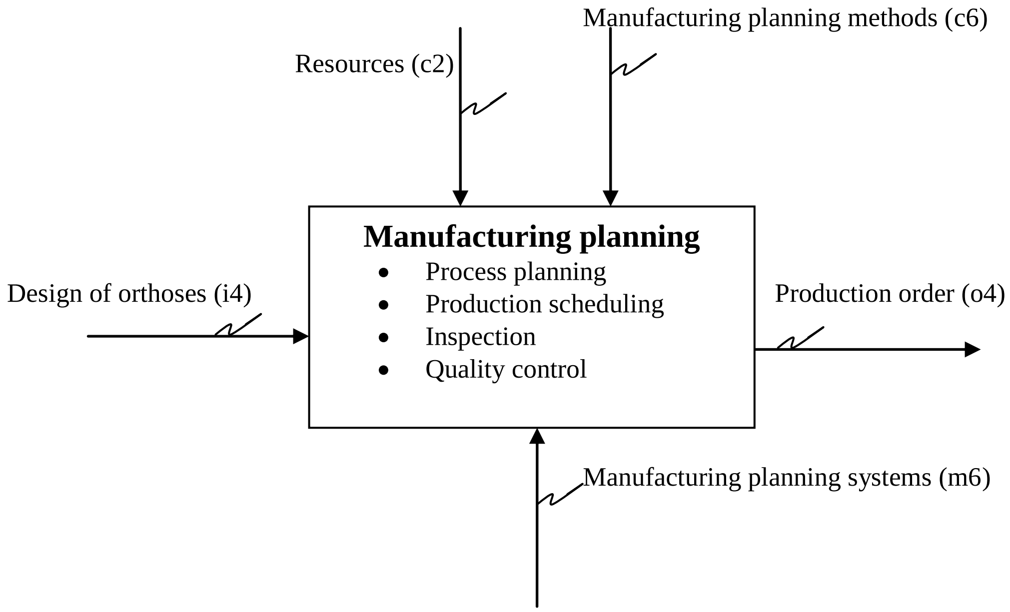


Figure 3:4 IDEF0 diagram of function of planning for manufacturing

- **Manufacturing of orthoses (A5).**

Figure 3:5 shows the function of manufacturing of the orthoses (A5) in the IDEF0 diagram. The activities in the function involve fabrication of the orthoses. The production order for the orthoses works as input (i5) for this function. The manufacturing techniques (m7) and machine operator (m8) work as the mechanisms in the system. In fabrication of orthoses currently conventional CAD/CAM techniques are used. The techniques involve turning and milling operation in the fabrication process. Further the orthoses require manual post processing work of trimming and finishing. The manufacturing techniques (c7) guide and regulate the fabrication function using the resources of the company (c2). The output from this function is the fabricated orthoses (o5).

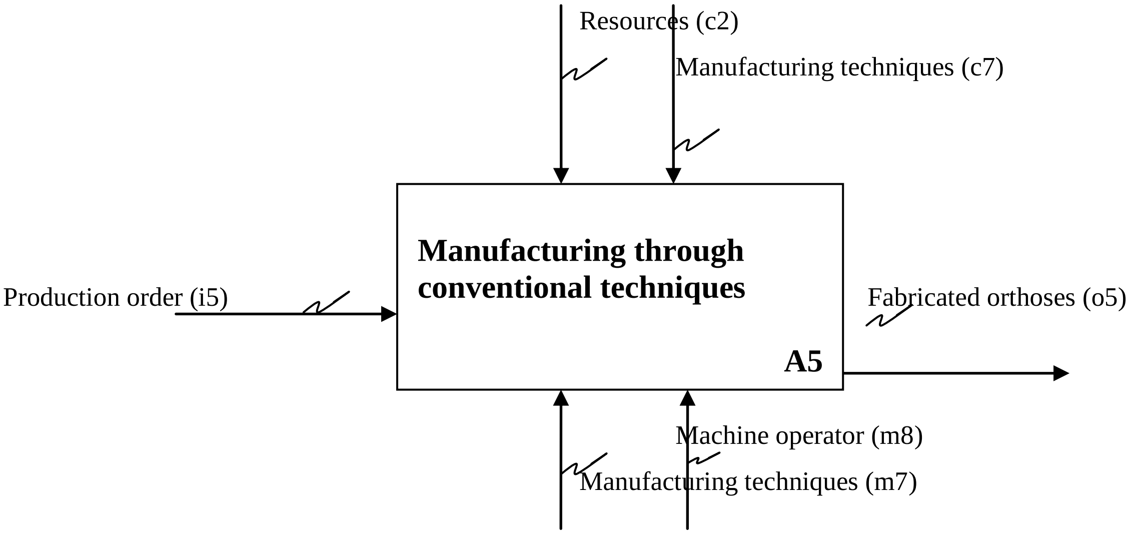


Figure 3:5 IDEF0 diagram of function of orthoses manufacturing

- **Delivery of the orthoses (A6).**

Figure 3:6 represents the IDEF0 diagram of function of delivery of the orthoses (A6) which is the last function in the system. The activities in the function are delivery of the orthoses to the patient either by collection at the manufacturing facility or delivering through an established delivery system. The fabricated orthoses work as input (i6) for this function. The system for delivering the orthoses (m9) works as the mechanism through which the orthoses is delivered to the patient using the resources (c2); collection of orthoses at company shop or delivering through courier services. The output from this function is the delivery of orthoses to the patient within pre specified delivery time (o6).

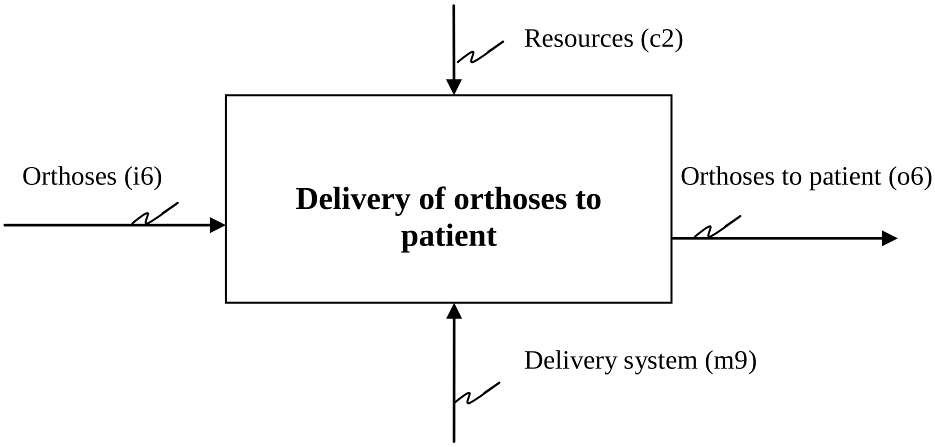


Figure 3:6 IDEF0 diagram.of function of delivery of orthoses

All the core functions in the system of design and manufacturing for custom foot orthoses are presented and described. Based on the core functions, controls and mechanisms in the system; a system for the design and fabrication of custom foot orthoses is modelled in the existing operate-based state in IDEF0 process model in the following sections.

3.6 Development of the process model.

A process model has been developed for the system of design and fabrication of custom foot orthoses. The methodology in the development of process model is adopted from the approach of (Cullinane et al., 1997). They used IDEF0 methodology for modelling the mass customisation production systems (MCP) and developed a generic IDEF0 operate-based process model. The model forms a basis which provides the guidelines in the development of specific models for the individual systems and companies.

As mentioned in the Section 2.5.10, various researchers also have used IDEF0 modelling methodology in developing the process model for design and fabrication system for production of customer-specific components and parts including Tuck and colleagues (Tuck et al., 2008) for fabrication of custom-made seat and Colombo and colleagues (Colombo et al., 2010) for the fabrication of customer-specific lower limb prostheses. In this work a process model for design and fabrication of custom foot orthoses is developed and modelled on IDEF0 modelling principles which are;

- Development of “context” model (A-0) of the system.
- Development of “as-is” model (A0) of the system in existing operate-based state.
- Development of “as-to-be” (A-1) rapid manufacturing based model of the system.

3.6.1 Development of generic model (A-0) of the system.

In the first step, a generic model (A-0) of the system is developed in which the purpose of the system is stated. The generic model (A-0) presents the generic view of the entire system. In IDEF0 modelling methodology the generic models are decomposed to a required level for capturing the details of the systems. Decomposition is a starting point in order to construct the detailed models generally called “as-is” models of the systems. An “as-is” model (A0) of the system represents the system in its existing “as-is” state and provides basis for functional analysis of the activities and functions involved in the systems (Ang et al., 1994). In Figure 3:7 a generic IDEF0 model (A-0) of the system of design and fabrication of custom foot orthoses is developed which shows all the required inputs, outputs, controls and mechanisms in the system.

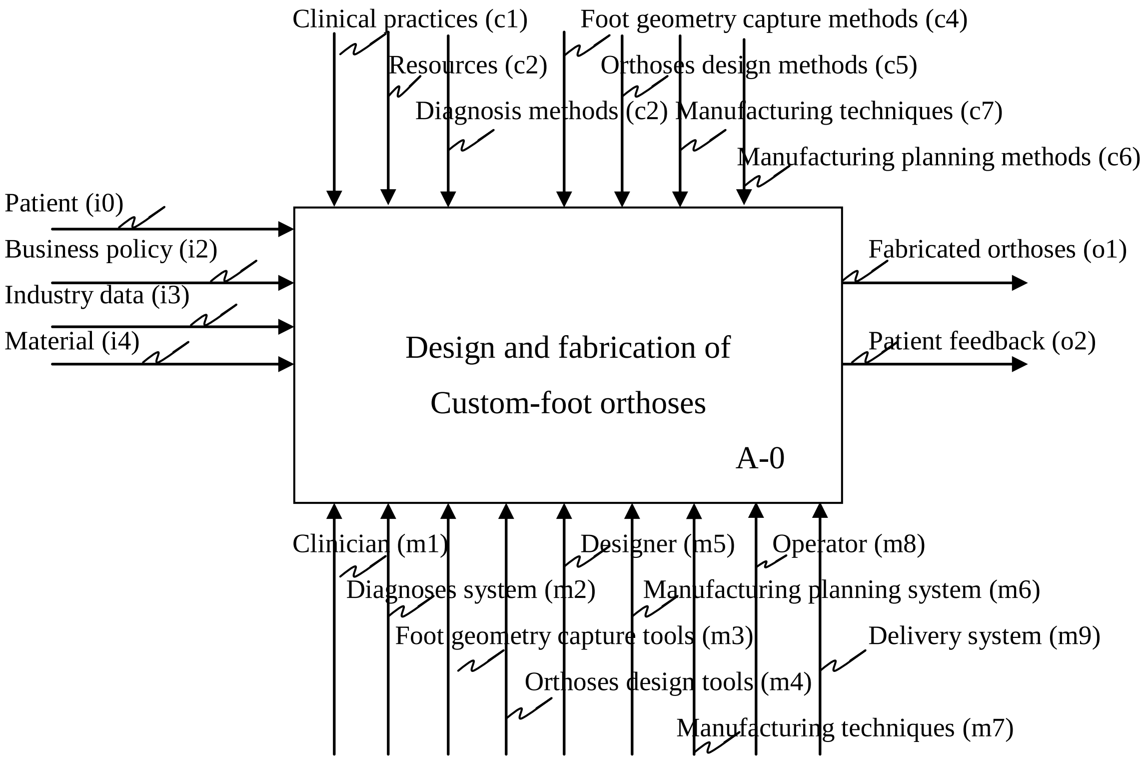


Figure 3:7 Generic model (A-0) of design and fabrication system for custom foot orthoses.

In following section, an "as-is" model (A0) of the system is developed from the generic model (A-0) of the system shown in Figure 3.7. All the functions and activities involved in the generic model (A-0) are exposed with detail in order to develop an "as-is" (A0) model of the system. An "as-is" model (A0) represents all the functions and activities of design and fabrication system in its existing operate-based state.

3.6.2 Development of an "as-is" model (A0) of the system.

In the development of "as-is" model (A0) of the system, the generic model (A-0) shown in Figure 3.7 is decomposed and the details of the system is generated. The main functions in the system discussed in the Section 3.5 are exposed by decomposition process. The main objective of development of an "as-is" model (A0) of the system is to understand the existing design and fabrication process and to review the whole system. The "as-is" model (A0) helps in to carryout functional analysis by evaluation of all the individual functions involved in the system in order to improve the existing design and fabrication process. Figure 3:8 shows the developed "as-is" model (A0) of the system.

In the “as-is” model (A0), all the functions shown in the system turn inputs into outputs through specified mechanisms under the guidelines of specified controls in the system. The functions in the systems generally are analysed and evaluated by the performance analysis of the functions. The performance measurement is a process of quantifying the effectiveness and efficiency of a function (Slack, 2001; Tangen, 2003). The performance of a function is generally stated in terms of cost, time, speed, quality, satisfaction and additional value (Zhang, 2000). The level of performance of a function in the system is a key factor in decision making for redesigning or replacing the existing function in order to improve the overall performance of the system (Xiao et al., 2004).

The “as-is” model (A0) of the existing design and fabrication system for custom foot orthoses is shown in Figure 3.8 which represents the core functions of; initial foot assessment, diagnosis, orthoses design, manufacturing planning, orthoses fabrication and orthoses delivery functions. All the specified controls and mechanisms used in the existing process of the system are shown in detail. The “as-is” model (A0) process model of the system provides the basis for improvements in the system by redesigning the existing design and fabrication process by integration of rapid manufacturing techniques in the system.

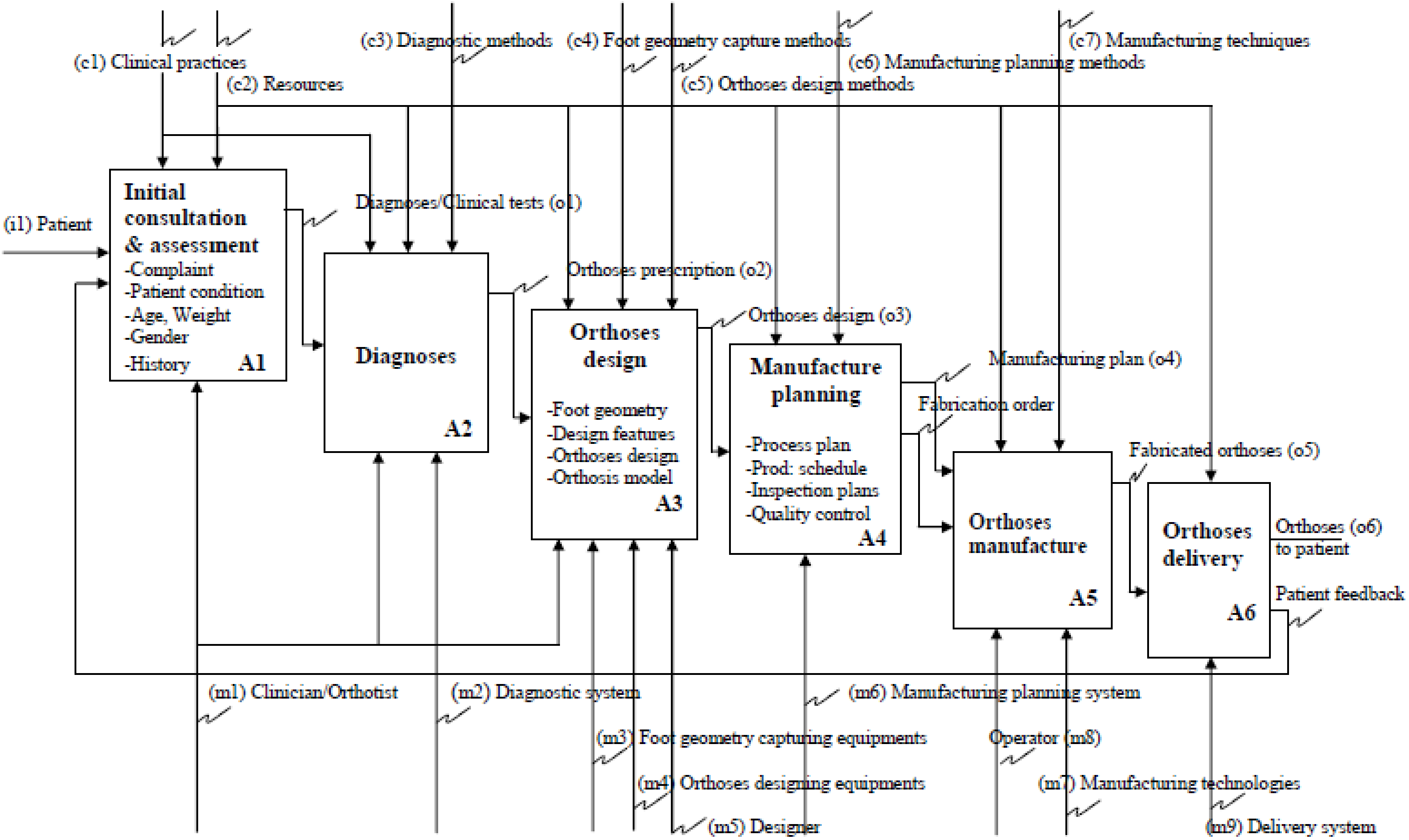


Figure 3:8 An “as-is” model (A0) of the system the in existing operate-base state.

3.6.3 Development of rapid manufacturing based model (A-1) of the system

An “as-is” (A0) model of the system is redesigned in order to integrate the rapid manufacturing approach in the system of design and fabrication of custom foot orthoses. A potential rapid manufacturing based “as-to-be” model (A-1) of the system is developed which shows the applications of rapid manufacturing approach in the system. Figure 3:9 represent the developed potential rapid manufacturing based “as-to-be” model (A-1) of the system.

3.6.4 Controls and mechanisms in rapid manufacturing based process model of the system

In the potential rapid manufacturing based design and fabrication system for custom foot orthoses, the identified controls and mechanisms in the system are listed in Table 3.2.

Controls	Mechanisms
Clinical practices (c1)	Clinician (m1)
Resources (c2)	Diagnostic system (m2)
Diagnostic methods (c3)	Foot scanning system (m3)
Foot scanning software (c4)	CAD orthoses design system (m4)
CAD orthoses design software (c5)	Orthoses designer (m5)
Manufacturing planning (c6)	Manufacturing planning system (6)
Rapid manufacturing techniques (c7)	Rapid manufacturing system (m7)
--------	Operator (m8)
--------	Delivery system (m9)

Table 3.2 Controls and mechanisms in the system

The application of rapid manufacturing approach has changed the system of design and manufacture of custom foot orthoses. As mentioned in Section 2.3, fabrication process in rapid manufacturing techniques use digital data which require the design of orthoses in the digital format. For this purpose a digital foot scanning system (m3) and a CAD system (m4) respectively are included as the mechanisms for performing the functions of foot geometry capture and orthoses design. The foot scanning software (c4) and CAD based orthoses designing software (c5) work as the controls and regulate and guide the digital impression capturing and CAD based orthoses designing functions in the system.

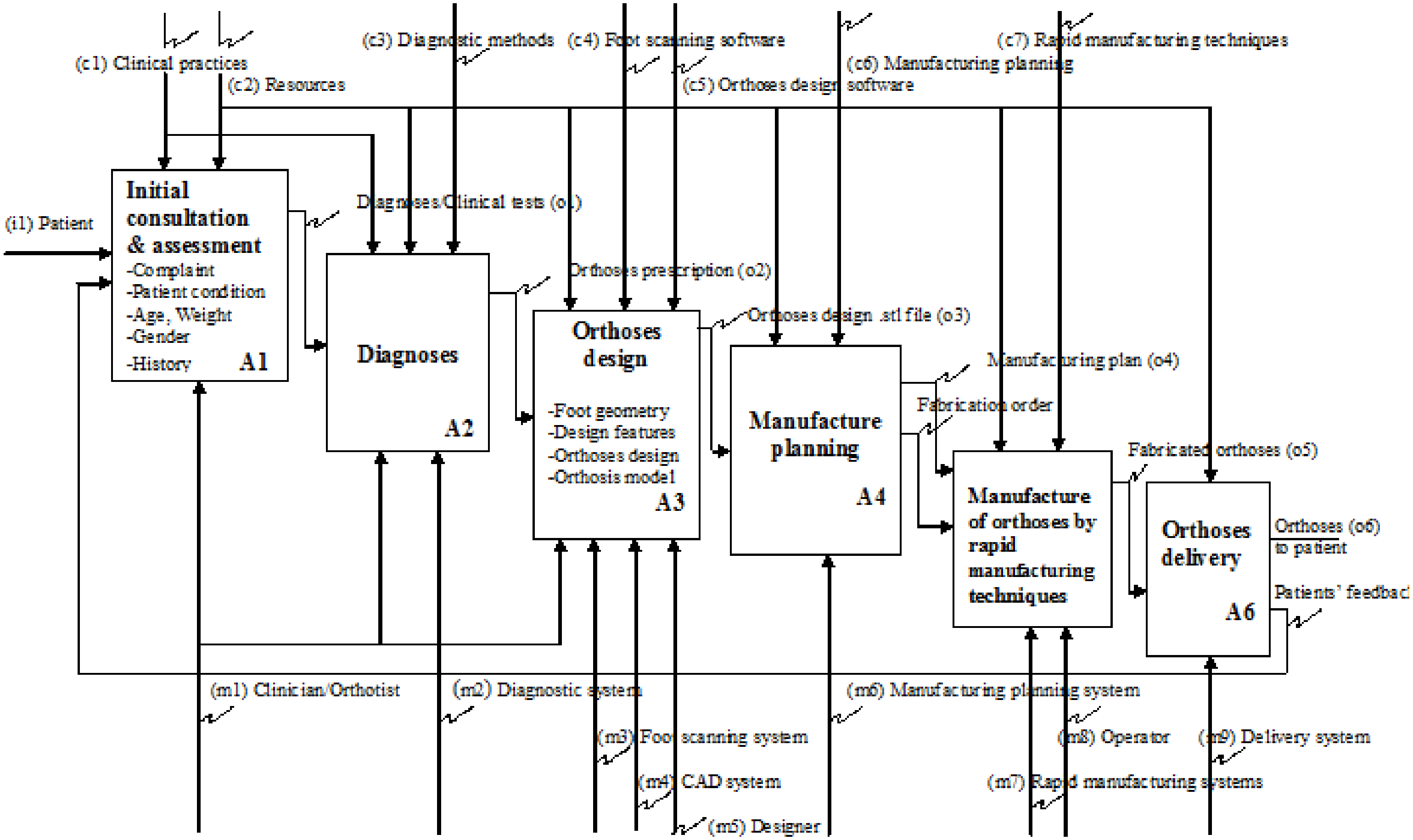


Figure 3:9 An “as-to-be” model (A-1) of the system with rapid manufacturing approach (A5 block) in the system

The developed IDEF0 based process models shown in Figure 3.8 and Figure 3.9 represents the “as-is” process model (A0) in its existing state and a proposed “as-to-be” model (A-1) of the system. In both models, step (i) and step (ii) involve same functions. However, in the proposed “as-to-be” model (A-1) the integration of rapid manufacturing approach has changed the functions and activities in the step (iii) and step (iv) in the system.

Step (iii) is the function of designing the orthoses (A3) in the “as-is” model (A-0) where the traditional foot geometry capture function is replaced by the digital geometry capture technique in which a 3D digital foot scanner is used. The function of orthoses design is replaced by the CAD system where the orthoses is designed and modelled at one place (i.e. through CAD system). This has removed the traditional manual laborious activities in the functions of foot geometry capture and orthoses design.

In step (iv) in the “as-is” model (A-0), the applications of rapid manufacturing approach reduces the traditional activities involved in the function of planning for the manufacturing (A4). The traditional activities of process planning, in process inspection and maintaining quality control requires relevant resources such as systems and software and labour work in performing the function of planning for manufacturing (A3) in the system. As discussed in the literature review in Section 2.3, rapid manufacturing techniques directly fabricate the parts designed through CAD based systems. The manufacturing preparation process (process planning) in rapid manufacturing techniques is simple and straight forward. The rapid manufacturing fabrication process consist one stage process chain; from product design to the final product. This reduces the need of process planning, in process inspection and in process quality control in comparison to traditional activities in function of planning for manufacturing in conventional production systems.

The step (v) in “as-is” model (A-0), rapid manufacturing approach has replaced the conventional manufacturing techniques such as computerised numerical controlled (CNC) for manufacturing of the orthoses (A5). The conventional techniques include both turning and milling operations. Based on the subtractive processes the techniques have limitations in the fabrication of complex geometrical parts and structures (Frank et al., 2003). Besides, the techniques require re-setting cutting tools for adjusting the varying shapes and prescribed features in the orthoses.

The rapid manufacturing approach in the system has several advantages in improving the design and manufacturing process for custom foot orthoses. The techniques are based on the additive manufacturing processes where the parts are directly fabricated from CAD based design information. This removes the requirement of tooling, moulds and equipment in the manufacturing process (Kruth et al., 1998; Pham and Dimnov, 2001; Levy et al., 2003; Tuck and Hague, 2006). In conventional manufacturing techniques, there is a direct link between complexity of the part and cost of manufacturing. The ability of rapid manufacturing techniques in the fabrication of complex geometrical parts reduces the manufacturing cost of the complex structured parts. Rapid manufacturing techniques only require raw material and digital design of parts in the fabrication process which minimise the requirements of high skilled operators (Tuck and Hague, 2006).

3.7 Potential advantages of rapid manufacturing approach in the system.

The main advantages of rapid manufacturing approach in the design and manufacturing process of custom foot orthoses identified are;

- Reduced lead-time.
- Reduced cost.
- Improved foot orthoses.
- **Reduced lead-time**

The digital foot geometry capture through digital scanning process is a quick method for capturing 3D foot impression which reduces the time in foot impression capturing process. The foot impression capturing time was reduced from 6 hours per pair in traditional methods to 1 hour 5 minutes per pair in the digital design methods mentioned in Section 4.2. The main advantage of the digital scanning process is increased accuracy and repeatability in the foot impressions capturing process (Boardman, 2007; Payne, 2007; Williams, 2010). Additionally, the scanning technique generates the 3D foot impressions in the digital format which can be easily stored and transferred electronically to different places for the fabrication.

The design of the orthoses using the CAD based systems is another advantage which improves the efficiency of the process and reduces the lead-time in the system. The orthoses design time was reduced from 5 hours 45 minutes per pair in traditional methods to 5 minutes per pair in digital methods mentioned in Section 4.5. The orthoses corrections and modifications can be digitally incorporated through CAD based designing system. The CAD system facilitates more control to the designer in designing and integrating digitally the required features in the orthoses as compared to manual incorporation of the design features in the orthoses. One of the main advantages of CAD design system is the digital incorporation of the features in the orthoses such as wedges, ramps, arch support and heel cupping which can be seen on the screen and viewed from various angles until the final model of the orthoses is designed according to required design prescription (Boardman, 2007; Williams, 2010).

- **Reduced cost.**

The rapid manufacturing approach in the system generates the digital design and manufacturing process for fabrication of custom foot orthoses. The use of various equipment, tooling and materials combined with extensive labour work during the different stages in fabrication of custom orthoses are replaced by digital design and manufacturing process which subsequently improve the efficiency of the process and increase the overall performance of the system.

In foot geometry capture process digital foot geometry capture method removes the traditional labour and cost intensive geometry capturing method. The cost benefit analysis study conducted by Payne (Payne, 2007) for foot impression casts through plaster of Paris and optical scanning has shown significant reduction in the impression capturing cost and lead-time through optical scanning. The impression capturing cost is reduced from £98 per pair to £56 per pair as mentioned in Section 4.3. Additionally, the digital scanning saves the cost for handling and storage of the foot impressions for the future use as compared to traditional storage of plaster of Paris casts and other type of impression casts.

In design stage of foot orthoses, the process involves CAD based designing system which replaces the traditional methods of designing the orthoses in which the positive moulds of the orthoses are developed from the negative casts involving labour work, tooling and materials. The traditional method involves manual corrections, modifications in designing the orthoses positive moulds (Madazahy, 2004). The manual corrections and modifications process is replaced by CAD design system. This has reduced the orthoses design cost from £18 per pair in conventional based methods to £2 per pair in digital based design method as mentioned in Section 4.6. In the fabrication stage, conventional fabrication techniques require high skill labour which is a major factor in increasing the manufacturing cost of the parts. However, in the rapid manufacturing techniques the burden of high skill labour cost is transferred to the technology itself i.e., the rapid manufacturing systems (Tuck and Hague, 2006). The rapid manufacturing systems involve minimum human interferences during the fabrication process due to the automated fabrication process and have the advantage of minimal requirements of skills and labour of the operator in the operations of the systems (Gibson et al., 2010). All these factors subsequently contribute in reducing the high skilled labour costs and overall manufacturing costs in the system.

- **Improved foot orthoses.**

The process involve digital techniques and digital systems in the design and manufacturing process that will result in increased accuracy in measurements of the foot geometry, digital incorporation of orthoses features reduces errors during the correction and modifications process and digital fabrication minimise the part errors, subsequently producing accurate and improved fit foot orthoses. The examples discussed in Section 2.3.5 of rapid manufacturing based hearing aids by Phonak and Siemens (Gibson et al., 2010), Dental braces by Invisalign and Dental bridges and Dental crowns by Sirona Dental Systems (Strub et al., 2006) have shown key advantages and benefits in terms of improved fit, easy repeatability and increased product performance and comfort in fabrication of custom made parts in comparison with the traditional fabrication process.

3.8 Summary

The rapid manufacturing based "as-to-be" process model (A-1) in Figure 3.9 shows that rapid manufacturing approach have significant advantages in the system especially in reducing the labour intensive time and cost activities. The rapid manufacturing techniques can be integrated in order to automate the system of design and fabrication of custom foot orthoses. The proposed "as-to-be" model is designed to integrate the rapid manufacturing approach in the system that will subsequently facilitate in improving the efficiency of the process and the clinical services to the patients.

The main functions in the proposed design and fabrication process model are based on digital foot geometry capturing, CAD based orthoses designing and digital fabrication through rapid manufacturing techniques. This results in development of a seamless digital design and manufacturing process for fabrication of customised foot orthoses. Overall, the automated fabrication process in rapid manufacturing systems without the need of tooling and equipments, continuous fabrication process, minimal involvement of labour and increased accuracy in the part development are the potential advantages and benefits of the rapid manufacturing approach in the design and fabrication of system for customised foot orthoses. The developed rapid manufacturing based "as-to-be" process model (A-1) will be used for the development of an automated, cost effective system with low lead-time for fabrication of custom foot orthoses. The main functions shown in "as-to-be" process model (A-1) of the system will be investigated and evaluated in detail in terms of cost, lead-time, efficiency of the individual functions and activities and their effects on performance of the overall system.

Chapter 4 Foot geometry capture and orthoses design methods.

4.1 Introduction.

In this chapter, assessment of foot geometry capture and orthoses design methods is presented. The efficiency, accuracy and reliability of different foot geometry capture and orthoses design methods are analysed and evaluated. The time and cost involved in using different foot geometry capturing and orthoses design methods for a pair of orthoses are modelled, evaluated and compared. At the end of chapter, the overall advantages and significance of the applications of 3D digital scanning method for foot geometry capture and design of orthoses using CAD system is discussed.

4.2 Time modelling of different foot geometry capture methods

Foot geometry capture time for different methods was gathered first hand by industry visits to four different orthotic manufacturers. (i) Peacocks Medical group, Newcastle UK, (ii) London Orthotics Consultancy UK, (iii) The Foot Clinic UK and (iv) The Barn Podiatry Clinic UK. Geometry capture time was cross-checked among those manufacturers using a similar manufacturing process for custom foot orthoses. The information regarding foot geometry capture time and orthoses design time was further discussed with USA based orthotic manufacturer and suppliers, Seamus Kennedy, from Hersco Ortho Labs, USA and Melanie Shelton, Amfit, Inc, USA; through personal communication. Data obtained covers both geometry capture and orthoses design times. The time required in different foot geometry capture methods was approximated through considering the time made up of (i) time required for assessment of one pair of feet by the podiatrist and (ii) time required in foot geometry capture process. In the following sections, modelling of the time required in different foot geometry capture methods is analysed and modelled.

4.2.1 Time in plaster of Paris based foot geometry capture method.

The steps involved in using plaster of Paris to obtain the foot impression casts are (i) assessment of the feet, (ii) impression casting and (iii) drying and curing of the impression cast. Step (i) approximately takes 1 hour of time and is assumed to involve a podiatrist. The assessment time was obtained through personal communication with leading orthotic clinics in United Kingdom, shown in Table 4.1. Step (ii) was assumed to take 30 minutes of podiatrist time for casting one pair of feet (Payne, 2007). Step (ii) further requires approximately 30 minutes of time to allow plaster of Paris to set properly on the foot (Saraswathy et al, 2004). Step (iii) takes at least 4 hours of curing time in order to completely dry and cure the impression casts before shipping to manufacturing facility (Seamus Kennedy, Hersco Ortho Labs, USA, Personal communication, 28.09.2010). Steps (ii) and (iii) were assumed to involve 1 hour of technician time during the casting process and performing post casting activities.

Contact name	Name of company	Contact date
1. Andrew Fisher	Orthotics Direct, UK	03.08.2010
2. Stuart Healey	The Foot Clinic, UK	03.08.2010
3. Pamela Martin	Instep Podiatry, UK	03.08.2010
4. Karin	Head & Short Footwear & Podiatry, UK	03.08.2010
5. Jo Ward	London orthotics consultancy, UK	05.10.2010
6. Yan Liu	London Medical, UK	05.08.2010
7. Sarah	The Barn Podiatry Clinic, UK	05.08.2010
8. Robbie Rooney	Sport Orthotics, UK	28.09.2010
9. Malanie Shelton	Amfit, Inc, USA	26.08. 2010
10.Seamus Kennedy	Hersco Ortho Labs, USA	28.09.2010

Table 4:1 Foot assessment time obtained from leading orthotic clinics in UK and USA.

4.2.2 Time in plaster slipper based geometry capture method.

The steps involved in plaster slipper foot impression casting method for obtaining the foot impression casts are (i) assessment of the feet, (ii) impression casting and (iii) drying. Step (i) was assumed to take 1 hour of time and to involve a podiatrist. Step (ii) was assumed to take 30 minutes of podiatrist time for impression casting of one pair of feet. Step (iii) was assumed to take at least 1 hour of curing time required for completely drying of the cast before shipping to the manufacturing facility. The use of plaster slippers impregnated with quick drying resin removes the need of assistance of the technician in the foot impression casting process.

4.2.3 Time in foam impression box geometry capture method.

The steps involved in using foam impression box to obtain the foot impression casts are (i) assessment of the feet and (ii) impression casting. Step (i) was assumed to take 1 hour of time and to involve a podiatrist. Step (ii) was assumed to take 10 minutes of podiatrist time for impression capturing of one pair of feet. The use of crushable foam in the foam impression box capturing method remove the need for drying and curing process, as required in the plaster casting methods.

4.2.4 Time in plaster casts/foam impression digitising method.

The digitisation of plaster impression casts/foam impression box casts using the scanning method to obtain foot geometry in digital format involves one step. The method involves direct scanning of the foot impression casts captured through plaster casting or foam box impression casting methods. The method was assumed to take 5 minutes of technician time for digitising the plaster casts or foam box impression casts through scanning process The scanning time was determined through personal communication with Mark Halford, Peacocks Medical group at Newcastle, UK. (Mark Halford. Peacocks Medical Group, UK, Personal communication, 25.05. 2010).

4.2.5 Time in contact digitising foot geometry capture method.

The steps involved in contact digitising method to obtain foot impression are (i) assessment of the feet and (ii) digital impression capturing. Step (i) was assumed to take 1 hour of time and to involve a podiatrist. Step (ii) was assumed to take 5 minutes of podiatrist time for capturing the impression of one pair of feet. The impression capturing time was determined through personal communication. Malanie Shelton (Melanie Shelton. Amfit, Inc, USA, personal communication, 26.08. 2010).

4.2.6 Time in 3D scan geometry capture method.

The steps involved in 3D digital scanning method for obtaining the foot impressions are (i) assessment of the feet and (ii) optical foot impression capture. Step (i) was assumed to take 1 hour of time and to involve a podiatrist. Step (ii) was assumed to take 5 minutes of podiatrist time for impression capture of one pair of feet using 3D digital scanning system. The foot impression capturing time was according to the time and motion study of digital foot scanning process conducted by Payne (Payne, 2007).

Foot impression casting method	Required time/pair (Assessment + casting)	Total Time/pair	Transportation Time for casts
Plaster of Paris casting	-1 hour and 30 minutes -30 minutes for setting -4 hours for cure time	6 hours	24 to 48 hours through courier.
Plaster slipper casting	-1 hour and 30 minutes -1 hour cure time	2 hours and 30 minutes	24 to 48 hours through courier
Foam impression box	-1 hour -10 minutes	1 hour and 10 minutes	24 to 48 hours through courier
Digitisation of plaster/foam box casts	-1 hour -5 minutes.	1 hour and 5 minutes	24 to 48 hours through courier
Contact digitising	-1 hour -5 minutes	1 hour and 5 minutes	Electronic
3D scanning	-1 hour -5 minutes	1 hour and 5 minutes	Electronic

Table 4:2 Time required in different foot geometry capture methods

Table 4.2 shows that the traditional foot impression capturing methods involve increased time to obtain the foot impression casts. The plaster of Paris casting method is labour intensive and involves manual activities in the casting process which results in increased casting time. Additionally, the methods require curing time and handling and transportation time for shipment of casts to the manufacturing facility. The plaster slipper casting method also involves manual activities in the impression capturing process and requires curing and physical transportation time for sending the casts to the manufacturing facility. In the foam box impression method the impression capturing time is lower than the plaster casting methods, as the method does not involve any liquids in the impression capturing process. However, the foam impression box casting method involves manual activities which increase the impression casting time. Additionally, the method requires transportation time for sending the foam impression box casts to the manufacturing facility.

The digitising of plaster casts and foam impression box using a scanning system involve 5 minutes of time in digitising the impression casts. However, the plaster impression casts and foam impression box casts consume significant amount of time in obtaining the foot impressions and the method requires additional time for shipment of the casts to the manufacturing facility.

The contact digitising method involves three steps process to obtain the foot impressions, which are (i) pin-up, (ii) lock and (iii) digitisation. In the first step, the mechanical pins are allowed to move upward in order to completely come in contact with plantar surface of the foot. In the next step, the mechanical moving pins are locked at the same position. In the third step, the positions of the pins are scanned in order to capture the digital impression of the foot. Although the contact digitisation method takes 5 minutes of time in obtaining the impressions of the feet and has the advantages of eliminating the manual activities and transportation time. However, the contact digitisers have limitations in capturing the posterior heel of the foot and it only captures the geometry of the plantar of the foot (Huppin, 2009).

The optical means for capturing the foot geometry in 3D scanning eliminates the labour work and other manual activities. The impression capturing is performed through direct scanning of the feet. The impression capturing process takes approximately 5 minutes of time per pair. The 3D optical scanning method is simple and one step process which significantly contribute in reducing the impression capturing time and eliminates the time for shipment and transportation of the casts.

4.3 Cost modelling of different foot geometry capture methods

The cost modelling of the different foot geometry capturing methods were approximated through considering the cost as made up of (i) cost of podiatrist labour time (ii) cost of technician labour time, (iii) cost of materials consumed and (iv) cost of equipment. The following costs were assumed in the cost modelling of foot geometry capture methods.

- Podiatrist labour cost: £50 per hour (Payne, 2007).
- Technician labour cost: £20 per hour (Peacocks Medical Group, UK, 2010).

- Plaster of Paris casting: £3 per pair (Payne, 2007)
- Plaster slipper casting: £4 per pair (STS Company, Synthetic Tubular Sock Impression Products, USA).
- Foam box impression casting: £2 per pair (A. Algeo Ltd, UK).
- Cost of plaster/foam impression box scanning system: £5150 (Amfit Inc, USA).
- Cost of contact digitiser system: £10,000 (Amfit Inc, USA).
- Cost of 3D scanning system: £10,000 (Precision 3D Limited, UK).

The costs for podiatrist labour time and plaster of Paris foot impression casting was adopted form the work of Payne (Payne, 2007) in his work for “cost benefit comparison of plaster casts and optical scans of the foot for manufacture of foot orthoses”. Labour cost per hour for the technician was obtained from Peacocks Medical Group, UK. The cost for Plaster slipper socks and foam box impression were obtained from generic orthotic material suppliers STS Company, Synthetic Tubular Sock Impression Products, USA and A. Algeo Ltd, UK, respectively. The cost for plaster/foam impression box scanning system, contact digitising system and 3D scanning system were obtained through email communication with Amfit Inc, USA and Precision 3D Limited, UK as their selling price for the equipment, materials and systems.

4.3.1 Cost in plaster of Paris based foot geometry capture method.

In the foot geometry capture method using plaster of Paris, the assessment of one pair of feet was assumed to take 1 hour of podiatrist time for assessment followed by the 30 minutes of time in the impression capturing process. This makes the podiatrist labour cost at the rate of £75 per pair in the process. The cost of consumables in the plaster of Paris casting was approximated at £3 per pair (Payne, 2007). The method also require 1 hour of time of technician labour at the rate of £20 per hour for assisting the podiatrist in the impression capturing process and packaging and shipment the impression casts to the manufacturing faculty. The total impression capturing cost using plaster of Paris geometry capturing method is approximated at £98 per pair.

4.3.2 Cost in plaster slipper based foot geometry capture method.

In the plaster slipper geometry capturing method, the assessment of one pair of feet was assumed to take 1 hour podiatrist time followed by the 30 minutes of time in the impression capturing process. This makes the podiatrist labour cost in the process at the rate of £75 per pair. The cost of consumables in the plaster slipper casting was approximated at £4 per pair (STS Company, Synthetic Tubular Sock Impression Products, USA, 2010). The total impression capturing cost using plaster slipper geometry capturing method was approximated at £79 per pair.

4.3.3 Cost in foam box impression based foot geometry capture method.

In the foam box impression geometry capturing method, the assessment of one pair of feet was assumed to take 1 hour of podiatrist time followed by the 10 minutes of time in foot impression capturing process. This makes the podiatrist labour cost in the process at the rate of £58 per pair. The cost of the consumables was approximated at £2 per pair (A. Algeo Ltd, UK, 2010). The total impression capturing cost using foam impression box geometry capture method was approximated at £60 per pair.

4.3.4 Cost in digitisation of plaster casts and foam impression box method

The digitisation of the plaster and foam impression box casts is assumed to involve less time in the foot geometry capture process. However, the plaster casts and foam box impression casts consume significant amount of time and cost in obtaining the plaster based and foam box based foot impression casts. The digitisation of the impression casts was assumed to take 5 minutes of technician time at the rate of £2 per pair. The technique does not involve any physical material in the digitisation of the impression casts. The method involves one-off cost of £5000 for the digitisation system (Amfit Inc, USA, 2010). The annual depreciation cost for digitising system is assumed at the rate of £1000 per year, considering the 5 years as a life span for digitising system. As the digitisation of one pair of impression casts takes 5 minutes of time, it is assumed that based on 220 working days per year 21120 pairs per year can be digitised at the depreciation cost of £1000 per year. This makes the digitisation cost per pair negligible in the process. The total digitisation cost for the plaster of Paris, plaster slipper and foam impression box casts were approximated at £100, £81 and £60 per pair, respectively.

The cost includes the impression capturing cost through plaster casting and foam impression box casting methods and the cost for digitisation of one pair of impression casts.

4.3.5 Cost in contact digitisation based geometry capture method

The contact digitisation method involve less time in the impression capturing process. The digitisation of one pair of feet takes 5 minutes of time and assumed to involve podiatrist labour cost at the rate of £5 per pair in the process. The contact digitisation technique does not involve any physical material in the impression capturing process; however, the method involves one-off cost of £10,000 for the contact digitising system (Amfit Inc, USA, 2010). The annual depreciation cost for a contact digitising system is assumed at the rate of £2000 per year, considering the 5 years life span for a contact digitiser system. As the assessment of one pair of the feet is assumed to take 1 hour of time, the orthotist can assess 1760 patients per year based on 220 working days per year. At the depreciation cost of £2000 per year, 1760 pairs per year can be digitised, which makes the impression capture cost approximately at the rate of £1 per pair. The total impression capturing cost in the contact digitisation method is approximated at £56 per pair which includes the assessment, foot impression capturing and equipment costs.

4.3.6 Cost in 3D scan based foot geometry capture method

The 3D digital scanning for foot geometry capturing is quick process and involve less time in impression capturing. The scanning of one pair of feet takes 5 minutes of time and assumed to involve podiatrist labour cost at the rate of £5 per pair. The technique involves one-off cost of £10,000 for the scanning system (Precision 3D Limited, UK, 2010). The annual depreciation cost for a 3D digital scanner was assumed at the rate of £2000 per year, considering the 5 years life span for a 3D digital scanner. As the assessment of one pair of feet is assumed to take 1 hour of time, the orthotist can assess 1760 patients per year, based on the 220 working days per year. At the depreciation cost of £2000 per year, 1760 pairs per year can be scanned using the 3D digital scanner. This makes the impression capture cost approximately at the rate of £1 per pair. The total impression capturing cost in the 3D digital scanning method was approximated at £56 per pair which includes the assessment, impression capturing and equipment costs.

Foot impression capturing techniques	**Assessment cost/pair**	**Geometry capture cost/pair**		**Material cost/pair**	**Total cost/pair**
	Podiatrist	Podiatrist	+Technician		
Plaster of Paris	£50	£25	+ £20	£3	£98
Plaster slipper	£50	£25	N/A	£4	£79
Foam impression box	£50	£8	N/A	£2	£60
Digitisation of impression casts					
Plaster of Paris	£50	£25 + £20 + £2		£3	£100
Plaster slipper	£50	£25 + £2		£4	£81
Foam impression box	£50	£8 + £2		N/A	£60
Digital scanning					
Contact digitising	£50	£5	N/A	£1	£56
3D digital scanning	£50	£5	N/A	£1	£56

Table 4:3 Foot geometry capturing cost involved in the different methods

Table 4.3 shows that the traditional foot geometry capturing methods have the higher impression capturing costs. In plaster of Paris casting method, the labour time of the podiatrist and technician increases the impression capturing cost. The plaster slipper casting and foam impression box casting methods also involve increased labour time, which subsequently increase impression capturing cost. The digitisation of plaster casts and foam impression casts although require less time in capturing the digital information of the cast. However, significant amount of labour time is already consumed in obtaining the plaster/foam box impression casts before the digitisation process. The contact digitising method compared with other impression capturing methods involve less time. However, the method has limitations in capturing 3D impression of the foot and captures only the geometry of the plantar of the foot.

4.4 Foot orthoses design methods

Design of custom foot orthoses involves traditional methods based on manual and labour intensive activities. However, with the technological advancements CAD based design methods were also introduced.

4.4.1 Plaster based foot orthoses design methods

Traditionally, orthoses design has been based on physically modifying the casts of the feet. The process requires development of a positive model of the impression cast using the plaster of Paris powder. The positive model is developed from negative impression cast, obtained through plaster casting method or foam impression box casting method (Hunter et al, 1995; Madazhy, 2004), as described in Section 2.4.6.

4.4.2 Steps in plaster based design method

The plaster based orthoses design process is based on two steps; (i) development of the positive model from negative impression cast and (ii) incorporation of design features in the positive model. Step (i) requires developing a positive mould by casting the plaster of Paris in the negative impression casts; creating a master model (Staats and Kriechbaum, 1989). The developed master model is then modified and corrected in order to incorporate the required design features such as adding wedges, arch height, ramps, heel lift/cupping, met pads etc to create the orthosis over it (Hunter, et al, 1995; Lasurdi and Nielson, 2000).

4.4.3 Digital based foot orthoses design methods

Digital based design process uses the CAD techniques in the orthoses design that has better efficiency, time and cost saving in the orthoses design process (Staats and Kriechbaum, 1989; Boardman, 2007, Williams, 2010). The CAD based design techniques remove the manual activities and minimises the labour work; as required in the plaster based designing methods.

4.4.4 Steps in digital based design methods

Digital based orthoses design is based on one step process in which a digital representation of the foot impressions/casts is used for designing the orthoses through CAD system. The orthoses design features such as wedges, ramps, arch support, met pads and heel lift/cupping are digitally incorporated in the digital representation of foot impression/casts using the specific orthosis design software.

4.5 Time modelling of conventional orthoses design methods

The time required in the plaster based design methods were approximated through considering the time as made up of (i) time required for development of positive mould and (ii) time required for corrections and incorporation of orthoses design features in the positive model.

4.5.1 Time modelling of plaster based design methods

The steps involved in design of foot orthoses using plaster of Paris casts are (i) development of the positive model of impression cast and step (ii) incorporation of the design features in positive model. Step (i) was assumed to take 15 minutes of time per pair and to involve a technician in the process. Step (i) further requires 1 hour of time as the setting time (Hunter et al, 1995) and 4 hours as the curing time for the positive model to be completely dry before the manual corrections and modifications (Seamus Kennedy, Hersco Ortho Labs, USA, Personal communication, 28.09.2010). Step (ii) was assumed to take 30 minutes of time per pair for corrections, modification and incorporation of design features in the positive model by an orthotic technician (Mark Halford, Personal communication Peacocks Medical Group UK, 2010).

The orthoses design process using plaster slipper negative impression casts and foam box impression method is identical to that of using a plaster of Paris cast. The only difference is the form of the initial negative cast/mould. The timing above is therefore also assumed for orthoses design from plaster slipper casts and foam box impression casts. Table 4.4 shows the orthosis design time when using plaster based designing methods.

Plaster based design methods	Positive mould/pair	Setting and cure time	Designing time/pair	Total time/pair
Plaster of Paris casts Plaster slipper casts Foam box casts	15 minutes	1hr + 4hrs	30 min	5hrs 45 min

Table 4:4 Time in conventional methods base designing

4.5.2 Time modelling of digital based orthoses design methods.

Design time in using the foot impression obtained through contact digitiser, 3D scanning and scanning of the plaster and foam impression box casts is based on one step. The design process is assumed to take 5 minutes of time per pair and to involve a designer in the process (Melanie Shelton, Amfit Inc, USA, Personal communication, 26.08.2010; Mark Halford, Peacocks Medical Group, UK, 2010). In the design process, the designer incorporates digitally the perspective alterations and prescribed design features using the specific orthoses design software tools. Finally, a virtual 3D model of the corrected orthoses is developed in the digital file format.

The digital based design processes are identical to each other, as all the techniques use the scanned information of the foot impression for designing the orthosis. The only difference is in the type of technique used for capturing the initial information of the foot impression. The orthoses design time mentioned above is therefore assumed identical in digital based impression capturing technique including; scanned information of the plaster/foam impression box casts, contact digitising and 3D scanned foot impression. Table 4.5 shows design time in the digital based methods.

Digital based design methods	Labour time/pair	Total time/pair
Plaster casts/foam box scanning Contact digitiser scanning 3D digital scanning	5 minutes	5 minutes

Table 4:5 Design time in digital based methods

4.6 Cost modelling of conventional based design methods.

Cost modelling of plaster based orthoses design methods were approximated through considering the cost as made up of (i) cost of the technician time and (ii) cost of material consumed. The following costs have been assumed in the cost modelling of plaster based designing methods.

- Orthotic technician labour cost: £20 per hour (Brocklesby and Wools, 2009)
- Material cost for 2 kgs of plaster of Paris powder per pair (Philips, 1990), @ £1.5 per kg (A. Algeo Ltd UK, 2010).

These assumptions give a labour cost of £15 per pair and the material cost of £3 per pair (Algeo Ltd UK, 2010), giving a total approximated cost of £18 per pair in the plaster based design processes. Table 4.6 shows the design cost using plaster based methods.

Plaster based design methods	Labour cost/pair	Material cost/pair	Total cost/pair
Plaster of Paris casts Plaster slipper casts Foam impression box casts	£15	£3	£18

Table 4:6 Design cost in plaster based methods

4.6.1 Cost modelling of digital based design methods.

The cost modelling of digital based orthoses designing methods has been approximated through considering the cost as made up of (i) cost of the designer time and (ii) equipment cost. The following costs have been assumed in cost modelling of digital based designing methods.

- Designer labour cost: £20 per hour (Peacocks Medical Group, UK)
- Cost of CAD system and design software £5000 (Amfit.com, 2010)

Digital based design methods	Labour cost/pair	Material cost/pair	Total cost/pair
Plaster casts/foam box scans Contact digitiser scans 3D digital scans	£2	N/A	£2

Table 4:7 Design cost in digital based methods

Table 4.7 shows the design cost in the digital based methods. Digital techniques remove the traditional activities in the design process. Additionally, the techniques eliminate the use of materials and manual activities which significantly reduces the designer labour time and cost. However, the digital orthoses design method involves one-off cost of £5000 for the CAD system and orthoses designing software. The annual depreciation cost for CAD design system and orthoses software is assumed at the rate of £1000 per year; considering 5 years life span for the CAD system and software. As the designing of one pair of orthoses takes only 5 minutes of time per pair of designer time (Mark

Halford, Peacocks Medical Group, UK, 2010), it is assumed that in 220 working days per year a total of 21120 pairs per year can be designed at the depreciation cost of £1000 per year for the CAD system. This makes the equipment cost per pair negligible in the process. The assumptions above give a design cost of approximately £2 per pair in the digital based design processes.

4.7 Summary.

Table 4.2 shows the time modelling in plaster based foot geometry capture methods and digital based geometry capture methods. The digital based geometry capture method involves reduced time of 1 hour and 5 minutes per pair as compared to 6 hours of time per pair in conventional foot geometry capture methods. Table 4.3 shows the cost modelling in plaster based geometry capture methods and digital based geometry capture methods. The digital based method involves lower cost of £56 per pair as compared to £98 per pair in the conventional based methods. The comparison shows that the plaster based methods involve longer time and are cost intensive methods. The methods are craft based and labour intensive involving manual and physical work, where the foot geometry capture is based on the experience and craftsmanship of the individual designer.

Table 4.4 shows the time modelling in plaster based orthoses design methods and Table 4.5 shows digital based orthoses design methods. The digital design methods involve decreased design time of 5 minutes per pair as compared to 5 hours 45 minutes per pair in conventional design methods. Table 4.6 shows the cost modelling in plaster based design methods and Table 4.7 shows the digital based design methods. The digital based design method involves £2 per pair as compared to £18 per pair in the conventional design based methods. The comparison shows that the plaster based design methods involve longer time and are cost-intensive methods. The methods are craft based and labour intensive involving manual and physical work, where the orthoses design is based on the experience and craftsmanship of the individual designer.

The digital based foot geometry capture and CAD based orthoses design methods have the additional advantages of increased accuracy, reliability and repeatability if necessary. Holding 3D foot geometry and CAD based orthoses designs in digital format also reduces the time and cost required for storage and handling of casts and designed orthoses. Based on the number of factors mentioned, it is concluded that digital based geometry capture and CAD based orthoses design offer significant benefits to the industry. However, for these to be realised, the downstream processes in fabrication of foot orthoses must be capable of operating with digital information.

Chapter 5 Foot orthoses fabrication methods

5.1 Introduction

In this chapter build-time and material consumption in fabrication of custom foot orthosis model through different rapid manufacturing techniques is presented. Commercially established rapid manufacturing techniques including (i) Fused deposition modelling (FDM) using Dimension SST 768 system and uPrint system by Stratasys, Inc, USA, (ii) PolyJet 3DP using Connex^{TM} 500 system by Objet Geometries, Israel, (iii) Stereolithography using *ipro* 8000 SLA system, (iv) V-Flash 3D system and (v) Selective laser sintering using *spro* SD 60 SLS system by 3D systems Inc. USA, for fabrication of foot orthosis model.

5.2 Selection of rapid manufacturing techniques for orthoses fabrication

The selection of rapid manufacturing techniques for fabrication of foot orthoses was based on various medical applications of RM techniques discussed in Section 2.3.4 for fabrication of surgical and diagnostic aids, tissue engineering and scaffolds, prosthetic fabrication and medical models (Gibson et al, 2010, Wohlers, 2010). The significant advantages of the rapid manufacturing techniques are; ease in the fabrication of custom-specific complex geometrical parts and devices, increased accuracy and consistency in final parts with the additional advantage of repeatability for custom-specific personalised parts and products.

5.2.1 Requirement of the process

- Low lead-time as the objective is to get custom made orthoses within 24 hours of time after initial foot assessment process and prescription of orthoses.
- Fabrication of complex orthoses design features with increased accuracy, and consistency.
- Established and seamless manufacturing process to minimise complications in the production.
- Increased automation in design and fabrication process.
- Reduced finishing and trimming time and manual labour.

5.2.2 Selection of materials

Most of materials for foot orthoses are rigid to semi rigid, as the primary aim of foot orthoses is to improve functionality and provide support. The soft materials tend to “bottom out” and break down quickly during the amount of activities in the service phase which significantly reduces the orthoses service life and support (Goodman, 2004; Caselli, 2004).

The material for foot orthoses must combine physical and mechanical properties characteristics including elasticity, density, durability, flexibility, compressibility, strength and stiffness, ease of fabrication and availability (Rome, 1990; Nicolopoulos et al, 2000). Stiffness and strength are the main two important characteristics in orthoses materials along with other mechanical and physical properties as the foot orthoses during the service phase have to carry out and withstand the whole body weight in parallel with serving and addressing specific treatment objectives for the patients.

- **Material selection**

Requirements of material used in foot orthoses are;

- Hard and stiff enough to be able to realign the foot when most of the body weight is going through it during the service phase.
- Impact resistant as the orthoses should be able to withstand rough handling.
- Should be able to withstand extended use with users without any change in material properties.
- Ease of fabrication.
- Ease of use.
- Availability.

Table 5.1 shows the mechanical properties of traditional materials from semi rigid to rigid materials used in the orthoses fabrication; discussed in Section 2.4.4. In rigid and semi-rigid custom orthoses, the thickness of orthoses shell commonly ranges from 2 mm to 4 mm (Mcpoil and Brocao, 1985; Lockard, 1998; Steven, 2002).

Mechanical properties		Units
Ethylene vinyl acetate EVA		
Young’s modulus	10 - 40	MPa
Yield strength	12-18	MPa
Tensile strength	16 - 20	MPa
Fracture toughness	0.5 – 0.7	MPa
Polypropylene PP		
Young’s modulus	89 - 1500	MPa
Yield strength	20.27 - 37.2	MPa
Tensile strength	27.6 - 41.4	MPa
Fracture toughness	3 – 4.5	MPa
Acrylonitrile butadiene styrene ABS		
Young’s modulus	1100 - 2900	MPa
Yield strength	18.5 - 51	MPa
Tensile strength	27.6 – 55.2	MPa
Fracture toughness	1.19 – 4.29	MPa
Polycarbonate PC		
Young’s modulus	2000 - 2400	MPa
Yield strength	59 - 70	MPa
Tensile strength	60 - 72	MPa
Fracture toughness	2.1 – 4.6	MPa
Poly methylmethacrylate (PMMA)		
Young’s modulus	2240 - 3800	MPa
Yield strength	53.8 – 72.4	MPa
Tensile strength	48.3 – 79.6	MPa
Fracture toughness	0.7 – 1.6	MPa
Polyamides PA		
Young’s modulus	2620 - 3200	MPa
Yield strength	50 -94.8	MPa
Tensile strength	90 - 165	MPa

Table 5:1 Mechanical properties of traditional materials (Edupac, 2011)

Traditional materials	Dimension (mm)			E (MPa)	Relative Bending Stiffness (N.mm)
	Length (l)	Width (w)	Thickness (d)		
1. Ethylene vinyl acetate EVA	**80**	**10**	**4**	**10**	640
			3.5		428.75
			3		270
			2.5		156.25
			2		80
2. Polypropylene PP	**80**	**10**	**4**	**89**	5696
			3.5		3815.875
			3		2403
			2.5		1390.625
			2		712
3. Acrylonitrile butadiene styrene ABS	**80**	**10**	**4**	**1100**	70400
			3.5		47162.5
			3		29700
			2.5		17187.5
			2		8800
4. Polycarbonate PC	**80**	**10**	**4**	**2000**	128000
			3.5		85750
			3		54000
			2.5		31250
			2		16000
5. Poly methyl methacrylate (PMMA)	**80**	**10**	**4**	**2240**	143360
			3.5		96040
			3		60480
			2.5		35000
			2		17920
6. Polyamides PA	**80**	**10**	**4**	**2620**	167680
			3.5		112332.5
			3		70740
			2.5		40937.5
			2		20960

Table 5:2 Relative bending stiffness in traditional material (2 to 4 mm thicknesses)

RM Materials	Dimensions (mm)			E (MPa)	Relative Bending Stiffness (N.mm)
	Length (l)	Width (w)	Thickness (d)		
1. ABS 400	**80**	**10**	**4**	**1834**	**117376**
			3.5		78632.75
			3		49518
			2.5		28656.25
			2		14672
2. ABS 430	**80**	**10**	**4**	**2204**	**141056**
			3.5		94496.5
			3		59508
			2.5		34437.5
			2		17632
3. ACCURA 55	**80**	**10**	**4**	**2690**	**172160**
			3.5		115333.75
			3		72630
			2.5		42031.25
			2		21520
4. Duraform PA	**80**	**10**	**4**	**1387**	**88768**
			3.5		59467.625
			3		37449
			2.5		21671.875
			2		11096
5. FTI-GN	**80**	**10**	**4**	**1700**	**108800**
			3.5		72887.5
			3		45900
			2.5		26562.5
			2		13600
6. VeroWhite fullcure 830	**80**	**10**	**4**	**2137**	**136768**
			3.5		91623.875
			3		57699
			2.5		33390.625
			2		17096

Table 5:3 Relative bending stiffness in RM material (2 mm to 4 mm thicnesses)

The custom foot orthoses are prescribed for provision of “comfort” or for “improving” the foot function. The implications of bending stiffness are to improve foot function and comfort. The value of bending stiffness depends on the specific intended function and comfort in the prescribed orthoses. The orthoses prescribed in order to primarily provide pain relief requires a quite low stiffness in order to be comfortable. The orthoses prescribed in order to improve the foot function typically require higher stiffness.

As earlier mentioned, in rigid and semi-rigid orthoses fabricated from nylon or propylene material the thickness of orthoses shell ranges from 2 mm to 4 mm, so there is not an ideal value of bending stiffness in custom-made orthoses. However, there is a useful range of values of bending stiffness according to thickness size of the orthoses shell prescribed for specific purposes (pain relief or foot function). Table 5.2 and 5.3 shows the range of relative bending stiffness of conventional materials and rapid manufacturing materials with varying thicknesses from 2 mm to 4 mm for orthoses shell.

The orthoses prescribed for improving the foot function and correct the walking behaviour is generally fabricated from rigid materials such as Polypropylene (PP) in different thickness sizes ranging from 2 mm to 4 mm according to conditions and requirements of the patients. Table 5.2 shows the calculated values for relative bending stiffness in Polypropylene (PP) material ranging from 712 to 5696 N.mm. The values of relative bending stiffness in rapid manufacturing materials shown in Table 5.3 qualify the range of values in traditional materials used for orthoses shell of varying shell thickness sizes. Figure 5.1 shows the relative bending stiffness of traditional materials with comparison to relative bending stiffness of rapid manufacturing materials, shown in Figure 5.2 used in fabrication of orthosis model. The comparison shows that the rapid manufacturing materials offer potential to be used as orthoses material for end use product.

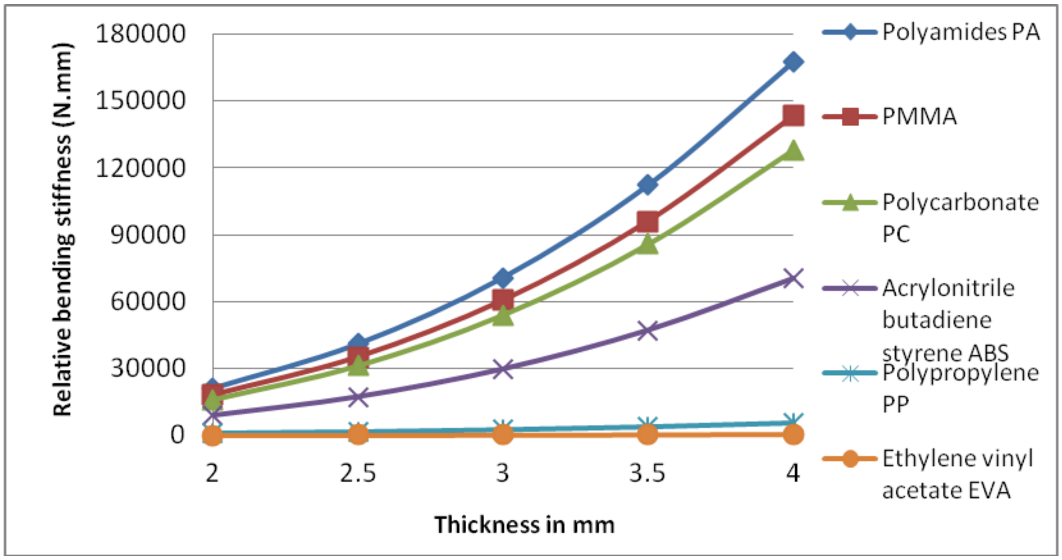


Figure 5:1 Relative bending stiffness in traditional materials

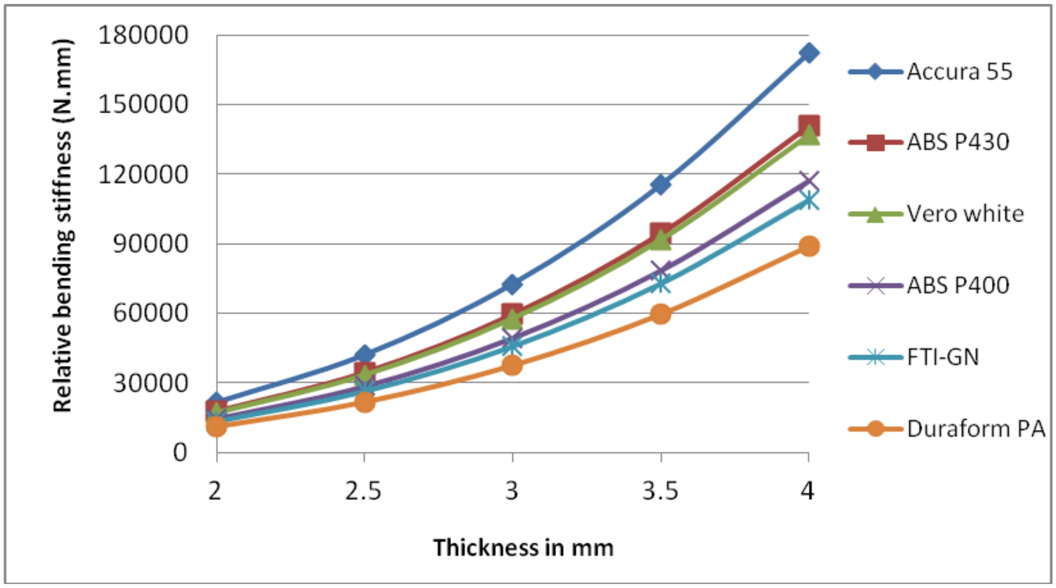


Figure 5:2 Relative bending stiffness in RM materials

5.3 Fabrication of the orthosis model.

The CAD based designed model of orthosis in stl. file format was used for fabrication of orthosis model. The orthosis model was adopted from the work of Pallari. J. H (Pallari, 2008) for mass customisation of foot orthoses for rheumatoid arthritis patients. The orthosis model was designed in order to realign and improve the biomechanical movements and foot functions for rheumatoid arthritis patients.

Table 5.4 shows the specifications of the fabricated orthosis model. Figure 5.3 show foot orthosis model with a volume of 83596.162mm^3, surface area of 32145.781 mm^2 and bounding box of 179.52 x 79.81 x 50.82 mm. The 3D CAD based model was fabricated and build-times were obtained from the proprietary machine software for the following RM technologies on well established 6 different rapid manufacturing systems with default software parameters having different slice thickness. There are good physical reasons to use particular slice thickness in different rapid manufacturing systems. This is related to physics and chemistry of the layer consolidation method during the fabrication process in different rapid manufacturing systems. Rapid manufacturing systems are optimised with standard operating parameters. Moving away from these parameters often invalidities the warranties and can deliver a poor quality product.

- Specifications of the orthosis model.

Measurements of orthosis model	
Orthosis model	Width 179.52, depth: 79.81 mm height 50.82 mm

Table 5:4 Measurements of fabricated orthosis model accorss all RM techniques

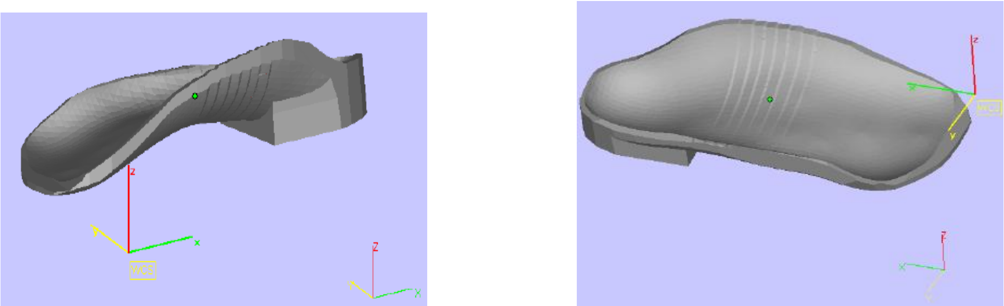


Figure 5:3 Orthosis 3D file used as benchmark part across all RM techniques (Pallari, 2008)

5.4 Rapid manufacturing systems used in orthosis model fabrication.

Table 5.5 shows the technical specifications and material cost in different rapid manufacturing techniques used for fabrication of orthosis model. The orthosis models were fabricated on default machine parameters with same specifications of the orthosis model were across the rapid manufacturing systems used.

Printer name	**Build volume mm**	**Approx. resolution mm**	**BV cm^3**	**Material cost £/kg**
spro 60 SD SLS	381 x 330 x 457	±0.08	57458.61	64.00
ipro 8000 SLA	650 x 350 x 300	±0.05	68250.00	285.00
Polyjet Connex 500	500 × 400 × 200	0.1 - 0.3	40000.00	225.00
3DP V-Flash	178 x 229 x 203	±0.22	8259.08	455.00
Dimension uPrint	203 x 152 x 152	±0.245	4719.47	330.00
Dimension SST 768	203 x 203 x 305	±0.245	19677.38	330.00

Table 5.5 Technical specifications of different rapid manufacturing systems

Table 5.6 presents build-times obtained through proprietary machine software and material consumption in fabrication of orthosis model using different rapid manufacturing systems. In SLS technique using *spro* SD 60 SLS system, Duraform PA (Nylon 12) material was used in the orthosis model. The orthosis model consumed 50.15 grams of material. In SLA technique using *ipro* 8000 system, Accura 55 resin material was used in the orthosis model. The material consumption was 60 grams in orthosis model and 30 grams in support structure. In polyjet technique using Connex 500 system, Vero White FullCure®830 material was used in the orthosis model and FullCure®705 in the support structure. In 3DP V-flash system, V-Flash ®FTI material was used in the orthosis model. In FDM technique using Dimension 768 system, ABS P400 material was used in orthosis model and P400 soluble material was used in the support structure. In uPrint system, ABS P430 material was used in orthosis model and P430 material was used in the support structure. The properties of materials used are presented in Appendix on page no: 220.

Printer name	**Build volume mm**	**Build time hours/part**	**Material used**	**Material consumed**
spro 60 SD SLS	381 x 330 x 457	3	Duraform	50.15 grams
ipro 8000 SLA	650 x 350 x 300	6	Accura 55	60 grams
Connex 500	500 × 400 × 200	6	Verowhite	180.9 grams
3DP V-Flash	178 x 229 x 203	10	FTI GN	52 grams
SST 768 FDM	203 x 203 x 305	7	ABS P400	90 grams
Dimension uPrint	203 x 152 x 152	7	ABS P430	55 grams

Table 5.6 Build time and material consumed in different rapid manufacturing systems

5.5 Summary.

Foot orthosis model was fabricated on 6 different commercially established rapid manufacturing systems using the default fabrication parameters established by proprietary software on the systems. In the orthosis model fabrication, different build-times were obtained due to different fabrication processes and materials used. The comparison of range of bending stiffness in rapid manufacturing based materials with range of bending stiffness in traditional materials showed that RM based materials qualify and can be used in the fabrication of custom foot orthosis shell. In the next Chapter, analyses of the cost and build time on different rapid manufacturing systems is presented.

Chapter 6 Cost and lead-time modelling

6.1 Introduction.

In this chapter modelling of the cost and lead-time for fabrication of foot orthoses using different rapid manufacturing techniques is presented. The cost and lead-time obtained from different techniques were analysed and compared with conventional orthoses fabrication technique. The analysis includes various cost elements and lead-time obtained in fabrication of orthosis model. The cost and lead-time modelling provide a basis for decision making for selection of appropriate rapid manufacturing technique that proves more efficient in comparison with conventional fabrication technique for fabrication of custom foot orthoses at commercial scale.

6.2 Cost modelling in rapid manufacturing

Fabrication costs in rapid manufacturing broadly fall into four main categories (Hopkinson and Dickens, 2003; Ruffo et al., 2006; Gibson et al., 2010; Atzeni et al., 2010). The cost categories are (i) production and administrative overheads, (ii) machine purchase and operation, (iii) labour and (iv) material costs. Table 6.1 shows various activities involved in rapid manufacturing and their descriptions (Wholers and Grimm, 2002, Ruffo et al, 2006).

Activity	Cost description
Material	Cost of material purchase
Software	Cost of software purchase and upgrades
Hardware	Cost of PC purchase and upgrade
Equipment depreciation	Cost of equipment depreciation
Maintenance	Cost of equipment maintenance per year
Labour	Cost of labour (machine set-up and post-processing)
Production overhead	Cost incurred due to production, energy and floor space
Administrative overhead	Cost for running enterprise and consumables

Table 6:1 Activities associated with rapid manufacturing

The work in this research is based on development of cost models for different rapid manufacturing based design and fabrication systems. Different rapid manufacturing based systems have given different total per pair cost of custom-made foot orthoses. In cost modelling process, a series of alternative scenarios were presented as part of a sensibility analysis of initial developed operating cost models; by including a fraction of an operator and by increasing the number of machines which has subsequently increased the machine operation hours and production volume per year and reduced the total per pair cost.

The initial operating cost models were further extended and “best case” operating cost models were developed. In the “best case” operating cost models the total estimated machine operation labour hours per year were balanced with total labour hours per year of the technicians in order to obtain optimal productivity from the models in terms of total per pair cost and total production volume per year.

6.3 Development of cost models

The cost models in this work are based on cost categories adopting a full costing system in comparison to cost model developed by Hopkinson and Dickens (Hopkinson and Dickens, 2003), splitting the cost into three categories; machine, labour and materials. In the development of full cost models different cost categories included were production and administrative overheads, machine purchase and operation, labour and material costs. The cost of material was considered as the direct cost whereas all the other cost elements were considered as indirect costs in the developed cost models.

In development of cost models for different rapid manufacturing techniques “initial operating cost models” were developed in order to obtain the total cost per pair of the foot orthoses. The initial operating cost models are based on one machine and one operator in a facility. The technician works for 220 working days per year which does not allow the operation of machine for 365 days per year. This is addressed with development of “best case” operating models. The “best case” operating models are based on balancing the machines operation labour hours per year and labour hours per year of the technician in order to ensure near full utilisation of both the equipment and staff and to obtain the optimal productivity from the model. A uniform floor space of $246.5m^2$ at the rate of £$120/m^2$, energy consumption cost of £1.5/hour and administration overheads at the rate of £2320 has been assumed for all cases in the cost modelling process which are based on UK trade and information enquiry services (www.ukti.gov.uk, 2010) and research work of Ruffo and colleagues (Ruffo et al, 2006). In "best case" developed models, the floor space for additional machines is included according to required space for machine installation, recommended by the suppliers. This has subsequently increased the production and administration over heads in the "best case" models. Table 6.2 shows the main assumptions used in the cost modelling process.

Cost elements and assumptions in development of cost models	
Machine operation hours per year	Total build time/run and total no: of runs/year
Floor space cost	246.5 m^2 @£120/m^2
Machine space for SLS and SLA	20m^2/machine
Machine space for Connex 500, V-Flash, SST 768, uPrint and Amfit.	6m^2/machine scaled according to space recommended from equipment suppliers.
Depreciation time for machines	5 years
Machine energy consumption cost	£1.5/hour
Administration overheads	£2320/year/machine
Technician labour cost/annum	£39980/year or £22.71/hour

Table 6:2 Assumptions in the cost modelling process

An important assumption was made for the productivity of machines per year. Hopkinson and Dickens in their cost modelling have assumed 7884 machine operation hours per year; utilisation of 90% of machine operation time per year. Gibson and associates have assumed 8332 machine operation hours per year; utilisation of 95% of machine operation time per year; whereas, Ruffo and colleagues have assumed 5000 machine operation hours per year; utilisation of 57% of machine operation time per year. In this work, the productivity assumption for machine operation time per year is based on total number of machine operation hours per year which was calculated on the basis of;

(i) Total build time per run

(ii) Total estimated number of runs per year.

Another important assumption was made regarding the useful life span of machines which was set for 5 years, as both the worst case and most realistic. Hopkinson and

Dickens (Hopkinson and Dickens, 2003), Gibson and colleagues (Gibson et al., 2010) and Atzeni and associates (Atzeni et al., 2010) in their cost modelling have considered 8 years, 7 years and 5 years, respectively as the useful life of machines for calculating the depreciation cost. The cost models for rapid manufacturing technique were developed through following calculations procedure.

6.3.1 Calculating production volume per year

Table 6.3 shows the calculation method for production volume per year of foot orthoses. The total production volume per year was calculated through total number of parts per build, build time per run and the total number of runs operated per year on a machine using different rapid manufacturing systems.

Production volume per year	**Variables**	**Obtained by**
Number of parts	N	Total number of parts per build
Build time per run	T	Hours
Production rate per hour	R	N/T
Total operation hours per year	HY	Build time/run and total no: of runs/year
Production volume per year	V	From operating model

Table 6:3 Calculation of production volume per year

6.3.2 Calculating machine cost

Table 6.4 shows the method for calculation for machine cost per year. Machine cost per year was obtained by depreciation cost per year and annual maintenance cost per year for the machine. Machine depreciation time was set for 5 years.

Machine cost per year	Variables	Obtained by
Machine and ancillary equipment	E	Machine capital cost
Depreciation cost per year	D	E/5*
Maintenance cost per year	M	10% of machine purchase cost (E)**
Total machine cost per year	MC	D + M

* Depreciation time was set for 5 years and **10% maintenance cost of machine (Wohlers, 2002).

Table 6:4 Calculation of machine cost per year.

6.3.3 Calculating material cost

The method for calculation of material cost in rapid manufacturing techniques is different due to the nature of fabrication processes in different techniques (Gibson et al., 2010). In stereolithography SLA, FDM, Polyjet and V-flash techniques, material cost is calculated by weighing the finished part including the material consumed in the support structure then multiplying these with the associated cost of the material (Hopkinson and Dickens, 2003). The method for calculating the cost of material in selective laser sintering technique SLS is slightly different. In SLS techniques material cost is calculated in terms of sintered material (weighing the finished parts) and unsintered material by calculating the volume of unsintered material. In SLS technique, according to the material manual by 3D systems Inc: USA unsintered material can be reused with the virgin material with ratio not exceeding to 67% of the total material per build (Ruffo et al., 2006). Table 6.5 shows the calculation method for material costs in different rapid manufacturing techniques.

Calculation of material cost	**Variables**	**Cost obtained by**
Material cost calculation for SLA		
Material cost per kg	SL cost	£285*
Material part including support	SLmass	weighing finished parts
Material cost per SLA part	SLMCP	SLmass x SLcost
Material cost calculation for SLS		
Material cost per kg	LSC	£64*
Mass of each part	LSM	weighing finished parts
Volume of each part	VP	From machine software
Total build volume	TBV	38.1 x 33 x 45.7 cm^3
Mass of sintered material/build	LSMS	N X LSM
Mass of unsintered material/build	LSMU	(TBV- N x VP) x 0.6
Cost of material used/build	LSMC	(LSMU + LSMS) x LSC
Material cost calculation for FDM		
Material cost/cartridge	FDMPC	£330**
Support material cost/cartridge	FDMSC	£330**
Material per part kg	FDMPM	weighing finished parts
Support material per part kg	FDMSM	weighing support material
Material cost per/part		FDMPM x FDMPC + FDMSM x FDMSC
Material cost calculation for Polyjet		
Material cost per kg	PJPC	£200***
Support material cost per kg	PJSC	£85***
Material per part kg	PJPM	weighing finished parts
Support material per part kg	PJSM	weighing support material
Material cost per part		(PJPM x PJPC) + (PJSM x PJSC)
Material cost calculation for V-flash		
Material cost per kg	VFPC	£455****
Support material cost per kg	VFSC	£455****
Material per part kg	VFPM	weighing finished parts
Support material per part kg	VFSM	weighing support material
Material cost per part		(VFPM x PJPC) + (VFSM x VFSC)

* Cost quotation from 3D Systems Europe Ltd, UK, 2010 **Cost quotation from Laser Lines Limited, UK, 2010, *** Cost quotation from, HK Technologies, Ltd. UK, 2010 and **** Cost quotation from Print IT 3D Ltd. UK, 2010.

Table 6:5 Calculation of material costs for RM techniques

6.3.4 Calculation of overheads

(i) Production overhead

Table 6.6 shows the calculation method for production overhead which includes floor space cost per annum and cost of energy consumption per year. A uniform floor space cost of £120/m^2 has been considered for all cases based on current UK industrial rates (www.ukti.gov.uk, 2010). For energy, a cost of £1.5 per hour was assumed as energy cost for calculation of production overhead (Grim and Wohler, 2002, Ruffo et al., 2006). The method of calculation of production overhead was adopted form the work of Ruffo and colleagues (Ruffo et al., 2006).

Production overheads	
Floor space cost	£120/m^2 per annum*
Energy consumption cost	£1.5 per hour** x machine operation hours per year from operating model

*UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ** Grim and Wohler, 2002, Ruffo et al, 2006.

Table 6:6 Calculation of production overhead

(ii) Administrative overhead

Table 6.7 shows the calculation method for administrative overhead which includes the cost per year for hardware, software and consumables. A cost of £1450 per year was assumed for consumables; whereas the useful life for software and hardware was set to be for 5 years. This gives a total of £2320 per year as the administrative overhead.

Administrative overhead	
Hardware purchase (one off cost)	£2175
Software purchase (one off cost)	£2175
Consumables cost per year (one off cost)	£1450
Hardware depreciation cost/year	£435*
Software depreciation cost/year	£435*
Total cost/year	£2320

*Depreciation time for computer hardware and software was set for 5 years.

Table 6:7 Calculation of administrative overhead

6.3.5 Calculation of labour cost

In this work, the annual labour cost of £32770 per year is adopted from the work of Ruffo and colleagues (Ruffo et al., 2006) for operator of rapid manufacturing system. This was added with 22% of labour cost as the employer contribution (Ruffo et al., 2006). This gives a total annual labour cost of £39980 for 220 working days per year which gives the cost of £22.71 per hour.

6.4 Mathematical calculations for cost modelling

The method for calculation of fabrication costs is presented in the following section.

$$C_{total} = C_{machine} + C_{material} + C_{overheads} + C_{labour} \qquad \text{Eq (6.1)}$$

Where C_{total} is the estimated total cost per year which is the sum of cost of machine including depreciation and maintenance cost per year, $C_{material}$ is the estimated cost of material consumed in model and support structure, $C_{overheads}$ is the estimated cost of production and administration overheads per year and C_{labour} is the labour cost per year. The first term in equation 6.1, cost of machine per year ($C_{machine}$) is estimated using equation (6.2).

$$C_{machine} = E/5 + M \qquad \text{Eq (6.2)}$$

Where, E is the capital cost of machine which is divided by 5 years in order to obtain depreciation cost per year. The maintenance cost (M) for RM system depends on individual agreement between system supplier and buyer. However, as a rule about 10% of purchase price of the machine was budgeted for a full annual maintenance cost of the system (Grim and Wohler, 2002). The second term in equation 6.1, cost of material per year ($C_{material}$) is calculated using equation (6.3)

$$C_{material} = V_{mod:} + V_{sup:} \text{ x (material cost £/kg)} \qquad \text{Eq (6.3)}$$

Where $V_{mod:}$ is material consumed in the model and $V_{supp:}$ is material consumed in the support structure. This is multiplied with the associated cost of material per kg. The third term in equation 6.1, overheads per year ($C_{overheads}$) is obtained by equation (6.4).

$$C_{overheads} = C_{prod:\ overhead} + C_{admin:\ overhead} \qquad \text{Eq (6.4)}$$

Where, $C_{prod:}$ is for production overhead per year which is added with the $C_{admin:}$ administrative overhead per year. The fourth term in equation 6.1, cost of labour (C_{labour}) is included as annual salary of technician per year.

$$C_{labour} = \text{Annual salary of technician.}$$

The cost per pair of orthoses is calculated from following equation.

$$C_{per\ pair} = C_{total} / \text{total number of pairs produced} \qquad \text{Eq (6.5)}$$

Where C_{total} is total cost in the fabrication of orthoses per year divided by total number of pairs produced per year in the operating cost model.

6.4.1 Cost and lead-time modelling

For modelling of the cost and lead-time, initial operating cost models were developed based on one operator working with one machine in a facility. The models were based on total estimated production volume per year of foot orthoses using *ipro* SD 60 SLS, *spro* SLA, Connex 500 polyjet, V-flash 3DP, Dimension 768 SST, uPrint and Amfit CAD/CAM systems. In following section detailed breakdown of the cost and lead-time models developed for all the techniques used are presented. The cost models include machine purchase and operation, material, production and administration overheads and labour costs. A uniform cost of cost of £2320 as the administration overhead per year and a cost of £39980 per year as the labour cost per year was standardised as annual salary of the technician per year in all the developed models.

6.4.2 Cost and lead-time modelling for SLS technique using *spro* SD system

In SLS technique using *spro* 60 SD SLS system one machine was assumed to work for one run of 16 hours of build time per day working for 220 days per year. Production volume per year was calculated by estimating the total production volume per year from the model. It was estimated that from one run of 200 mm build height on average 30 parts or 15 pairs of orthoses can be fitted. The build time of 16 hours per run was given by the build setup^{TM} machine controlling software. The machine was assumed to work for 220 days per year which gives a total of 3520 machine operation hours per year; approximately 40% of machine utilisation time per year.

Table 6.8 shows the estimated total cost of £363360 for fabrication of 3300 pairs per year at the rate of £110.10 per pair. Machine cost per year was calculated by depreciation cost of machine and 10% of actual cost of machine as the maintenance cost per year. The depreciation time for machine was set for 5 years. This gives an estimated total of £75000 as the machine cost per year. Material cost per pair was calculated in terms of sintered material per build by weighing the fabricated parts and unsintered material per build by calculating the volume of unused material and multiplying it by unsintered material density. This gives an estimated material cost of £64 per pair. Production overhead per year was calculated by floor space cost at the rate of £120/m^2

per year. This cost was added with cost of energy for machine at the rate of £1.5 per hour (Ruffo et al, 2006). This gives an estimated total of £34860 per year as production overhead. A uniform administrative overhead per year at the cost of £2320 was included in the model.

Labour cost was calculated by required labour time for operation of machine; based on one hour of time for setting of machine and loading of material and 2 hours of time for cleaning the fabricated parts. The operation of one run on *spro* SD 60 SLS system requires 3 hours of labour time of the technician. However, in initial cost model, labour cost of £39980 is included as the annual salary of the technician.

Cost calculations using *ipro* SD 60 system in SLS technique		
Production volume per year		
Number of parts/build	N	30
Build time/run	T	16 hours
Production rate/hour	R = N/T	1.87
Operation hours/year	HY	3520
Total production volume/year	V = R x HY	6600 parts
Total pairs/year		3300 pairs
Machine costs per year		
Machine & ancillary equipment	E	£250000*
Machine depreciation cost/year	D = E/5	£50000
Machine maintenance cost/year	M	£25000
Total machine cost/year	MC = D+M	£75000
Material cost per pair		
Material cost	per kg	£64/kg*
Volume of each part cm^3	83596 mm^3	83.59 cm^3
Mass of each part	83.59 cm^3 x 0.6g/cm^3= 50.15g	0.050 kg
Mass of sintered material/build	(30 x 83.59 cm^3) x 0.6g/cm^3 =1504.62g	1.50 kg
Mass of unsintered material/build	(25146 cm^3–30 x 83.59 cm^3)x0.6g/cm^3	13.50 kg
Cost of material used/build	(1.50 kg + 13.50 kg) x £64/kg	£960
Material cost/part	£960/30 parts per build	£32/part
Total cost/pair		£64/pair
Production overhead per year		
Building area	246.5/m^2*@ £120/m^2/annum**	£29580
Energy consumption by machine	@ £1.5/hour x 3520 machine operation hours/per year from operating model	£5280
Total cost/year		£34860
Administrative overhead per year		
Hardware purchase	one of cost	£2175*
Software purchase	one of cost	£2175*
Consumables cost/year		£1450
Hardware depreciation cost/year		£435**
Software depreciation cost/year		£435**
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980
Total cost/year	3300 pairs/year	£363360
Cost/pair	£363360/3300 pairs	£110.10

*, ** Ruffo et al, 2006, *** and **** Cost quotation from system and material supplier, Laser Lines Limited UK, 2010.

Table 6:8 Cost calcualtion using *ipro* SD 60 SLS sytem

Figure 6:1 shows the detailed cost breakdown showing the weight of different activities on the total cost in the initial operating model based on 220 working days per year. The indirect cost accounts for 42% of the total cost. This includes machine cost 21%, production and administrative overheads 10% and labour cost 11% of the total cost. The cost of material accounts for 58% of the total cost as the direct cost in the model.

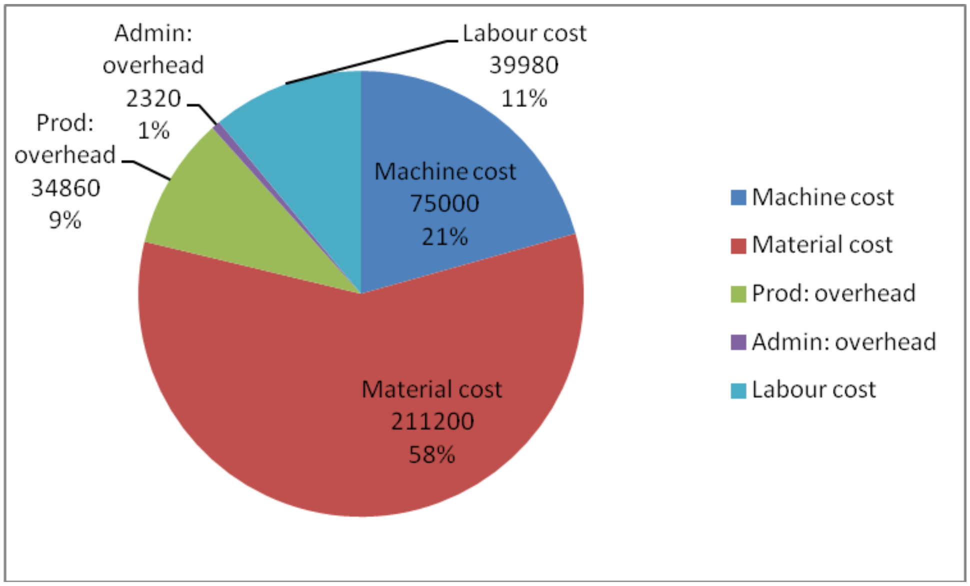


Figure 6:1 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year

The initial operating model is sensitive to any variation or change in different parameters such as increasing the machine operation hours per year. This subsequently increases the total number of runs per year, labour and material costs resulting in increased production volume per year.

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.9 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 3 hours of time per day for 145 days was included. The model has increased the production volume from 3300 pairs to 5475 pairs per year at the rate of £94.23 per pair. This has reduced approximately 15% in total cost per pair compared to initial operating model based on 220 working days per year.

Total cost per pair using *spro* 60 SD SLS system		
Machine cost per year		£75000
Material cost for 5475 pairs	@£64 per pair	£350400
Production overhead per year		£38340
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operator	£49859
Total cost	5475 pairs per year	£515919
Cost per pair	£515919/5475 pairs	£94.23

Table 6:9 Total cost per pair in initial operating model based on 365 working days per year

Figure 6.2 shows the detailed breakdown of different cost elements in initial operating model based on 365 days per year. The indirect costs account for 32% of the total cost. This includes machine cost 15%, production and administrative overheads 7% and labour cost 10% of the total cost. Material cost accounts for 68% of the total cost as the direct cost in the model.

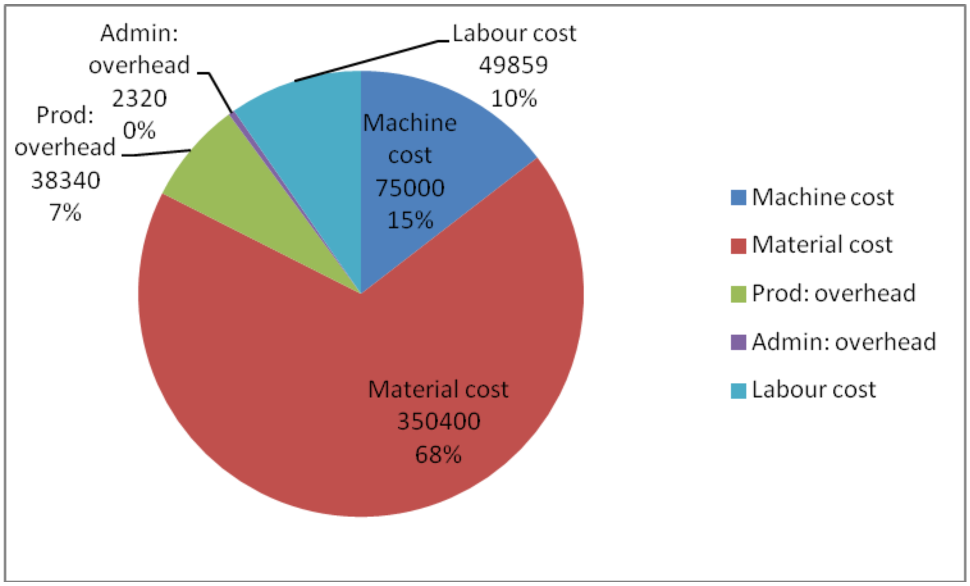


Figure 6:2 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of “Best case” operating model

A “best case” operating model was developed based on one run of 16 hours of build time per day working for 365 days per year. The developed model is based on 5 technicians working with 8 machines in order to obtain optimal productivity by balancing the required labour hours per year for machines and labour hours of technicians per year. In the model one machine was assumed to work for one run of 16 hours of build time per day for 365 days year. This gives 5840 machine operation hours per year for one machine; approximately 66% machine utilisation time per year.

Table 6.10 shows the operation hours of machines per year and labour hours per year for technicians in the “best case” operating model. The operation of one run on one machine requires 3 hours of labour time. The operation of 365 runs per year on one machine requires a total of 1095 machine labour hours per year. This gives an estimated total of 8760 labour hours per year required for operation of 8 machines. The labour hours for one technician are based on 1760 labour hours per year which gives a total of 8800 labour hours per year for 5 technicians. The operating model was assumed to fabricate a total of 5475 pairs per year on each machine, which gives an estimated annual production volume of 43800 pairs per year.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	1095	1	1760
2	2190	2	3520
3	3285	3	5280
4	4380	4	7040
5	5475	5	8800
6	6570	6	10560
7	7665	7	12320
8	8760	8	14080
9	9855	9	15840
10	10950	10	17600

Table 6:10 Machine labour hours/year and technicians labour hour/year in “best case” cost model

Table 6.11 shows details of cost categories in “best case” model based on 5 technicians working with 8 machines. A floor space of 20m^2 at the rate of £120/m^2 for each machine and ancillary equipment and energy consumption cost of £1.5 per hour for each machine is included. This is added with the machine purchase and operation cost for 8 machines and material consumption cost of £2803200 per year. The labour cost for 5 technicians is estimated for £199900 per year at the rate of £22.71 per hour. The model gives an estimated total of £3738120 for fabrication of 43800 pairs per year at the rate of £85.34 per pair; approximately 23% reduction in cost per pair compared to initial operating model based on 220 working days per year.

“Best case” operating model for 5 technicians working with 8 machines		
Machine cost per year for 8 machines		£600000
Material cost for 43800 pairs	@£64 per pair	£2803200
Production overhead per year for 8 machines		£116460
Administrative overhead per year for 8 machines		£18560
Labour cost for 5 technicians		£199900
Total cost for 43800 pairs		£3738120
Cost per pair	£3738120/43800 pairs/year	£85.34

Table 6:11 Total estimated fabrication cost per pair in “best case” SLS cost model

Figure 6.3 shows breakdown of different costs in “best case” cost model. In the total cost, material cost accounts for 75% as the direct cost in the model. The indirect costs account for 25% of the total cost. This includes machine cost 16%, production and administrative overheads 4% and labour cost 5% of the total cost as the indirect cost in the model.

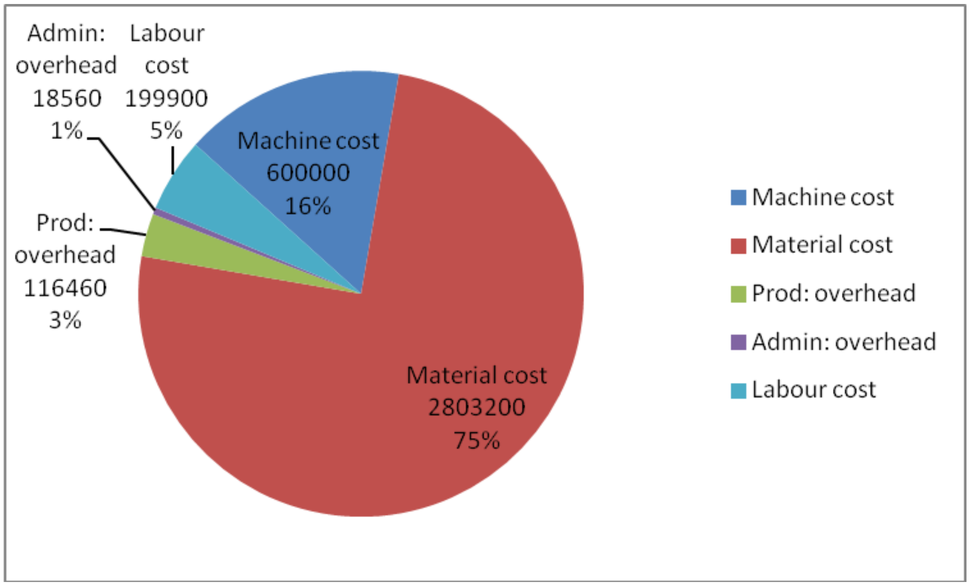


Figure 6:3 Cost categories in “best case” SLS based cost model

6.4.3 Cost and lead-time modelling for SLA technique using *ipro* system

In SLA technique using *spro* SLA system, one machine was assumed to work for 2 runs of 7 hours of build time per run for 220 working days per year. Production volume per year was calculated from the model. An *ipro* 8000 SLA system has a build volume of 650 (length), 350 (width) and 300 mm (height) in which 10 parts can be fitted per build. A build time of 7 hours for fabrication of 10 parts was given by 3DPrint™ machine controlling software. The machine is assumed to work for 14 hours of time for 220 days per year which gives a total of 3080 machine operation hours per year; approximately 35% of machine utilisation time per year.

Table 6.12 shows the estimated total cost of £439560 for fabrication of 2200 pairs per year at the rate of £199.8 per pair. Machine cost per year was calculated by depreciation cost of machine and 10% of actual cost of machine as the maintenance cost per year. The depreciation time for machine was set for 5 years. This gives an estimated total of £210000 as the machine cost per year. Material cost per pair was calculated by weighing the material consumed in the model part and material consumed in the support structure. The weight of total material consumed is then multiplied with associated cost of material.

The material consumed in orthosis model was 60 grams and material consumed in support structure was 30 grams. The total material consumed including support material was 90 grams per part which gives an estimated material cost of £25.2 per part or £50.4 per pair.

Production overhead per year was calculated by floor space cost at the rate of £120 per m^2 per year. This cost was added with energy consumption cost for the machine at the rate of £1.5 per hour (Ruffo et al, 2006). This gives an estimated total of £34200 per year as production overhead. A uniform administrative overhead per year at the cost of £2320 was included in the model. Labour time was calculated by required labour time of the operator**.** The operation of one run on *ipro* 8000 SLA system requires 2 hours of labour time of the technician. The labour time is based on 1 hour of time for setting of machine and loading of material vat and 1 hour of time for removing the parts and post processing of the fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 is included as the annual salary of the technician.

Cost calculations for *spro* system in SLA technique		
Production volume per year		
Number of parts/build	N	10
Build time/run	T	7 hours
Production rate/hour	R = N/T	1.42
Operation hours/year	HY	3080
Production volume/year	V = R x HY	4400 parts
Total pairs/year		2200 pairs
Machine cost per year		
Machine & ancillary equipment	E	£700000*
Depreciation cost/year	D = E/5	£140000
Machine maintenance/year	M	£70000
Total machine cost/year	MC = D+M	£210000
Material cost per pair		
Model material/part	60 grams @£0.28/grams	£16.8
Support material/part	30 grams @£0.28/grams	£8.4
Material cost/kg		£285*
Material cost/part		£25.2
Cost/pair		£50.4
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumption by machine	@£1.5/hour***x3080machine operation hours/year from operating model	£4620
Total cost/year		£34200
Administrative overhead per year		
Hardware		£2175*
Software purchase		£2175*
Consumables cost/year		£1450
Hardware depreciation cost/year		£435**
Software depreciation cost/year		£435**
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost	2200 pairs/year	£439560
Cost/pair	£439560/2200 pairs	£199.8

*Cost quotation from system supplier, 3D Systems Europe Ltd, UK, 2010, **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006.

Table 6:12 Cost calcualtion per pair using *spro* SLA sytem

Figure 6.4 shows the detailed breakdown of different cost elements in the initial operating model based on 220 working days per year. Material cost accounts for 35% of the total cost as the direct cost in the model. Machine cost accounts for 48%, production and administrative overheads 8% and labour cost accounts for 9%, which makes 65% of the total cost as the indirect cost in the model.

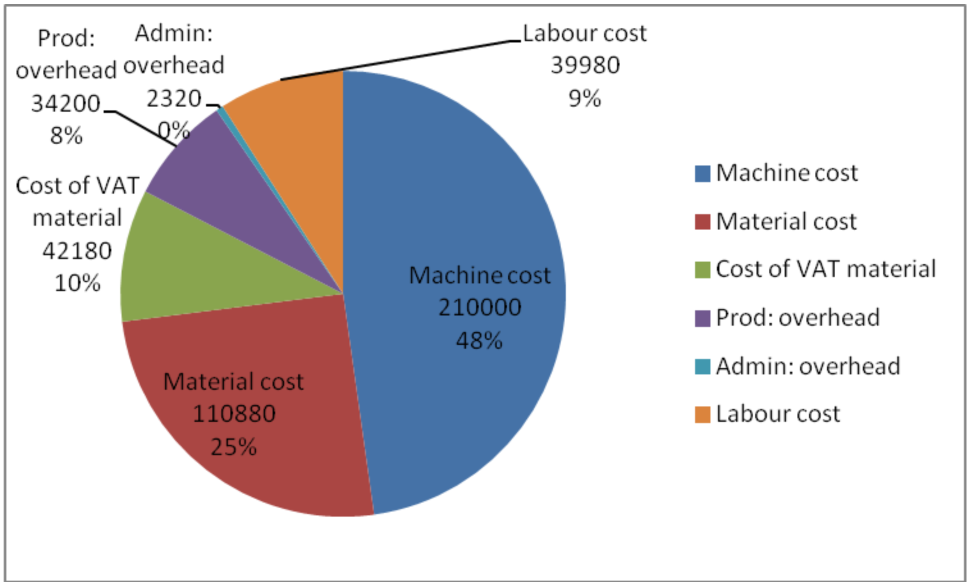


Figure 6:4 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the operation hours per year

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.13 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 4 hours of time per day for 145 working days was included. This has increased the production volume from 2200 pairs to 3650 pairs per year at the rate of £144.89 per pair. This has reduced approximately 28% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Total cost per pair using *ipro* 8000 SLA system		
Machine cost per year		£210000
Cost of VAT of material	@£285 per litre for 148 litres	£42180
Material cost for 3650 pairs	@ £50.4 per pair	£183960
Production overhead per year		£37245
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operator	£53152
Total cost	3650 pairs per year	£528857
Cost per pair	£528857/3650 pairs	£144.89

Table 6:13 Total cost per pair in intial operating model based on 365 working days per year

Figure 6.5 shows the detailed breakdown of different cost elements in initial operating model based on 365 days per year. Material cost accounts for 43% of the total cost as direct cost in the model. Machine cost accounts for 40%, production and administrative overheads 7% and labour cost accounts for 10% of the total cost which makes 57% of the total cost as indirect cost in the model.

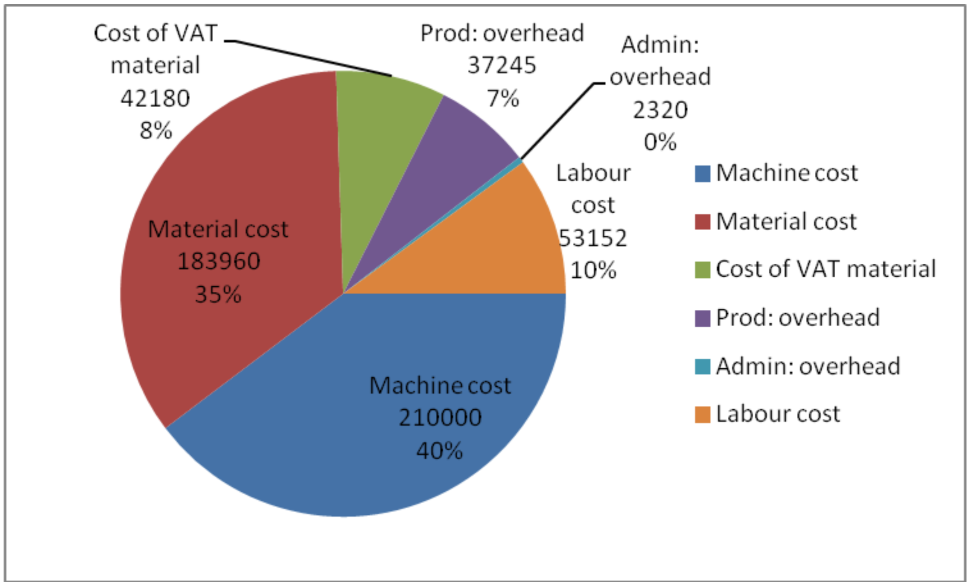


Figure 6:5 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of “Best case” operating model

A “best case” operating model was developed based on 2 runs of 7 hours of build time per day working for 365 days per year. The developed model is based on 5 technicians working with 6 machines in order to obtain optimal productivity by balancing the required labour hours per year for machines and labour hours for technicians per year. In the model one machine was assumed to work for 2 runs of 7 hours of build time per day for 365 days per year. This gives a total of 5110 working hours per year for each machine and a total of 30660 machine hours per year; approximately 41% machines utilisation time per year.

Table 6.14 shows the operation hours of machines per year and labour hours per year for technicians in the “best case” operating model. The operation of one run on one machine requires 2 hours of labour time as mentioned in the Table 6.22. The operation of 730 runs per year on each machine requires a total of 1460 labour hours per year. This gives a required estimated total of 8760 labour hours per year for operation of 6 machines. The labour hours per year for one technician based on 1760 labour hours per year give a total of 8800 labour hours per year for 5 technicians. The operating model was assumed to fabricate a total of 3650 pairs on each machine per year. This gives an estimated production volume of 21900 pairs per year of orthoses on 6 machines.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	1460	1	1760
2	2920	2	3520
3	4380	3	5280
4	5840	4	7040
5	7300	5	8800
6	8760	6	10560
7	10220	7	12320
8	11680	8	14080
9	13140	9	15840
10	14600	10	17600

Table 6:14 Machine labour hours/year and technicians labour hour/year in “best case” cost mode

Table 6.15 shows details of cost categories in “best case” cost model based on 5 technicians working with 6 machines. A floor space of 20 m^2 at the rate of £120/m^2 for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with the machine purchase and operation cost for 6 machines and material consumption cost per year. The labour cost for 5 technicians is estimated for £199900 per year at the rate of £22.71 per hour. The model gives an estimated total of £2918230 for fabrication of 21900 pairs per year at the rate of £133.25 per pair; approximately 33% reduction in cost per pair compared to initial operating model based on 220 working days per year.

“Best case” operating model for 5 technicians working with 6 machines		
Machine cost per year for 6 machines		£1260000
Material cost for 21900 pairs	@£50.4 per pair	£1103760
Production overhead per year for 6 machines		£87570
Administrative overhead per year for 6 machines		£13920
Labour cost for 5 technicians		£199900
Total cost for 21900 pairs		£2918230
Cost per pair	£2918230/21900 pairs/year	£133.25

Table 6:15 Total estimated fabrication cost per pair in “best case” SLA based cost model

Figure 6.6 shows breakdown of different costs categories in the “best case” cost model. Material cost accounts for 47% of the total cost as the direct cost in the model. Machine cost accounts for 43%, production and administrative overheads 3% and labour cost accounts for 7%, which makes 53% of the total cost as the indirect cost in the model.

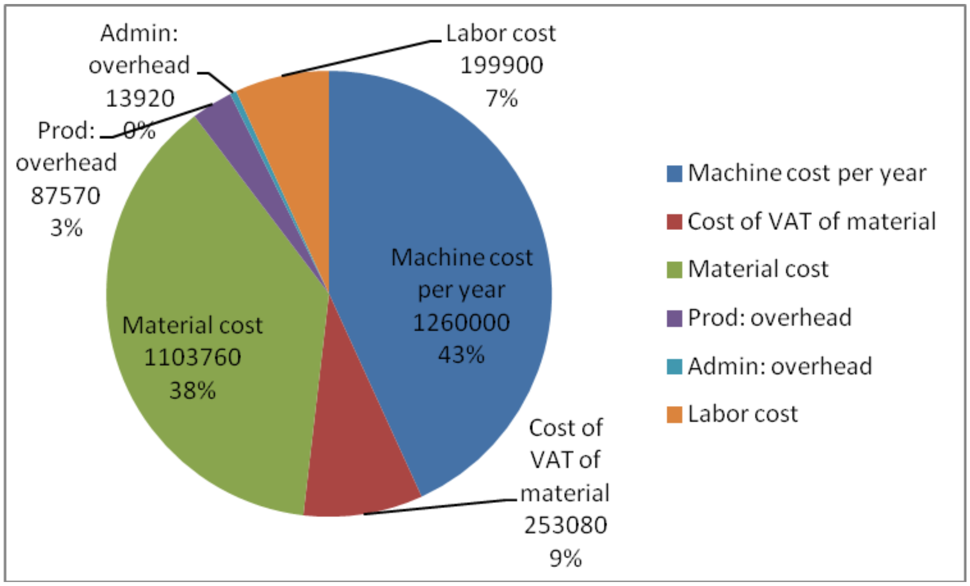


Figure 6:6 Cost categories in “best case” SLA based cost model.

6.4.4 Cost and lead-time modelling for polyjet technique using Connex 500 system

In polyjet technique using Connex 500 system one machine was assumed to work for one run of 30 hours of build time for 220 working days per year. Production volume per year was calculated from the model. Connex 500 system has a build volume of 500 (length), 400 (width) and 200 mm (height) in which 10 parts can be fitted per build. A build time of 30 hours per run for fabrication of 10 parts was given by Objet Studio™ machine controlling software. The machine was assumed to work for 220 days per year in which a total of 110 runs can be operated. This gives a total of 3300 hours per year at the rate of 30 hours of build time per run; utilisation of 37% of machine time per year.

Table 6.16 shows an estimated total cost of £190755 for fabrication of 550 pairs per year at the rate of £346.82 per pair. Machine cost per year was calculated by depreciation cost of machine and 10% of actual cost of machine as the maintenance cost per year. The depreciation time for machine was set for 5 years. This gives an estimated total of £57000 as the machine cost per year. Material was cost calculated by weighing the material consumed in the model part and material consumed in support structure.

The weight of total material consumed is then multiplied by the associated cost of the material. The material consumed in orthoses model was 180.9 grams and material consumed in support structure was 194.7 grams. The total material consumed including support material was 375.6 grams per part which gives an estimated material cost of £51.75 per part or £103.50 per pair.

Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost of the machine at the rate of £1.5 per hour which gives an estimated total of £34530 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead. Labour cost was calculated by the time of labour time of the operator per run. For operation of one run on Connex 500 system, it was estimated that 2 hours of labour time of the technician was required. The labour time is based on 60 minutes of time for setting of machine and loading the cartridges of model and support material and 60 minutes of time for post processing of the fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 is included as the annual salary of the technician.

Cost calculations using Connex 500 system in polyjet technique		
Production volume per year		
Number of parts/build	N	10
Build time/run	T	30 hours
Production rate/hour	R = N/T	0.33
Operation hours/year	HY	3300
Production volume/year	V = R x HY	1100 parts
Total pairs/year		550 pairs
Machine cost per year		
Machine & ancillary equipment	E	£190000*
Depreciation cost/year	D = E/5	£38000
Machine maintenance cost/year	M	£19000
Total machine cost/year	MC = D+M	£57000
Material cost per pair		
Material/part	180.9 grams @£0.2/grams	£36.18
Support material/part	194.7 grams @£0.08/grams	£15.57
Model material cost/kg		£200*
Support material cost/kg		£85*
Material cost/part		£51.75
Total cost/pair		£103.50
Production overhead per year		
Building area	246.5/m^2 @ £120/m^2 per annum**	£29580
Energy consumption by machine	@£1.5/hour x 3300 machine operation hours per year from operating model	£4950
Total cost/year		£34530
Administrative overhead per year		
Hardware		£2175***
Software purchase		£2175***
Consumables cost/year		£1450
Hardware depreciation cost/year		£435
Software depreciation cost/year		£435
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost	550 pairs per year	£190755
Cost/pair	£190755/550 pairs	£346.82

* Cost quotation from system supplier, HK technologies, UK, 2010, **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006.

Table 6:16 Cost calculation per pair using Connex 500 polyjet technique

Figure 6.7 shows the detailed breakdown of different cost elements in initial operating model based on 220 working days per year. The indirect cost accounts for 70% of the total cost. This includes machine cost 30%, production and administrative overheads

19% and labour cost 21% of the total cost. Material cost accounts for 30% of the total cost as the direct cost in the model.

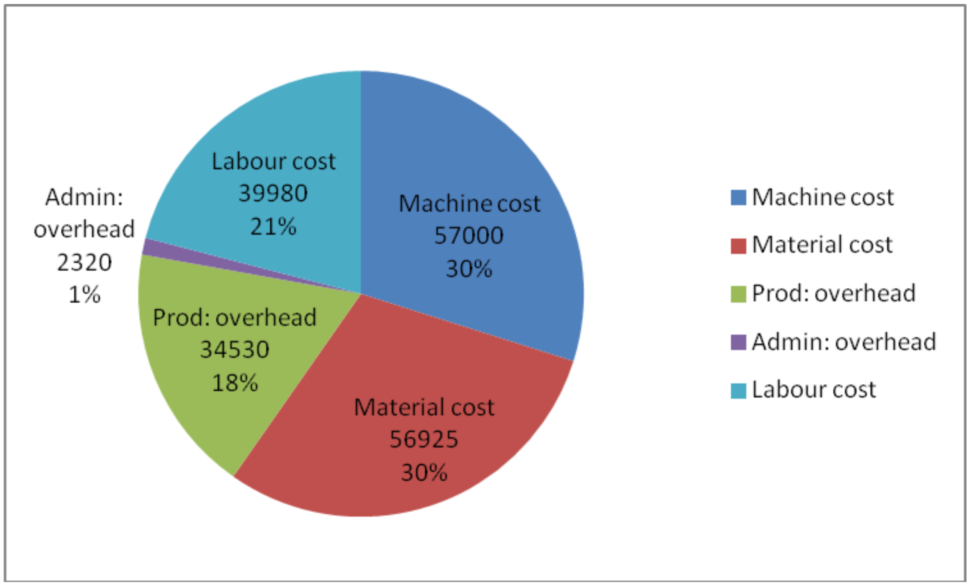


Figure 6:7 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year.

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.17 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 2 hours of time per run was included in order for operation of 72 runs in 145 days. This has increased the production volume from 550 pairs to 910 pairs per year at the rate of £257.71 per pair. This has reduced approximately 26% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Cost modelling in Connex 500 system		
Machine cost per year		£57000
Material cost for 910 pairs per year	@£103.5 per pair	£94185
Production overhead per year		£37770
Administrative overhead per year		£2320
Labour cost per year	Full and part time technicians	£43250
Total cost	910 pairs per year	£234525
Cost per pair	£234525/910 pairs per year	£257.82

Table 6:17 Total cost per pair in initial operating model based on 365 working days per year

Figure 6.8 shows the detailed breakdown of different cost elements in initial operating model based on 220 working days per year. The indirect cost accounts for 60% of the total cost. This includes machine cost 24%, production and administrative overheads 17% and labour cost 19% of the total cost. Material cost accounts for 40% of the total cost as the direct cost in the model.

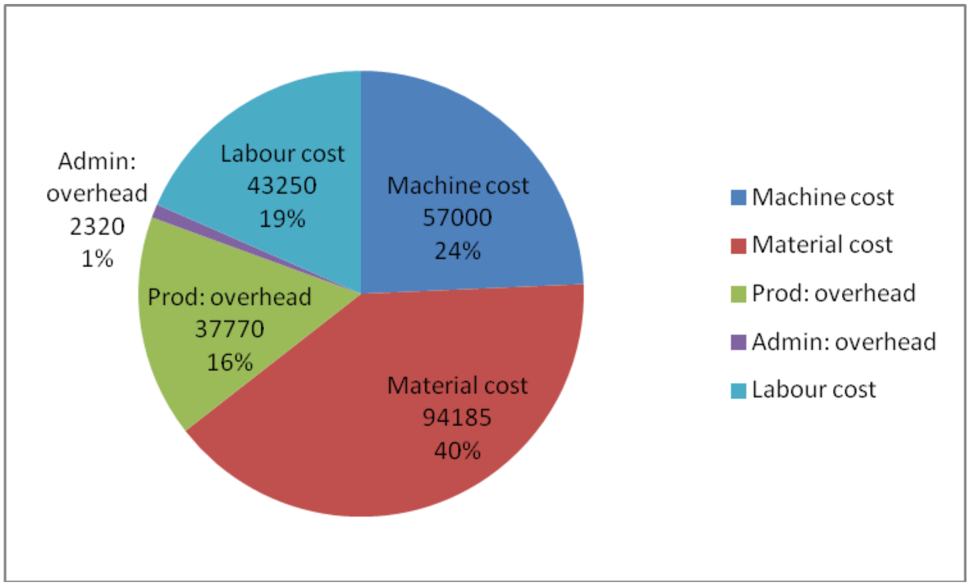


Figure 6:8 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of "Best case" operating model

A "best case" operating model was developed based on 30 hours of build time per run operating for 182 runs per year. The developed model is based on 2 technicians working with 10 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the model one machine was assumed to work for 30 hours of build time per run operating for 182 runs per year. This gives a total of 5460 working hours per year for each machine; approximately 62 % machine utilisation time per year.

Table 6.18 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" model. The operation of one run on one machine requires 2 hours of labour time as mentioned in the Table 6.32. The operation of 182 runs per year on one machine requires a total of 364 hours of labour hours per year. This gives a required estimated total of 3640 machine labour hours per year for operation of 10 machines. The labour hours per year for one technician based on 1760 labour hours per year gives a total of 3520 labour hours per year for 2 technicians. The operating model based on one run of 30 hours of build time on one machine was assumed to fabricate a total of 910 pairs per year which gives an estimated annual production volume of 9100 pairs of orthoses per year using 10 machines.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	364	1	1760
2	728	2	3520
3	1092	3	5280
4	1456	4	7040
5	1820	5	8800
6	2184	6	10560
7	2548	7	12320
8	2912	8	14080
9	3276	9	15840
10	3640	10	17600

Table 6:18 Machine labour hours/year and technicians labour hour/year in "best case" cost model

Table 6.19 shows details of cost categories in “best case” cost model based on 2 technicians working with 10 machines. A floor space of 6m^2 at the rate of £120/m^2 for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with the machine purchase and operation cost of 10 machines and material consumption cost per year. The labour cost for 2 technicians is estimated for £79960 per year at the rate £22.71 per hour. The model gives an estimated total of £1705760 for fabrication of 9100 pairs per year at the rate of £187.44 per pair approximately 46% reduction in cost per pair compared to initial operating model based on 220 working days per year.

“Best case” operating model for 2 technicians working with 10 machines	
Machine cost per year for 10 machines	£570000
Material cost for 9100 pairs @£103.5 per pair	£941850
Production overhead per year for 10 machines	£90750
Administrative overhead per year for 10 machines	£23200
Labour cost for 2 technicians	£79960
Total cost for 9100 pairs	£1705760
Cost per pair £1705760/21900 pairs/year	£187.44

Table 6:19 Total estimated fabrication cost per pair in “best case” polyjet based cost model

Figure 6.9 shows breakdown of different costs in “best case” cost model. The indirect cost accounts for 45% of the total cost. This includes machine cost 34%, production and administrative overheads 6% and labour cost 5% of the total cost. Material cost accounts for 55% of the total cost as the direct cost in the model.

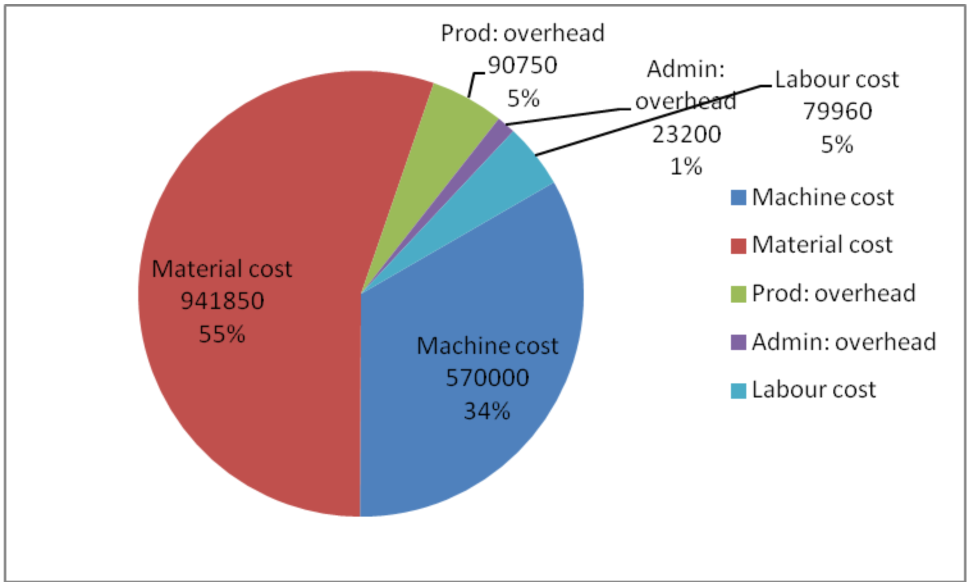


Figure 6:9 Cost categories in “best case” polyjet based cost model

6.4.5 Cost and lead-time modelling for 3DP technique using V-Flash system

In 3DP technique using V-Flash system, one machine was assumed to work one run of for 10 hours of time per day working for 220 working days per year. Production volume was calculated by the total estimated production volume form the model. A build time of 10 hours for fabrication of one part was given by V-flash™ machine controlling software. The machine is assumed to work for 220 days per year. This gives a total of 2200 machine hours per year at the rate of 10 hours of build time per day; approximately 25% of machine utilisation time per year.

Table 6.20 shows the estimated total cost of £87839 for fabrication of 110 pairs per year at the rate of £798.53 per pair using V-flash 3DP system. Machine cost per year was calculated by the depreciation cost of the machine per year and 10% of the actual cost of the machine as the maintenance cost per year. The depreciation cost for the machine was assumed for 5 years. This gives a total cost of £4640 per year for machine cost. Material cost was calculated by weighing the material consumed in the model part and in support structure. The weight of total material consumed is then multiplied by the associated cost of the material.

The material consumed in the fabrication of orthoses model was 52 grams and material consumed in support structure was 29 grams. The total material consumed including support material was 81 grams per part. This gives an estimated material cost of £36.45 per part or £72.90 per pair cost. Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost of the machine at the rate of £1.5 per hour. This gives an estimated total of £32880 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead.

Labour cost was calculated by the required labour time for operation of machine. For the operation of one run using V-Flash system, it was estimated that one hour of labour time of the technician was required. The labour time is based on 30 minutes of the time for setting of the machine and loading material cartridge and 30 minutes of time for removing the part and post processing the fabricated part. However, in the initial model with one machine and one technician, the labour cost of £39980 was included as the annual salary of the technician.

Cost calculations using V-Flash system in 3DP technique		
Production volume per year		
Number of parts/build	N	1
Build time/run	T	10 hours
Production rate/hour	R = N/T	0.1 hours
Operation hours/year	HY	2200
Production volume/year	V = R x HY	220 parts
Total pairs/year		110 pairs
Machine cost per year		
Machine & ancillary equipment	E	£15465*
Depreciation cost/year	D = E/5	£3093
Machine maintenance cost/year	M	£1546
Total machine cost/year	MC = D+M	£4640
Material cost per pair		
Material/part	52 grams @£0.45/grams	£23.40
Support material/part	29 grams @£0.45/grams	£13.05
Model material cost/kg		£453*
Support material cost/kg		£453
Material cost/part		£36.45
Total cost/pair		£72.90
Production overhead per year		
Building area	246.5/m^2 @ £120/m^2 per annum**	£29580
Energy consumption by machine	@ £1.5/hour x 2200 machine operation hours per year from operating model	£3300
Total cost/year		£32880
Administrative overhead per year		
Hardware		£2175***
Software purchase		£2175***
Consumables cost/year		£1450
Hardware depreciation cost/year		£435
Software depreciation cost/year		£435
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost	110 pairs per year	£87839
Cost/pair	£87839/110 pairs	£798.53

* Cost quotation for material from Print IT 3D Ltd, UK, 2010, **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006.

Table 6:20 Calculations of cost per pair using V-Flash system in 3DP technique.

Figure 6.10 shows the detailed breakdown of the costs in the initial operating model based on 220 working days per year. The indirect cost accounts for 91% of the total cost. This includes machine cost 5%, production and administrative overheads 40% and labour cost 46 % of the total cost in the model. Material cost accounts for 9% of the total cost as the direct cost in the model.

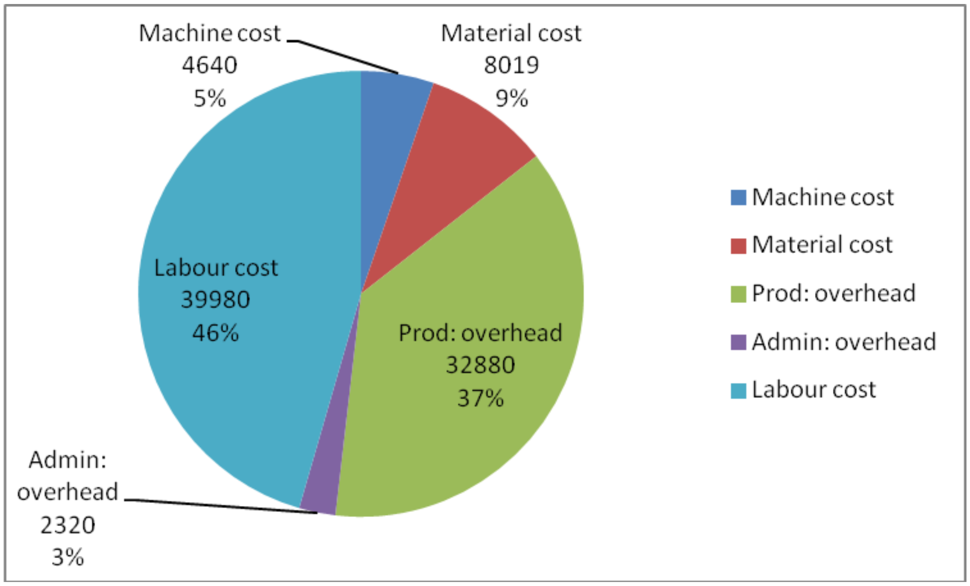


Figure 6:10 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.21 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for one hour of time per day for 145 working days was included. This has increased the production volume per year from 110 pairs to 182 pairs per year at the rate of £541.50 per pair. This has reduced approximately 32% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Total cost per pair using V-flash system		
Machine cost per year		£4640
Material cost for 182 pairs	@ £72.90/pair	£13267
Production overhead per year		£35055
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operator	£43272
Total cost	182 pairs per year	£98554
Cost per pair	£98554/182 pairs	£541.50

Table 6:21 Total cost per pair in intial operating model based on 365 working days per year

Figure 6.11 shows the detailed breakdown of the costs in the initial operating model based on 365 working days per year. The indirect cost accounts for 87% of the total cost. This includes machine cost 5%, production and administrative overheads 38% and labour cost 44 % of the total cost in the model. Material cost accounts for 13% of the total cost as the direct cost in the model.

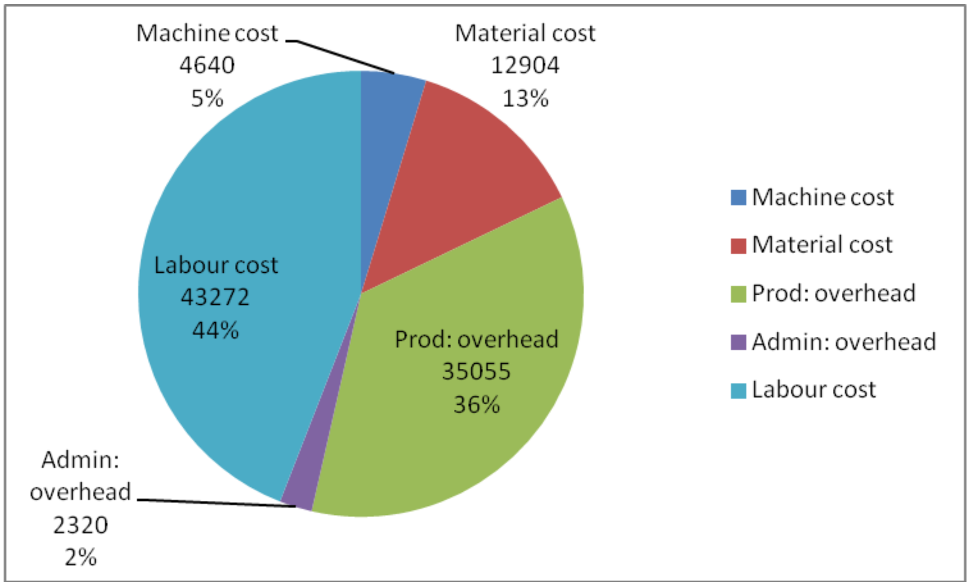


Figure 6:11 Cost categories in initial operating model based on 365 working days per year

Scenario 2- Development of "Best case" operating model

A "best case" operating model was developed based on one run of 10 hours of build time per day using V-Flash 3D system. The developed model is based on 2 technicians working with 10 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the developed operating model one machine was assumed to work for one run of 10 hours of build time per day for 365 days year. This gives 3650 machine working hours per year for each machine and a total of 36500 machines working hours per year for 10 machines; approximately 58% machine utilisation time per year.

Table 6.22 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" operating model. The operation of one run on one machine requires one hour of labour time as mentioned in the Table 6.42. The operation of 365 runs per year on one machine requires a total of 365 hours of labour hours per year. This gives a required estimated total of 3650 machine labour hours per year for operation of 10 machines. The labour hours per year for one technician are based on 1760 labour hours per year which gives total of 3520 hours per year for 2 technicians. The operating model assumed to fabricate a total of 182 pairs per year based on one run of 10 hours build time per day on one machine. This gives an estimated annual production volume of 1820 pairs of orthoses per year for 10 machines.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	365	1	1760
2	730	2	3520
3	1095	3	5280
4	1460	4	7040
5	1825	5	8800
6	2190	6	10560
7	2555	7	12320
8	2920	8	14080
9	3285	9	15840
10	3650	10	17600

Table 6:22 Machine labour hours/year and technicians labour hour/year in "best case" cost model

Table 6.23 shows details of cost categories in “best case” cost model based on 2 technicians working with 10 machines. A floor space of $6m^2$ at the rate of $£120/m^2$ for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with the machine purchase and operation cost of 10 machines and material consumption cost per year. The labour cost for 2 technicians is estimated for £79960 per year at the rate £22.71 per hour. The model gives an estimated total of £372988 for fabrication of 1820 pairs per year at the rate of £288.55 per pair; approximately 64% reduction in the cost per pair compared to initial operating model based on 220 working days per year.

“Best case” model of 2 technicians working with 10 machines		
Machine cost per year		£46400
Material cost for 1820 pairs	@ £72.90/pair	£132678
Production overhead per year		£90750
Administrative overhead per year		£23200
Labour cost per year	Full time + part time operator	£79960
Total cost	1820 pairs per year	£372988
Cost per pair	£372988/1820 pairs	£288.55

Table 6:23 Total estimated fabrication cost per pair in “best case” V-Flash based cost model

Figure 6.12 show the detailed breakdown of the costs in “best case” cost model. The indirect cost accounts for 64% of the total cost. This includes machine cost 13%, production and administrative overheads 30% and labour cost 21% of the total cost in the model. Material cost accounts for 36% of the total cost as the direct cost in the model.

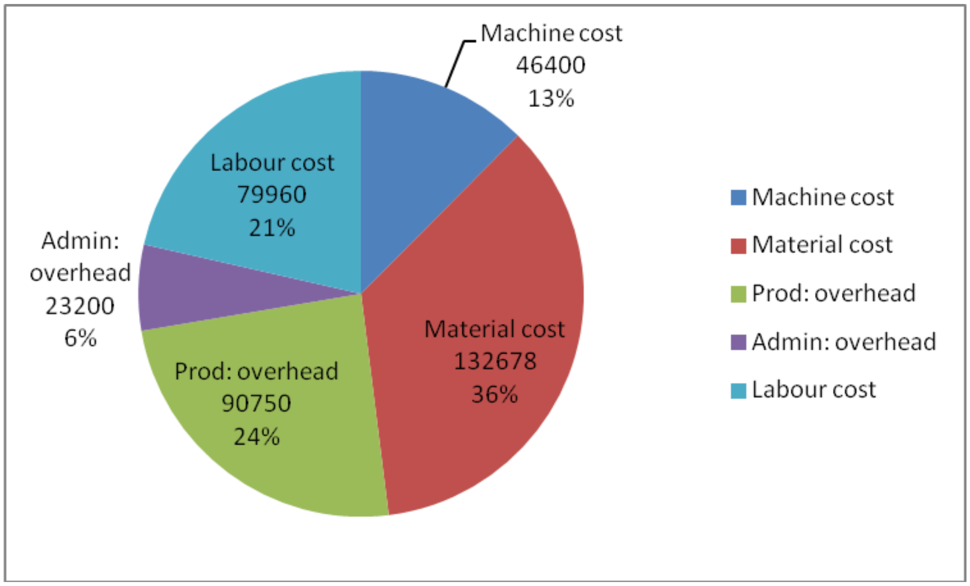


Figure 6:12 Cost categories in “best case” V-Flash based cost model

6.4.6 Cost and lead-time modelling for FDM technique using Dimension SST 768 system

In FDM technique using Dimension SST 768 system, one machine was assumed to work for one run of 14 hours of build time per day for 220 working days per year. Production volume was calculated by estimated annual production volume form the model. A Dimension SST 768 FDM system has a build volume of (length) 203, (width) 203 and (height) 305 mm in which two parts can be fitted per platform. A build time of 14 hours per run for fabrication of 2 parts was given by the catalyst® EX machine controlling software. The machine was assumed to work for 220 days per year. This gives a total of 3080 machine hours per year at the rate of 14 hours of build time per run per day approximately 35% of machine utilisation time per year.

Table 6.24 shows an estimated total cost of £101452 for fabrication of 220 pairs per year at the rate of £461.14 per pair. Machine cost per year was calculated by depreciation cost of the machine per year and 10% of the actual cost of the machine as the maintenance cost per year. The depreciation cost for machine was assumed for 5 years. This gives a total of £7000 as the machine cost per year.

Material cost was calculated by weighing the material consumed in model part and material consumed in support structure. The weight of total material consumed was then multiplied by associated cost of the material. The material consumed in fabrication of orthoses model was 90 grams and material consumed in support structure was 30 grams. The total material consumed was 120 grams per part which gives an estimated material cost of £40.80 per part or cost of £81.60 per pair. Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost of the machine at the rate of £1.5 per hour. This gives an estimated total of £34200 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead.

Labour cost was calculated by required labour time for operation of machine. For operation of one run using Dimension SST 768 FDM system it was estimated that 2 hours of labour time of the technician was required. The labour time is based on 60 minutes of time for setting of machine and loading the cartridges of model and support material and 60 minutes of time for post processing of fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 per year is included as the annual salary of the technician for 1760 labour hours per year, based on 220 working days per year.

Cost calculations using Dimension SST 768 system in FDM technique		
Production volume per year		
Number of parts/build	N	2
Build time/run	T	14 hours
Production rate/hour	R = N/T	0.142
Operation hours/year	HY	3080
Production volume/year	V = R x HY	440 parts
Total pairs/year		220 pairs
Machine cost per year		
Machine & ancillary equipment	E	£20000*
Depreciation cost/year	D = E/5	£5000
Machine maintenance cost/year	M (10%/year)	£2000
Total machine cost per year	MC = D+M	£7000
Material cost per pair		
Material/part	90 grams @£0.34/grams	£30.60
Support material/part	30 grams @£0.34/grams	£10.20
Model material cost/kg	968.1 grams	£330*
Support material cost/kg	968.1 grams	£330*
Material cost/part		£40.80
Total cost/pair		£81.60
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumption by machine	@ £1.5/ hour x 3080 machine operation hours per year from operating model	£4620
Total cost/year		£34200
Administrative overhead per year		
Hardware		£2175***
Software purchase		£2175***
Consumables cost/year		£1450
Hardware depreciation cost/year		£435
Software depreciation cost/year		£435
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost	220 pairs per year	£101452
Cost/pair	£101452/220pairs	£461.14

*Cost quotation from system supplier (Laser Lines Limited UK, 2010), **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006

Table 6:24 Calculation of cost per pair using SST 768 system in FDM technique

Figure 6.13 shows the detailed breakdown of the costs in the initial operating model based on 220 working days per year. The indirect cost accounts for 82% of the total cost. This includes machine cost 7%, production and administrative overheads approximately are 36% and labour cost 39% of the total cost in the model. Material cost accounts for 18% of the total cost as the direct cost in the model.

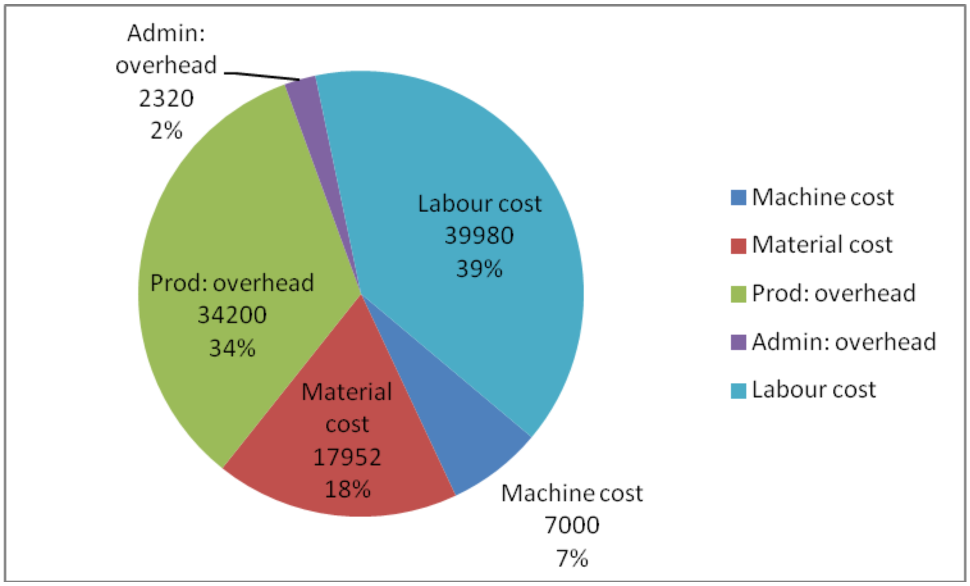


Figure 6:13 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.25 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 2 hours of time per day for 145 working days was included. The model has increased the production volume from 220 pairs to 365 pairs per year at the rate of £336.75 per pair. This has reduced approximately 18% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Total cost per pair using Dimension SST 768 system		
Machine cost per year		£7000
Material cost for 365 pairs	@ £81.60/pair	£29784
Production overhead per year		£37245
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operator	£46566
Total cost	365 pairs per year	£122915
Cost per pair	£122915/365 pairs	£336.75

Table 6:25 Total cost per pair in intial operating model based on 365 working days per year

Figure 6.14 shows the detailed breakdown of different cost elements in initial operating model based on 365 days per year. The indirect costs accounts for 76% of the total cost. This includes machine cost accounts for 6%, production and administrative overheads 32% and labour cost 38% of the total cost in the model. Material cost accounts for 24% of the total cost as the direct cost in the model.

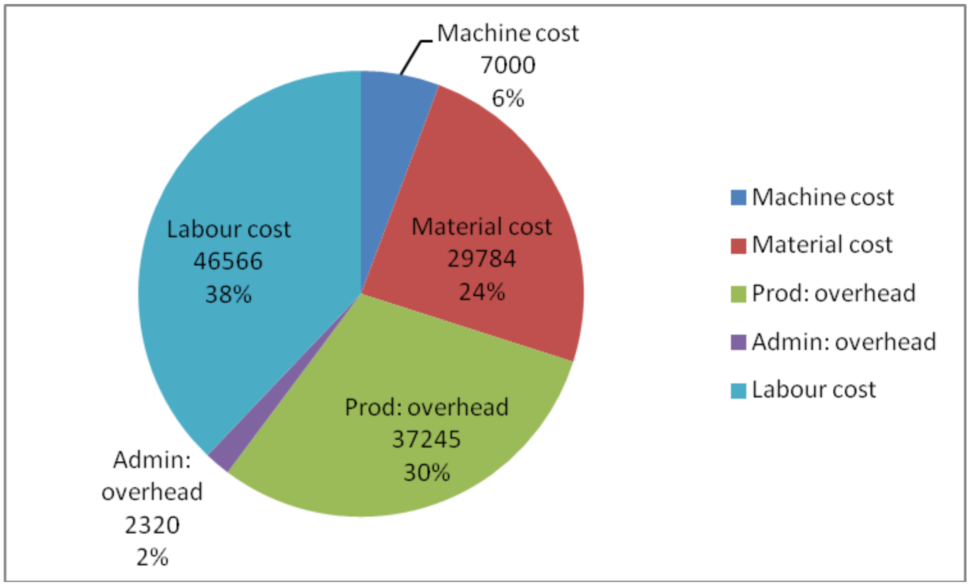


Figure 6:14 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of "Best case" operating model

A "best case" operating model was developed based on one run of 14 hours of build time per day using Dimension SST 768 system. The developed model is based on 5 technicians working with 12 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the developed operating model one machine was assumed to work for one run of 14 hours of build time per day for 365 days year. This gives 5110 machine working hours per year and a total of 61320 machine working hours per year for 12 machines. For the labour hours in the model, one technician was assumed to work for 8 hours per day for 220 working days per year which gives a total of 8800 labour hours per year for 5 technicians.

Table 6.26 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" operating model. The operation of one run on one machine requires 2 hours of labour time as mentioned in the Table 6.52. The operation of 365 runs per year on one machine requires a total of 730 hours of labour hours per year. This gives a required estimated total of 8760 machine labour hours per year for operation of 12 machines. The labour hours per year for one technician are based on 1760 labour hours per year, which gives total of 8800 hours per year for 5 technicians. The operating model assumed to fabricate a total of 365 pairs per year based on one run of 14 hours build time per day on one machine. This gives an estimated annual production volume of 4380 pairs of orthoses per year using 12 machines.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	730	1	1760
2	1460	2	3520
3	2190	3	5280
4	2920	4	7040
5	3650	5	8800
6	4380	6	10560
7	5110	7	12320
8	5840	8	14080
9	6570	9	15840
10	7300	10	17600
11	8030	11	19360
12	8760	12	21120

Table 6:26 Machine labour hours/year and technicians labour hour/year in "best case" cost model

Table 6.27 shows details of cost categories in "best case" cost model based on 5 technicians working with 12 machines. A floor space of 6 m^2 at the rate of £120/m^2 for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with machine purchase and operation cost for 12 machines and material consumption cost per year. The labour cost for 5 technicians is estimated for £199900 per year at the rate of £22.71 per hour. The model gives an estimated total of £798628 for fabrication of 4380 pairs per year at the rate of £182.33 per pair; approximately 60% reduction in cost per pair compared to initial operating model based on 220 working days per year.

"Best case" model based on 5 technicians working 12 machines		
Machines cost per year		£84000
Material cost for 4380 pairs	@ £81.60/pair	£357408
Production overhead per year		£128480
Administrative overhead per year		£27840
Labour cost per year	Full time + part time operator	£199900
Total cost	4380 pairs per year	£798628
Cost per pair	£798628/4380 pairs	£182.33

Table 6:27 Total estimated fabrication cost per pair in "best case" SST 768 FDM cost model

Figure 6.15 shows breakdown of different costs in "best case" cost model. The indirect cost accounts for 55% of the total cost in the model. This includes machines cost 11%, production and administrative overheads 19% and labour cost 25% of the total cost in the model. Material cost accounts for 45% of the total cost as the direct cost in the model.

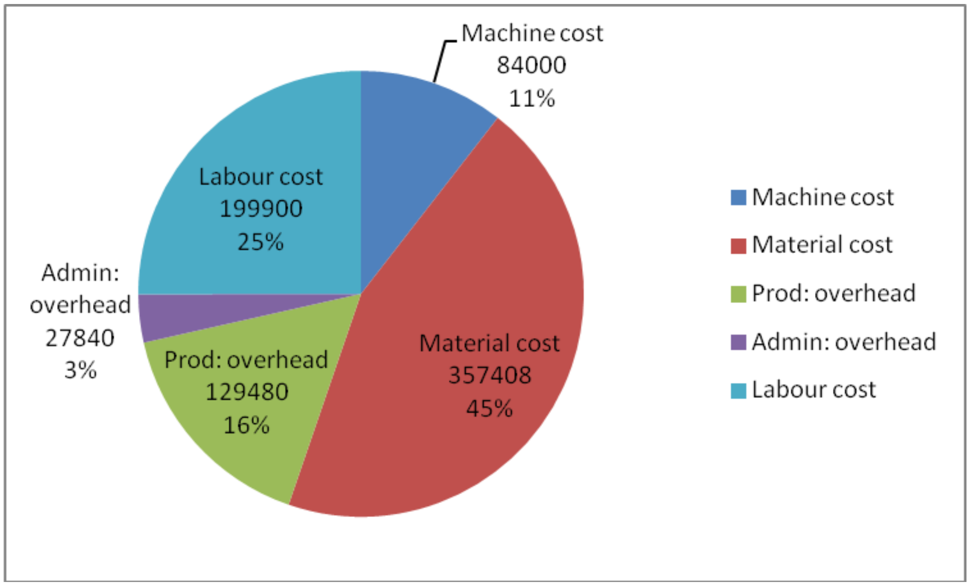


Figure 6:15 Cost categories in “best case” Dimension 768 SST FDM based cost model

6.4.7 Cost and lead-time modelling for FDM technique using Dimension uPrint system

In FDM technique using Dimension uPrint system, one machine was assumed to work for 14 hours of build time per day based on 2 runs per day for 220 working days per year. Production volume was calculated by total estimated production volume per year from the model. uPrint FDM system has a build volume of (length) 203, (width) 152 and (height) 152 mm in which one part can be fitted per platform. A build time of 7 hours per run for fabrication of one part was given by catalyst® EX machine control software. The machine was assumed to work for 14 hours of time per day for 220 days per year. This gives a total of 3080 machine hours per year at the rate of 2 runs of 7 hours of build time per day; approximately 35% of the machine utilisation time per year.

Table 6.28 shows the estimated total of £94912 for fabrication of 220 pairs per year at the rate of £431.41 per pair using the uPrint FDM system. Machine cost per year was calculated by depreciation cost of the machine per year and 10% of the actual cost of the machine as the maintenance cost per year. The depreciation cost for the machine was assumed for 5 years. This gives a total cost of £4200 per year for machine cost.

Material cost was calculated by weighing the material consumed in the model part and material consumed in support structure. The weight of the total material consumed is then multiplied by the associated cost of the material. The material consumed in orthoses model was 55 grams and material consumed in support structure was 40 grams. The total material consumed was 95 grams per part. This gives an estimated material cost of £32.30 per part or £64.60 per pair cost.

Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost of the machine at the rate of £1.5 per hour. This gives an estimated total of £32880 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead.

Labour cost was calculated through required machine operation labour time. For the operation of one run using it was estimated that one hour of labour time of the technician was required. The labour time is based on 30 minutes of time for setting of machine and loading the material cartridges of model and support material and 30 minutes of time for post processing of the fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 is included as the annual salary of the technician.

Cost calculations using Dimension uPrint system in FDM technique		
Production volume per year		
Number of parts/build	N	1
Build time/run	T	7 hours
Production rate/hour	R = N/T	0.142
Operation hours/year	HY	3080
Production volume/year	V = R x HY	440 parts
Total pairs/year		220 pairs
Machine cost per year		
Machine & ancillary equipment	E	£14000*
Depreciation cost/year	E/5	£2800
Machine maintenance cost/year	M (10% /year)	£1400
Total machine cost/year	MC = D+M	£4200
Material cost per pair		
Material/part	55 grams @£0.34/grams	£18.70
Support material/part	40 grams @£0.34/grams	£13.60
Model material cost/kg	968.1 grams	£330*
Support material cost/kg	968.1 grams	£330*
Material cost/part		£32.30
Total cost/pair		£64.60
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumption by machine	@ £1.5/hour x 3080 machine operation hours per year from operating model	£4620
Total cost/year		£34200
Administrative overhead per year		
Hardware		£2175***
Software purchase		£2175***
Consumables cost/year		£1450
Hardware depreciation cost/year		£435
Software depreciation cost/year		£435
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost		£94912
Cost/pair	£94912/220 pairs	£431.41

*Cost quotation from system supplier (Laser Lines Limited UK, 2010), **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006

Table 6:28 Calculations of cost per pair using uPrint system in FDM technique

Figure 6.16 shows the detailed breakdown of the costs in the initial operating mode based on 220 working days per year. The indirect cost accounts for 85% of the total cost. This includes the production and administrative overheads 39%, labour cost 42%

and machine cost 4% of the total cost in the model. Material cost account for 15% of the total as the direct cost in the model.

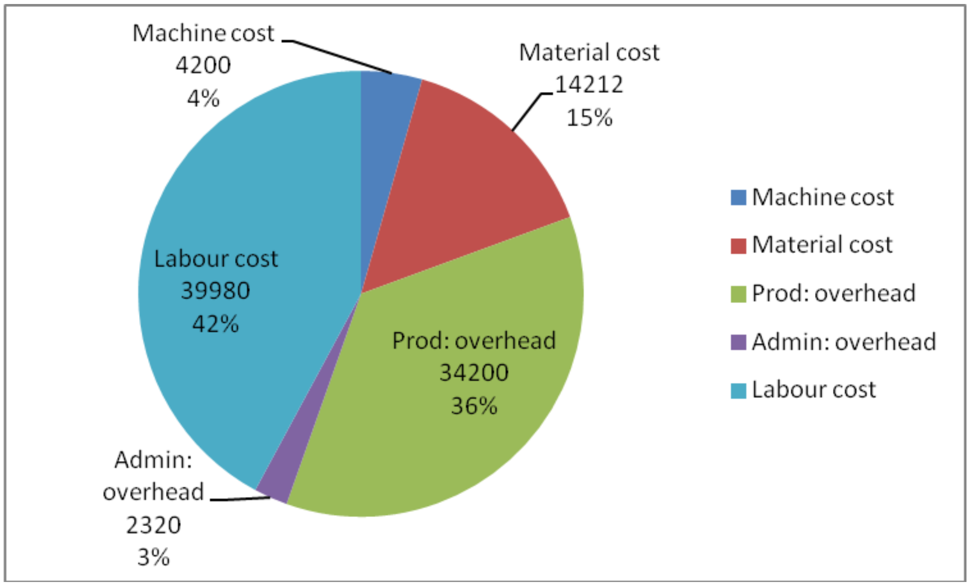


Figure 6:16 Cost categories in initial operating model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year.

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.29 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 2 hours of time per day for 145 working days was included. The model has increased the production volume from 220 pairs to 365 pairs per year at the rate of £312.08 per pair. This has reduced approximately 28% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Total cost per pair using Dimension uPrint FDM technique		
Machine cost per year		£4200
Material cost	@£64.60/pair for 365 pairs	£23579
Production overhead per year		£37245
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operators	£46566
Total		£113910
Cost per pair	£113910/365 pairs	£312.08

Table 6:29 Total cost per pair in intial operating model based on 365 working days per year

Figure 6.17 shows the detailed breakdown of different cost elements in initial operating model based on 365 working days per year. The indirect costs accounts for 79% of the total cost in the model. This includes machine cost 3%, production and administrative overheads approximately 35% and labour cost 41% of the total cost. Material cost accounts for 21% of the total cost as the direct cost in the model.

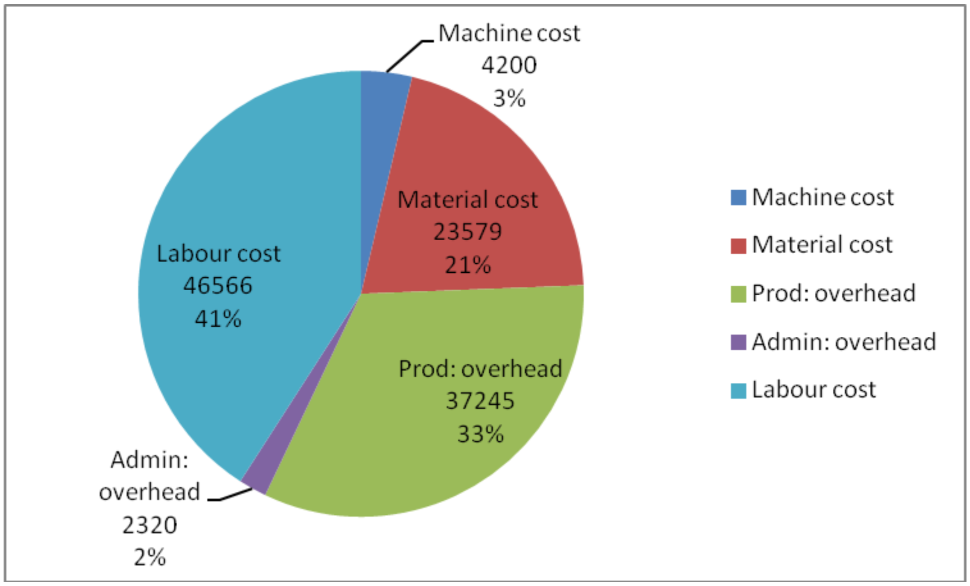


Figure 6:17 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of "Best case" operating model

A "best case" operating model was developed based on 2 runs of 14 hours of build time per day using Dimension uPrint system. The developed model is based on 5 technicians working with 12 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the developed operating model one machine was assumed to work for 2 runs of 14 hours of build time per day for 365 days year. This gives 5110 machine working hours per year and a total of 61320 machine working hours per year for 12 machines. For the labour hours in the model, one technician was assumed to work for 8 hours per day for 220 working days per year which gives a total of 8800 labour hours per year for 5 technicians.

Table 6.30 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" operating model. The operation of one run on one machine requires 1 hour of labour time. The operation of 730 runs per year on one machine requires a total of 730 hours of labour hours per year. This gives a required estimated total of 8760 machine labour hours per year for operation of 12 machines. The labour hours per year for one technician are based on 1760 labour hours per year which gives total of 8800 hours per year for 5 technicians. The operating model assumed to fabricate a total of 365 pairs per year based on 2 runs of 14 hours build time per day on one machine. This gives an estimated annual production volume of 4380 pairs of orthoses per year using 12 machines. Table 6.26 in Section 2.4.6 referred as the machine operation hours and technician hour per year.

Table 6.30 shows details of cost categories in "best case" cost model based on 5 technicians working with 12 machines. A floor space of 6 m^2 at the rate of £120/m^2 for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with machine purchase and operation cost for 12 machines and material consumption cost per year. The labour cost for 5 technicians is estimated for £199900 per year at the rate of £22.71 per hour. The model gives an estimated total of £689568 for fabrication of 4380 pairs per year at the rate of £157.43 per pair approximately 64% reduction in cost per pair compared to initial operating model based on 220 working days per year.

Best case model based on 5 technicians working 12 machines		
Machines cost per year		£50400
Material cost for 4380 pairs	@£64.60/pair	£282948
Production overhead per year		£128480
Administrative overhead per year		£27840
Labour cost per year	Full time + part time operator	£199900
Total cost	4380 pairs per year	£689568
Cost per pair	£689568/4380 pairs	£157.43

Table 6:30 Total estimated fabrication cost per pair in "best case" uPrint FDM based cost model

Figure 6.18 shows breakdown of different costs in "best case" cost model. The indirect cost accounts for 59% of the total cost. This includes machines cost 7%, production and administrative overheads 23% and labour cost 29% of the total cost in the model. Material cost accounts for 41% of the total cost as the direct cost in the model.

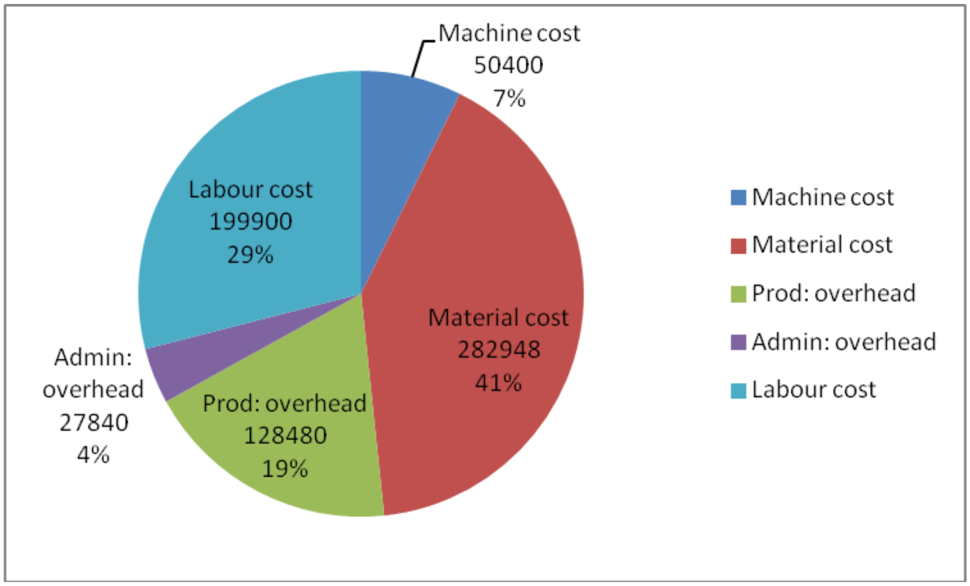


Figure 6:18 Cost categories in "best case" uPrint FDM based cost model

6.4.8 Cost and lead-time modelling for CAD/CAM using Amfit system

In CAD/CAM technique Amfit CAD/CAM system one machine was assumed to work for 8 hours of time per day for 220 working days per year. Production volume was calculated by total estimated production volume per year from the developed model.

Amfit CAD/CAM system fabricates 3 pairs per hour of foot orthoses. This gives a total of 24 pairs per day based on 8 hours of working time per day (Malanie Shelton, Personal communication, Amfit Inc, USA, 2010). The operating model developed is based on 8 hours of machine working time per day in which 24 pairs can be fabricated per day. The machine is assumed to work for 220 days per year. This gives a total of 1760 machine hours per year at the rate of 8 hours of working time per day; approximately 20% of machine utilisation time per year.

Table 6:31 shows the estimated total cost of £94912 for fabrication of 5280 pairs per year at the rate of £29.96 per pair. Machine cost per year was calculated by depreciation cost of machine per year and 10% of the actual cost of the machine as the maintenance cost per year. The depreciation cost for the machine was assumed for 5 years. This gives a total of £4500 as the machine cost per year. Material cost per pair n CAD/CAM technique was calculated by standard cost £15 for one pair of blank which makes a total cost of £79200 per year or 5280 pairs of blanks. Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost for the machine at the rate of £1.5 per hour. This gives an estimated total of £32220 per year as production overhead. A cost of £2320 per year was included as administrative overhead. In the initial model with one machine and one technician, the labour cost of £39980 per year was included as the annual salary of the technician for 1760 labour hours per year based on 220 working days per year.

Cost calculations using Amfit milling system		
Production volume per year		
Number of pairs/hour	N	3 pairs
Production rate/day	N x hours per day	24 pairs
Hours per year in operation	HY	1760 hours
Production volume/year		5280 pairs
Machine cost per year		
Machine & ancillary equipment	E	£15000*
Depreciation cost/year	E/5	£3000
Machine maintenance cost/year	M (10%/year)	£1500
Total machine cost/year	MC = D+M	£4500
Material cost per pair		
Cost of blanks per pair		£15.00
Total cost for 5280 pairs/year		£79200
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumption by machine	@ £1.5 per hour x 1760 machine operation hours per year from operating model	£2640
Total cost/year		£32220
Administrative overhead per year		
Hardware		£2175***
Software purchase		£2175***
Consumables cost/year		£1450
Hardware depreciation cost/year		£435
Software depreciation cost/year		£435
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980/year
Total cost		£94912
Cost/pair	£94912/5280 pairs	£29.96

*Cost quotation from Amfit Inc USA, 2010, **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006.

Table 6:31 Calculations of cost per pair using Amfit CAD/CAM milling technique

Figure 6.19 shows the detailed breakdown of the costs in the initial operating model based on 220 working days per year. The indirect costs accounts for 50% of the total cost. This includes production and administrative overheads 22%, labour cost 25% and machine cost 3% of the total cost in the model. Material cost accounts for 50% of the total cost as direct cost in the model.

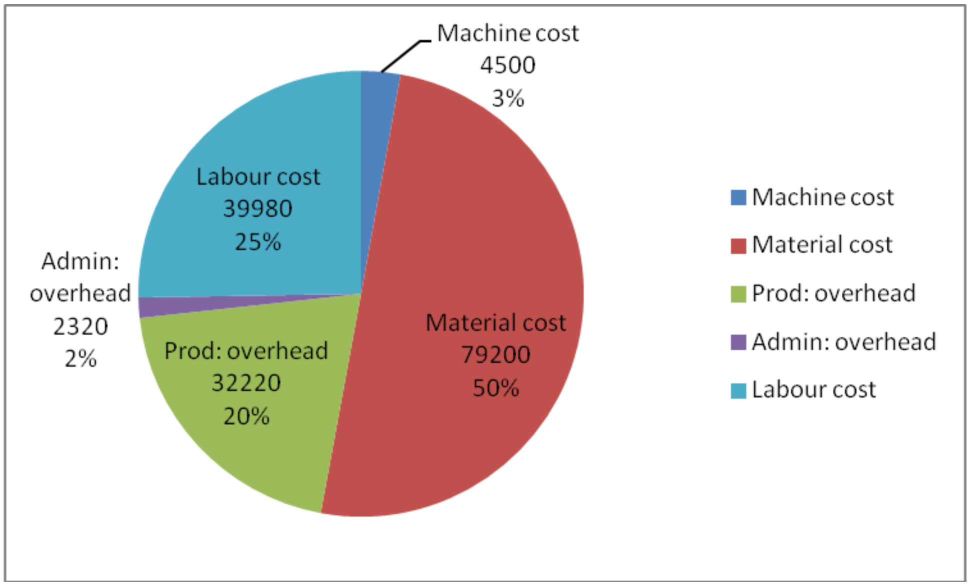


Figure 6:19 Cost categories in initial operating cost model based on 220 working days per year

- **Sensitivity analysis of the model**

Scenario 1-Increasing the machine operation hours per year.

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 6.32 shows the cost categories in assumed initial operating model working for 365 days per year. A part time technician working for 8 hours of time per day for 145 working days was included. The model has increased the production volume from 5280 pairs to 8760 pairs per year at the rate of £27.22 per pair. This has reduced approximately 9% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Total cost per pair using Amfit system in CAD/CAM technique		
Machine cost per year		£4500
Material cost	@£15/pair for 8760 pairs	£131400
Production overhead per year		£33960
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operators	£66323
Total		£238503
Cost per pair	£238503/8760 pairs	£27.22

Table 6:32 Total estimated cost per pair in initial operating model based on 365 days per year

Figure 6.20 shows the detailed breakdown of the costs in the initial operating model based on 365 working days per year. The indirect costs accounts for 45% of the total cost. This includes production and administrative 15%, labour cost 28% and machine cost 3% of the total cost in the model. Material cost accounts for 55% of the total cost as the direct cost in the model.

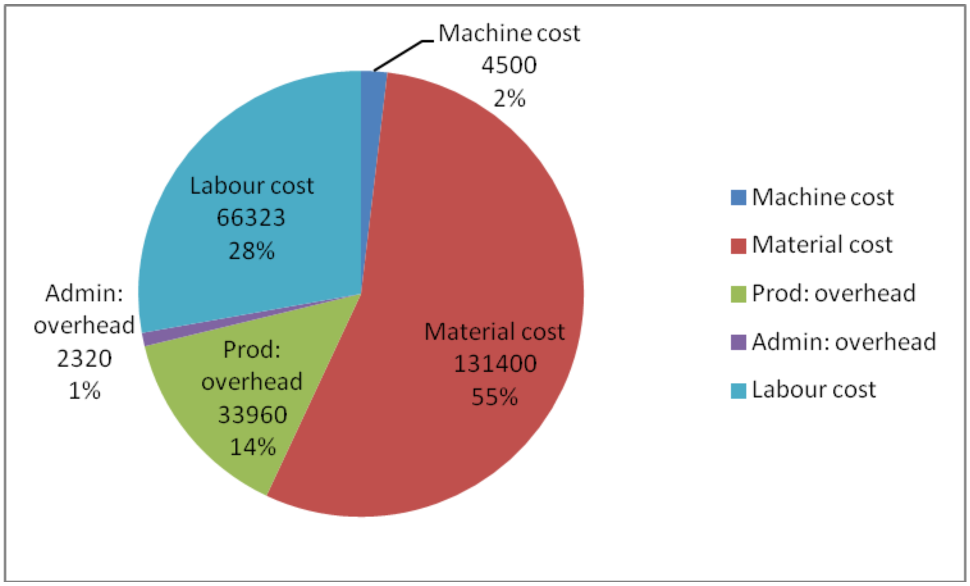


Figure 6:20 Cost categories in initial operating model based on 365 days per year

Scenario 2-Development of “Best case” operating model

A “best case” operating model was developed based on 8 hours of machine working time per day. The developed model is based on 5 technicians working with 3 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the developed operating model one machine was assumed to work for 8 hours of time per day for 365 days per year which gives 2920 machine working hours per year; utilisation of 33% of machine time per year. This gives a total of 8760 machine working hours per year for 3 machines. For the labour hours in the model one technician was assumed to work for 8 hours per day for 220 working days per year. This makes a total of 1760 labour hours per year for one technician and a total of 8800 labour hours per year for 5 technicians.

Table 6.33 shows the required machines labour hours per year and labour hours of technicians per year in the “best case” operating model. In the “best case” operating model one machine was assumed to fabricate a total of 8760 pairs per year based on 8 hours of working time per day. This gives an estimated annual production volume of 26280 pairs of orthoses per year for 3 machines.

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	2920	1	1760
2	5840	2	3520
3	8760	3	5280
4	11680	4	7040
5	14600	5	8800
6	17520	6	10560
7	20440	7	12320
8	23360	8	14080
9	26280	9	15840
10	29210	10	17600

Table 6:33 Machine labour hours/year and technicians labour hour/year in “best case” cost model

Table 6.34 shows the details of the cost categories in the “best case” developed model based on 5 technicians working with 3 machines. A floor space of 6m^2 at the rate of £120/m^2 was included for each additional machine and ancillary equipment and energy cost of £1.5/hour for each additional machine is included. The model gives an estimated total cost of £658720 per year for fabrication of 26280 pairs of orthoses per year which include the production and administration overhead costs, machine costs and material costs per year. The cost of £199900 was estimated for annual salary of the 3 technicians per year. The operating model gives a total estimated cost of £25.06 per pair for foot orthoses using Amfit CAD/CAM milling technique. This has reduced approximately 9% cost for a pair of orthoses compared to initial operating model based on 220 days per year.

“Best case” operating model of 3 machines and 5 technicians	
Machine cost per year for 3 machines	£13500
Material cost for 26280 pairs of blanks	£394200
Production overhead per year for 3 machines	£44160
Administrative overhead per year for 3 machines	£6960
Labour cost for 5 technicians	£199900
Total cost for 26280 pairs per year	£658720
Cost per pair £658720/26280 pairs/year	£25.06 per pair

Table 6:34 Total estimated fabrication cost per pair in “best case”CAD/CAM based cost model

Figure 6.21 show the detailed breakdown of the costs in “best case” developed model. The indirect cost accounts for 40% of the total cost in the model. This includes the production and administrative overheads 8%, labour cost 30% and machine cost accounts for 2% of the total cost in the model. Material cost accounts for 60% of the total cost as the direct cost in the model.

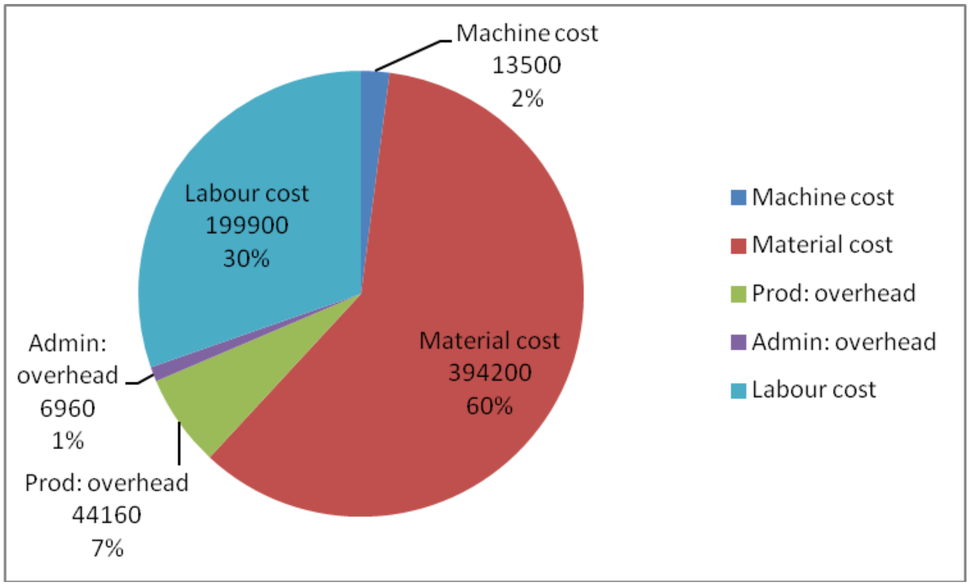


Figure 6:21 Cost categories in “best case” Amfit CAD/CAM system based cost model

6.5 Summary

In “best case” cost models for selective laser sintering SLS, stereolithography SLA and polyjet techniques showed the direct cost (cost of material) were approximately 75%, 47% and 55% respectively of the total cost. Machine purchase and operation, labour, production and administration overheads account for 25%, 53% and 45% as the indirect costs of the total cost. The models gave a total per pair cost of £85.34, £133.25 and £190.51, respectively. The lead-times of 16 hours for fabrication of 15 pairs in SLS, 7 hours for 5 pairs in SLA and 30 hours for 5 pairs in polyjet gave the productivity of nearly one hour of time in SLS, one and half hour of time in SLA and 6 hours of time per pair in polyjet technique.

In FDM technique using Dimension SST 768 and uPrint systems, the "best case" developed models showed direct costs were (material cost) approximately 45% and 41% of the total cost in both techniques. The costs for machines, labour and production and administration overheads were approximately 55% and 59% of the total cost in both techniques. The models give a total cost of £182.33 and £157.43, respectively for one pair of orthoses. The lead-times were also high giving approximately 14 hours of time for fabrication of one pair of orthoses in both techniques. In V-Flash technique, the "best case" developed model showed the direct cost (material cost) was 36% of the total cost. The labour, machines and production and administration overheads account for 64% of the total cost. The model gives a total cost of £288.55 for one pair of orthoses. The lead-time of 20 hours per pair was higher than all other fabrication techniques giving 20 hours time per pair.

In CAD/CAM fabrication technique, the "best case" developed model showed that material cost were major incurring categories approximately 60% of the total cost whereas production and administration overheads and machines and labour costs account for 40 % of the total cost. The model gives the total cost of £25.06 per pair. The lead-time of 3 pairs per hour is the higher productivity ratio in comparison to all RM based fabrication techniques. Figure 6.22 shows fabrication cost per pair and lead-times and Figure 6.23 shows the cost per pair and productivity in hours per pair in different orthoses fabrication techniques. The development of "best case" models showed that indirect costs (initial capital costs) in all the RM based cost models were reduced from the initial capital costs in the initial operating cost model. The indirect costs of 42% in SLS, 65% in SLA, 70% in polyjet, 91% in V-flash, 82% in Dimension 768 SST and 85% in Dimension uPrint were reduced to 25% in SLS, 53% in SLA, 45% in polyjet, 64% in V-flash, 55% in Dimension SST and 59% in Dimension uPrint based models, respectively in the “best case” developed models. The burden of initial capital cost is lowered in all the best case developed models because of increasing the number of machines and balancing the machine labour hours and technician labour hours in the developed “best case” models.

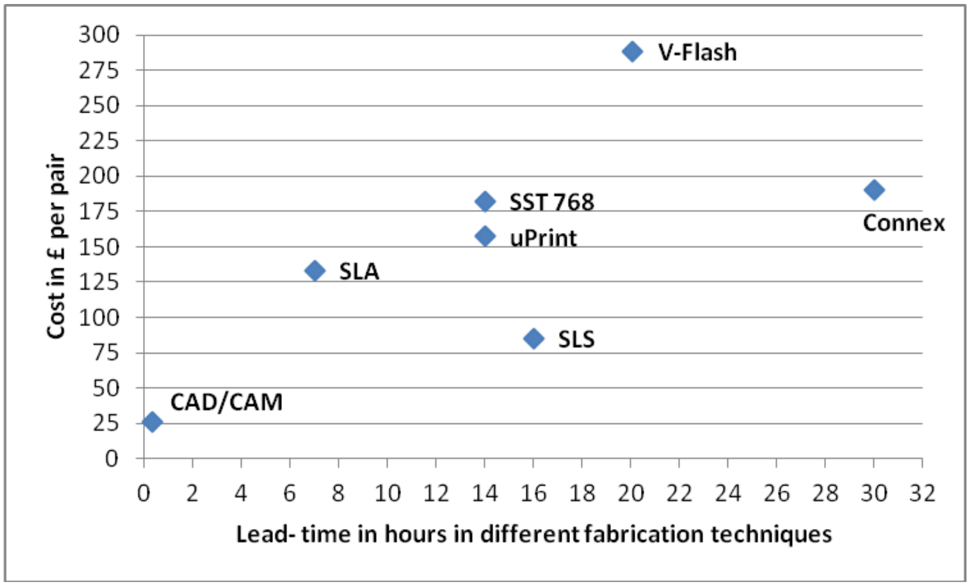


Figure 6:22 Fabrication lead-time and cost per pair in “best case” developed models

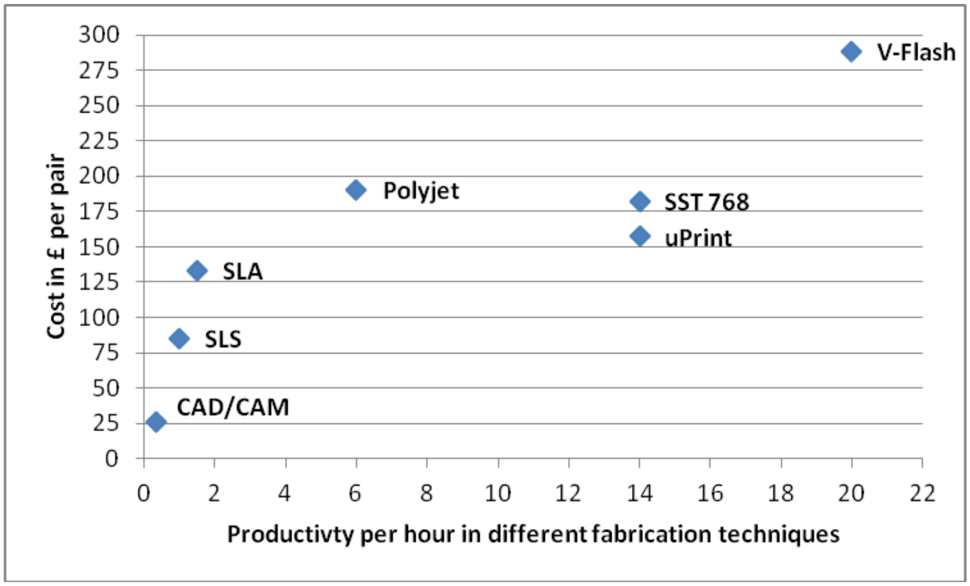


Figure 6:23 Cost per pair and productivity per hour in “best case” developed models

Chapter 7 Discussion and conclusions

7.1 Introduction.

The aim of this work was to assess the potential for rapid manufacturing techniques in the design and fabrication of custom-made foot orthoses. The main objective was to evaluate the application of rapid manufacturing techniques for production of cost effective custom-made foot orthoses at a commercial scale with low lead-time. The previous work had demonstrated the feasibility of rapid manufacturing techniques in fabrication of custom-made foot orthoses (Pallari, 2008; Pallari et al, 2010). In the following sections step by step research findings from this work is discussed.

7.2 Discussion

7.2.1 Design of rapid manufacturing based process model through IDEF0.

In Chapter 3, Section 3.6 “rapid manufacturing” approach in the design and fabrication process has shown significant advantages in reducing the traditional manual activities in orthoses fabrication process. The automated fabrication processes in rapid manufacturing without the need of moulding, tooling and equipment; requiring minimal labour intervention during the fabrication process. Re-modelling of the process of design and fabrication of custom foot orthoses showed improvements and increased the process efficiency by applications of rapid manufacturing approach in the system. Different commercially established rapid manufacturing techniques integrated in the process have demonstrated the transformation and shift from the conventional design and fabrication functions to a digital design and fabrication process.

In IDEF0 based “as-to-be” process model (A-1) of the system, the main functions and activities are based on digital foot geometry capture, CAD based orthoses design and digital fabrication process; using rapid manufacturing techniques. This has resulted in development of a seamless digital design and fabrication process for production of custom-made foot orthoses. The analysis of main functions in the developed rapid manufacturing based process model has demonstrated significant improvements in the main functions. Applications of digital foot geometry capture and CAD techniques in design of orthoses replaced the traditional time, cost and labour intensive activities in functions of foot geometry capture and orthoses design. The developed model further showed that the function of “planning for manufacturing” in the system require less work after integration of rapid manufacturing techniques in the design and fabrication process.

7.2.2 Digital foot geometry capture.

The application of digital foot geometry capture method has shown significant improvements in terms of time and cost in comparison to traditional foot geometry capturing methods (Payne, 2007; Boardman, 2007; Williams, 2010). Digital foot geometry capture generates the output information in a digital format which is a requirement for the rapid manufacturing based design and fabrication system.

Digital foot geometry capturing method removes the steps involved in traditional foot geometry capturing methods which require time for setting and drying of the impression cast and efforts for physical shipment of casts to manufacturing facility. The main advantages of digital based geometry capture are removing the need of physical material in foot impression casting and manual labour work in the process which has subsequently reduced the geometry capture time and cost.

In Chapter 4, Sections 4.2 and 4.3, time and cost modelling of different geometry capturing methods showed that the 3D digital foot geometry capturing method significantly reduced the time and cost in foot impression capturing process. Digital geometry capturing method reduced the estimated cost of foot geometry capturing from £48 per pair in plaster based methods to £6 per pair in digital based methods. The estimated time in foot geometry capture process was also reduced from 5 hours of time in plaster based methods to 5 minutes of time per pair in digital foot geometry capture methods.

Digital foot geometry capture methods have additional advantages of removing the need for managing and storing physical inventories of foot impression casts, material and waste generation in impression capturing process. Overall, it is concluded that digital foot geometry capture offers significant benefits to the industry. However, for these to be realised, the downstream processes in fabrication of orthoses must be capable of operating with digital information.

7.2.3 CAD design of orthoses.

In designing of the orthoses, applications of CAD have shown increased advantages over the plaster based designing methods particularly in reducing the designing time and cost, labour. CAD based designing methods have shown several advantages over the plaster based designing methods. The required orthoses design features, corrections and modifications (such as adding wedging angles, heel cupping, ramps, etc.) can be incorporated accurately and can be viewed and reviewed on the CAD system.

The significant advantage in CAD based orthoses design is elimination of manual errors in the designing process where the designer can view on screen the designed orthosis features which facilitate determining the appearance and final shape of the product after actual fabrication of the orthoses. One of the other additional advantages of CAD based design method is removing the need of physical storage of designed foot impression casts and material in the orthoses design process. The CAD based design method facilitates in managing the data base and electronic storage of the orthoses designs where the designs can be easily stored and quickly transferred to manufacturing facility which makes the orthoses design and fabrication process faster and reliable. Efficient data base management of digital records of orthoses designs eliminates the cost and time in handling the physical inventory and transferring and shipping of the designed orthoses.

In Chapter 4, Sections 4.5 and 4.6, time and cost modelling of the different orthoses design methods showed that an estimated orthosis design cost of £18 per pair in plaster based design methods was reduced to cost of £2 per pair in the CAD based design methods. The orthoses design time of 5 hours and 45 minutes in plaster based designing methods was also reduced by CAD based designing methods; consuming only 5 minutes of time per pair in design of the orthoses. The comparison of plaster based and CAD based orthoses design methods showed that the plaster based design methods involve higher time and are cost intensive. The methods are craft based and labour intensive involving manual and physical work, where the orthoses design is based on the experience and craftsmanship of the designer. The accuracy and conformance of the design features depend on the individual expertise rather than the systematic engineering design principles.

In CAD based design methods the designers have increased control in incorporating the orthoses design features which has the potential to reduce dependency on individual skills and craftsmanship and show advantages in terms of increased precision accuracy and consistency. The CAD based designing method simplifies and speed up the orthoses designing process. The method facilitates the orthoses designer with increased control in design alterations and in adding and incorporating the prescribed design features more effectively and accurately. The designing process is expected to be more effective, quick and consistent with increased accuracy. One of the additional advantages of CAD based orthoses design is the easy repeatability of the design of the orthoses if required.

Overall, CAD based designing methods have increased advantages over the plaster based designing methods in terms of reduced design time and cost. The method has increased process efficiency, control, precision, repeatability and advantages of reduced dependency on the individual skills, which have significant impacts on the consistency and quality in the final orthoses product.

7.2.4 Rapid manufacturing techniques in fabrication of orthoses.

In the fabrication of orthoses, feasibility of various rapid manufacturing techniques were investigated in terms of cost, lead-time and production of complex geometries and design features in custom-made foot orthoses. Conventional fabrication techniques have shown limitations in incorporating and fabricating the required complex design features at specific sites in the orthoses; such as fabrication of metatarsal dome and supporting wedges in the custom-made foot orthoses. Rapid manufacturing techniques are based on additive manufacturing process where the parts are fabricated layer by layer without tooling and equipments. The main advantages of rapid manufacturing techniques are increased design freedom, ability to fabricate complex geometrical features with increased accuracy, consistency and overall quality improved product.

The significant advantages of rapid manufacturing techniques are; ease in fabrication of custom-specific complex geometrical parts and devices, increased accuracy and consistency with the key advantage of repeatability for custom-specific personalised parts and products (Gibson et al, 2010, Wohlers, 2010). In fabrication of orthoses these techniques have shown advantages of fabricating complex geometrical design features with increased accuracy and consistency in comparison to conventional milling techniques (Pallari et al, 2010).

7.2.5 Orthoses materials

In Section 5.2.2 analysis of mechanical and other properties of traditional orthoses materials used for fabrication of custom foot orthoses with the potential rapid manufacturing materials showed that currently commercially available rapid manufacturing materials could be used in the orthoses fabrication as an end use product material.

7.2.6 Cost and lead-time modelling

The cost and lead-time modelling in chapter 6 showed that RM based systems are still expensive; giving higher per pair cost in comparison to conventional fabrication technique. However; with progressing developments in RM machines and materials, the cost of raw materials and systems are falling down which could bring the RM fabrication processes competitive with conventional fabrication techniques.

7.3 Key features of rapid manufacturing based design and fabrication system for production of custom-made foot orthoses.

In rapid manufacturing based design and fabrication systems the functions of foot geometry capture and design of orthoses are digital based and are identical. However, fabrication lead-time and fabrication costs are different in different rapid manufacturing techniques used.

7.3.1 Lead-time modelling

The method for estimation of lead-time in different rapid manufacturing techniques was obtained through equation no 1.

$$T_{\text{lead-time}} = T_{gc} + T_{od} + T_{fab} \qquad \text{Eq (7.1)}$$

Where $T_{\text{lead-time}}$ is the estimated total lead-time per pair, which is the sum of foot geometry capture time per pair (T_{gc}), orthoses design time per pair (T_{od}) and orthoses fabrication time per pair (T_{fab}) in different rapid manufacturing techniques.

7.3.2 Total estimated design and fabrication lead-time and total estimated cost per pair in different rapid manufacturing based systems.

In the following section (i) Total estimated design and fabrication lead-time (ii) Total estimated design and fabrication cost and (iii) total estimated productivity in hours in different rapid manufacturing techniques based systems are presented.

i. Total estimated design and fabrication lead-time

The total estimated design and fabrication lead-time is made up of (i) time in foot geometry capture, (ii) time in orthoses design and (iii) time in fabrication of orthoses. As earlier mentioned that foot geometry capture and orthoses design times are identical in all the systems and were estimated to take 5 minutes of time for each function, respectively. However, orthoses fabrication lead-time is different due to different build time given by the rapid manufacturing systems.

Table 7.1 shows the total estimated design and fabrication lead-time in different rapid manufacturing techniques based systems. In selective laser sintering technique, using *spro* SLS system gave the total estimated design and fabrication lead-time of 18 hours and 30 minutes for 15 pairs of orthoses. In stereolithography technique, using *ipro* 8000 system gave total estimated design and fabrication lead-time of 7 hours and 50 minutes for 5 pairs of orthoses. In Polyjet technique, using Connex 500 system gave total estimated design and fabrication lead-time of 30 hours and 50 minutes for 5 pairs of orthoses. In 3DP technique using V-Flash system gave total estimated design and fabrication lead-time of 20 hours and 10 minutes per pair. In FDM technique, using Dimension SST 768 and uPrint systems have given the total estimated design and fabrication lead-time of 14 hours and 10 minutes per pair.

RM based systems	**Pairs/ build**	**Geometry capture**	**Design of orthoses**	**Fabrication time/build**	**Estimated lead-time**
spro SD SLS	15	75 min/15 pair	75min/15 pairs	16 hours	18 hrs 30 min
ipro SLA	5	25 min/5 pairs	25 min/5 pairs	7 hours	7 hrs 50 min
Connex 5000	5	25 min/5 pairs	25 min/5pairs	30 hours	30 hrs 50 min
3DP V-Flash	1	5 min/pair	5 min/pair	20 hours	20 hrs 10 min
SST 768	1	5 min/pair	5 min/pair	14 hours	14 hrs 10 min
uPrint	1	5 min/pair	5 min/pair	14 hours	14 hrs 10 min

Table 7:1 Total estimated design and fabrication lead-time in different RM based systems

ii. Total estimated design and fabrication cost per pair.

Table 7.2 shows the total estimated design and fabrication cost per pair in different rapid manufacturing based systems. The total estimated design and fabrication cost per pair is made up of (i) foot geometry capture cost, (ii) orthoses design cost and (iii) orthoses fabrication cost. The costs for geometry capture and design of orthoses are identical in all systems. However, fabrication costs are different due to different rapid manufacturing techniques and materials used. This has resulted in different total estimated design and fabrication costs per pair in different rapid manufacturing techniques based systems.

Rapid manufacturing based systems	**Geometry capture cost/pair**	**Orthoses design cost/pair**	**Orthoses fabrication cost/pair**	**Total estimated cost/pair**
spro SD SLS	£6	£2	£85.34	£93.34
ipro SLA	£6	£2	£133.25	£141.25
Connex 500	£6	£2	£190.51	£198.51
3DP V-Flash	£6	£2	£288.55	£296.55
SST 768	£6	£2	£182.33	£190.33
uPrint	£6	£2	£157.43	£165.43

Table 7:2 Total estimated design and fabrication cost per pair in different RM based systems

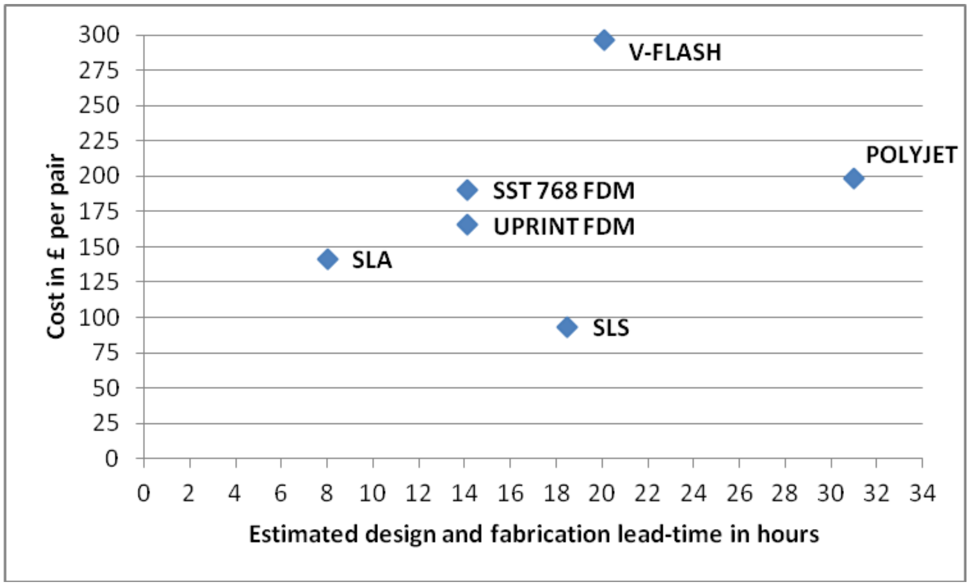


Figure 7:1 Design and fabrication lead-time and cost per pair in RM based systems

Figure 7.1 shows the total estimated design and fabrication lead-time and total estimated design and fabrication cost per pair in different rapid manufacturing based systems These estimates show clearly that SLS technique is projected to have the lowest overall cost, with SLA the next most competitive. For all of the other processes the cost of materials makes the projected cost of orthoses much higher than for these two systems.

iii. Estimated productivity in hours per pair.

Table 7.3 shows the productivity in hours per pair in rapid manufacturing based design and fabrication systems. The productivity in hours per pair is made up of (i) geometry capture time, (ii) orthoses design time and (iii) orthoses fabrication time.

RM based systems	**No: of pairs/ build**	**Estimated design and fabrication lead-time**	**Productivity in hours/pair**
spro SD SLS	15	18 hrs 30 min	1 hrs 22 min
ipro 8000 SLA	5	07 hrs 50 min	1 hrs 50 min
Polyjet connex	5	30 hrs 50 min	6 hrs 10 min
3DP V-Flash	1	20 hrs 10 min	20 hrs 10 min
SST 768 FDM	1	14 hrs 10 min	14 hrs 10 min
uPrint FDM	1	14 hrs 10 min	14 hrs 10 min

Table 7:3 Estimated productivity in hours per pair in different RM based systems

Figure 7.2 shows estimated productivity in hours per pair and total estimated design and fabrication cost per pair in different RM based systems.

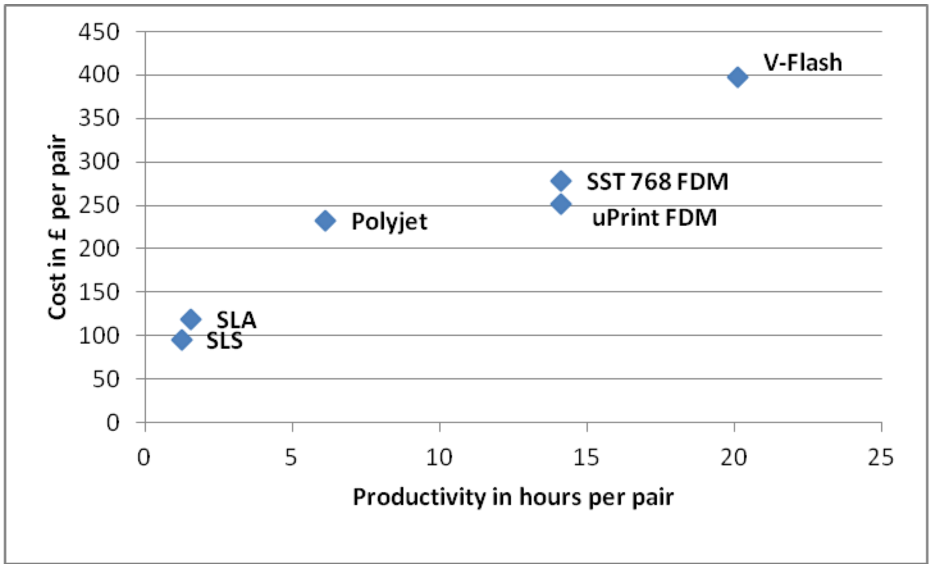


Figure 7:2 Productivity in hours and cost per pair in RM based systems

Again the results show SLS and SLA, because of the build capacities associated with these machines, to have the greatest productivities, with SLS projected to be slightly more productive than SLA.

7.3.3 Total estimated customer lead-time and total estimated overall cost per pair in different rapid manufacturing techniques based systems

i. Total estimated customer lead-time

The total estimated customer lead-time has been developed on the basis of design and fabrication lead-time, but amended to take into consideration the projected operating model, and likely delivery times assuming a centralised fabrication facility.

The time for foot assessment, geometry capture and design of orthoses is assumed to take one day; whereas delivery of orthoses is assumed to take 2 days of time. The time for foot assessment and geometry capture, design of orthoses and delivery are identical in all the systems. This is added with orthoses fabrication lead-time given by different rapid manufacturing techniques based systems.

Table 7.4 shows total estimated customer lead-time and total estimated cost per pair in different rapid manufacturing techniques based systems. Figure 8.3 shows the total estimated customer lead-time and total estimated cost per pair in different rapid manufacturing techniques based design and fabrication systems

RM based systems	**Foot assessment, geometry capture and orthoses design**	**Fabrication time/build**	**Delivery time in**	**Customer lead-time**
spro SD	1 day	16 hours	2 days	4 days
ipro 8000	1 day	7 hours	2 days	4 days
Polyjet	1 day	30 hours	2 days	5 days
V-Flash	1 day	20 hours	2 days	4 days
SST 768	1 day	14 hours	2 days	4 days
uPrint	1 day	14 hours	2 days	4 days

Table 7:4 Total estimated customer delivery lead-time in different RM based systems

ii. Total estimated overall cost per pair.

Table 7.5 shows the estimated total cost per pair. The total estimated cost per pair is made up of (i) foot assessment, (ii) foot geometry capture, (iii) orthoses design and (iv) orthoses fabrication costs. The cost for foot assessment, geometry capture and design of orthoses are identical in all the systems. These costs are added with total estimated fabrication cost per pair per given by different rapid manufacturing based developed models.

RM based systems	**Foot assessment cost/pair**	**Geometry capture cost/pair**	**Orthoses design cost/ pair**	**Fabrication cost/pair**	**Total cost /pair**
spro SD	£50	£6	£2	£85.34	£143.34
ipro 8000	£50	£6	£2	£133.25	£191.25
Polyjet	£50	£6	£2	£190.51	£248.51
V-Flash	£50	£6	£2	£288.55	£346.55
SST 768	£50	£6	£2	£182.33	£240.33
uPrint	£50	£6	£2	£157.43	£215.43

Table 7:5 Total estimated overall cost per pair in different RM based systems

Figure 7.3 shows the total estimated cost per pair and estimated delivery lead-time in days in rapid manufacturing techniques based design and fabrication systems.

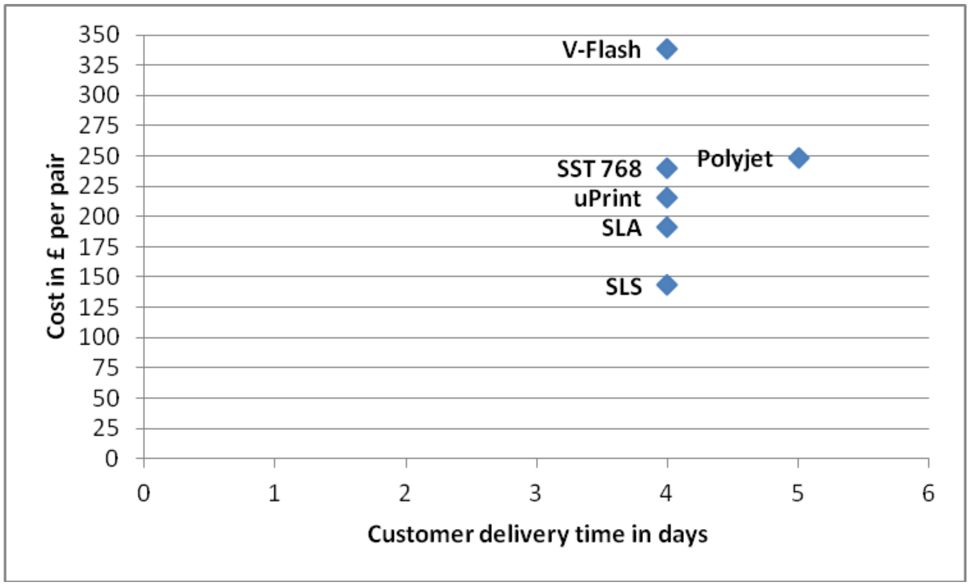


Figure 7:3 Total estimated delivery lead-time and total estimated cost per pair in RM based systems

Again it is clear that SLS and SLA are the most competitive processes, with SLS estimated to be more cost competitive than SLA with comparison to other rapid manufacturing based systems.

7.3.4 Total estimated design and fabrication lead-time and total estimated cost per pair in conventional resources based methods.

i. Total estimated design and fabrication lead-time

Table 7.6 shows the total estimated design and fabrication lead-time in conventional systems having different geometry capture methods and using digital means of orthoses design and CAD/CAM fabrication techniques. The total estimated lead-time is made up of (i) time in foot assessment (ii) time in geometry capture, (iii) time in orthoses design and (v) time in orthoses fabrication.

In conventional design and fabrication systems, orthosis is designed through CAD systems and fabricated by milling process where a block of material is milled using CAD/CAM milling machine. The time in foot assessment, orthoses design and orthoses fabrication is identical in all conventional resources based methods. However, total estimated lead-time is different due to different foot geometry capture methods.

The total estimated design and fabrication lead-time in conventional system based on plaster of Paris foot geometry capture method is made up of 1 hour of time in foot assessment per pair, 5 hours of time in foot geometry capture per pair, 5 minutes of time in design of orthoses per pair and 20 minutes of time in fabrication of orthoses per pair. This gives an estimated total lead-time of 6 hours and 25 minutes of time for design and fabrication of one pair of orthoses.

The conventional design and fabrication system based on plaster slipper geometry capture method give the total estimated lead-time of 2 hours and 55 minutes of time per pair. Conventional design and fabrication system using foam box foot geometry capture method gives total estimated lead-time of 1 hour and 35 minutes per pair. Conventional design and fabrication systems using contact digitising and 3D digital foot scanning methods gave the total estimated lead-time of 30 minutes per pair.

Conventional resources based systems	**Geometry Capture time/ pair**	**Orthoses design time/ pair**	**Fabrication time/pair**	**Estimated lead-time/pair**
Plaster of Paris	5 hrs	5 min	20 min	6 hrs 25 min
Plaster slipper	1 hr 30 min	5 min	20 min	2 hrs 55 min
Foam box	10 min	5 min	20 min	1 hrs 35 min
Contact digitising	5 min	5 min	20 min	30 min
3D scanning	5 min	5 min	20 min	30 min

Table 7:6 Total estimated design and fabrication lead-time in conventional resouces based systems

The lead-time estimates clearly show that digital means of foot geometry capture have significant impact in reducing the time in foot geometry capture process. This subsequently reduces the total estimated design and fabrication lead-time in contact digitising and 3D scanning based conventional systems; with foam box impression based system the next most competitive. However, foam box impression method further requires time and efforts in physical shipment of the impression casts to manufacturing facility. For the plaster based systems, the time in foot geometry capture makes the total estimated lead-time higher than the both of the digital based foot geometry capture systems and also requires physical shipment of the plaster casts to manufacturing facility.

ii. Total estimated design and fabrication cost per pair.

Table 7.7 shows total estimated cost per pair in conventional design and fabrication systems. The total estimated cost per pair is made up of (i) foot assessment (ii) geometry capture, (iii) orthoses design and (v) orthoses fabrication costs. In conventional resources based systems, fabricated orthoses further takes 5 minutes of time in finishing the orthoses through manual grinding and trimming for smoothing and finishing the edges of milled orthoses.

The costs in foot assessment, orthoses design and fabrication are identical in all conventional systems. However, the cost in foot geometry capture is different due to different methods involved. This has resulted in different total estimated cost per pair in conventional design and fabrication systems. Plaster of Paris and plaster slipper based foot geometry capturing systems give the estimated costs of £75.06 and £56.06, respectively. Foam impression box foot geometry capturing based system involves total estimated cost of £37.06 per pair. Contact digitising and 3D scan foot geometry capture based system involve total estimated cost of £33.06 per pair.

Conventional resources based systems	Geometry capture cost/ pair	Orthoses design cost/ pair	Fabrication cost/pair	Estimated total cost/pair
Plaster of Paris	£48	£2	£25.06	£75.06
Plaster slipper	£29	£2	£25.06	£56.06
Foam box	£10	£2	£25.06	£37.06
Contact digitising	£6	£2	£25.06	£33.06
3D scanning	£6	£2	£25.06	£33.06

Table 7:7 Total estimated design and fabrication cost per pair in conventional resources based systems

Figure 7.4 shows the total estimated design and fabrication lead-time and total estimated design and fabrication cost per pair in conventional resources based systems. Again the total cost per pair estimates show that digital means of foot geometry capture have the advantage of reducing total estimated cost per pair in conventional systems. This subsequently reduces total estimated design and fabrication cost per pair in contact digitising and 3D scanning based conventional systems, with foam box impression based system the next most competitive. For plaster based geometry capture systems, foot geometry capture cost makes the total estimated cost per pair much higher than the digital foot geometry capture based systems.

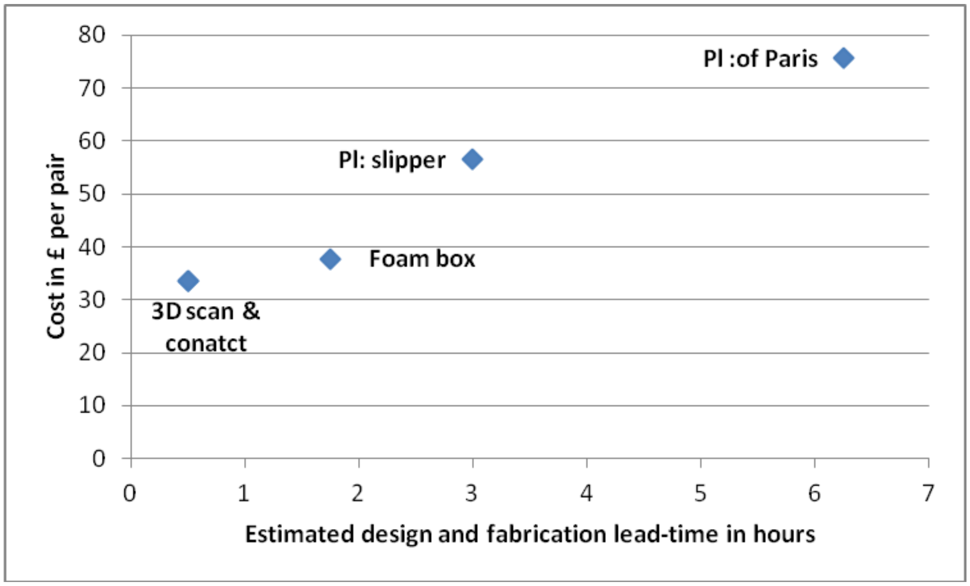


Figure 7:4 Estimated design and fabrication cost per pair in conventional resources based systems

7.3.5 Total estimated customer lead-time in conventional techniques system.

i. Total estimated customer lead-time

The total estimated customer lead-time has been developed on the basis of design and manufacture lead-time, but amended to take into consideration the projected operating model for conventional systems, and likely delivery times assuming a centralised fabrication facility.

Table 7.8 shows the estimated customer lead-time in conventional based design and fabrication methods. The total customer lead-time in conventional systems is made up of (i) foot assessment time (ii) shipment time in foot impression casts/foam box casts to manufacturing facility (iii) fabrication time and (vi) time in delivery of orthoses.

The Plaster and foam box foot geometry capture based conventional systems assumed to take one day of time in foot assessment, plaster based foot geometry capture and two days of time in shipment of captured plaster/foam box impression casts to fabrication facility. The fabrication of orthoses is assumed to take one day of time whereas delivery of orthoses is assumed to take two days of time. This gives the total estimated customer lead-time of 5 days in conventional systems using plaster/foam impression box based foot geometry capture. The conventional systems based on contact digitising and 3D foot geometry capturing assumed to take one day of time in foot geometry capture, one day of time in fabrication of orthoses and two days of time in delivery of the orthoses. The captured foot geometry information is transferred digitally to the manufacturing facility. This gives a total of 4 days of customer lead-time in conventional resources based methods using digital means of foot geometry capture.

Conventional systems	**Foot assessment and geometry capture**	**Fabrication time**	**Delivery time**	**Customer lead-time**
Pl Paris	2 days (physical shipment)	1 day	2 days	5 days
Pl slipper	2 days (physical shipment)	1 day	2 days	5 days
Foam box	2 days (physical shipment)	1 day	2 days	5 days
Contact digit:	1 day (electronic)	1 day	2 days	4 days
3D scan	1 day (electronic)	1 day	2 days	4 days

Table 7:8 Total estimated delivery lead-time in conventional based systems

The customer lead-time estimates show that digital means of foot geometry capture have the advantage of removing the need for physical shipment of foot impression casts to manufacturing facility. This subsequently makes the total estimated customer lead-time lower in conventional systems using direct foot geometry capture through digital means with comparisons to systems using plaster and foam box geometry capture methods. Figure 7.5 shows the estimated customer lead-time in days and total cost per pair in conventional design and fabrication methods using different means of foot geometry capture.

ii. Total estimated overall cost per pair.

Table 7.9 shows the estimated total cost per pair. The overall total estimated cost per pair is made up of (i) foot assessment, (ii) foot geometry capture, (iii) orthoses design and (iv) orthoses fabrication costs. The cost for foot assessment, geometry capture and design of orthoses are identical in all the systems. These costs are added with total estimated fabrication cost per pair per given by different rapid manufacturing based developed models. Figure 7.5 shows the total estimated design and fabrication lead-time in days and total estimated overall cost per pair in conventional resources based systems.

Conventional resources based systems	Foot assessment/ pair	Geometry capture/ pair	Orthoses design/ pair	Fabrication time/pair	Estimated total cost/pair
Plaster of Paris	£50	£48	£2	£25.06	£125.06
Plaster slipper	£50	£29	£2	£25.06	£106.06
Foam box	£50	£10	£2	£25.06	£87.06
Contact digitising	£50	£6	£2	£25.06	£83.06
3D scanning	£50	£6	£2	£25.06	£83.06

Table 7:9 Estimated overall total cost per pair in conventional resources based systems

Figure 7:5 Total estimated delivery lead-time and cost per pair in conventional resources based systems

7.4 Comparison of "best case" rapid manufacturing based system with conventional resources based system.

In cost modelling of different rapid manufacturing techniques based operating models SLS techniques based operating model was the most competitive process in comparison to other rapid manufacturing techniques. Because of more competitive operating model, SLS based process was compared with conventional resources based operating model. Table 7.10 shows the comparison of best rapid manufacturing based design and fabrication operating model with best conventional resources based operating model. The comparison is based on (i) total estimated fabrication cost per pair (ii) total estimated overall cost per pair (iii) total estimated customer lead-time and (iv) total estimated productivity pairs per day from the two models.

Design and fabrication systems models	**Fabrication cost/pair**	**Overall cost/pair**	**Customer lead-time**	**Productivity pairs/day**
SLS based system	£85.34	£143.34	4 days	75 pairs
Conventional system	£25.06	£83.06	4 days	72 pairs

Table 7:10 Comparison of conventional and SLS based system modeles

In rapid manufacturing based systems, selective laser sintering techniques based system give total estimated fabrication cost of £85.34 per pair and overall cost of £143.34 per pair which include the costs for foot assessment, geometry capture and orthoses design. The SLS based system model gives the estimated customer lead-time of 4 days with productivity of 75 pairs per day from the best case developed operating model. In conventional resources based systems, digital foot geometry capture based system give total estimated fabrication cost of £25.06 per pair and overall total estimated cost of £83.06 per pair which include the costs for foot assessment, geometry capture and orthoses design. The system model gives total estimated customer lead-time of 4 days with productivity of 72 pairs per day from the best case developed operating model.

The comparison show that total estimated cost per pair in conventional resources based system is lower than the SLS based design and fabrication system. However, SLS based design and fabrication system has significant advantage of increased design freedom and fabrication of complex geometrical design features in the foot orthoses; that have limitations in the conventional resources based system. The other advantage in SLS based system is removal of manual grinding and trimming function for finishing the fabricated orthoses; as required in the conventional technique based systems. This gives advantage of increased accuracy and consistency in the SLS based fabricated orthoses in the final product (Pallari et al, 2010).

- **Reuse of unsintered material.**

The total estimated fabrication cost of £85.34 per pair in SLS based fabrication system can be further reduced by reuse of unsintered material in the build. According to Duraform material guide by 3D systems unsintered material can be used not exceeding 67% with the ratio of total material (Guide to Duraform materials, 3D Systems, Inc, USA, 2002). Swell and colleagues have experimented that five time reuse of unsintered Duraform PA material does not compromise overall material properties and strength (Swell et al, 2008). Table 7.11 shows the estimated total fabrication cost per pair in SLS technique with reuse of 60% of the unsintered material.

“Best case” operating model for 5 technicians working with 8 machines		
Machine cost per year for 8 machines		£600000
Material cost for 43800 pairs	@£25.60 per pair	£1121280
Production overhead per year for 8 machines		£116460
Administrative overhead per year for 8 machines		£18560
Labour cost for 5 technicians		£199900
Total cost for 43800 pairs		£2056200
Cost per pair	£2056200/43800 pairs/year	£46.94

Table 7:11 Total estimated fabrication cost per pair by reuse of unsintered material in SLS technique

The reuse of 60% of unsintered material with 40% of virgin powder reduces the material cost from £64 per pair to £25.60 per pair. This gives a total estimated fabrication cost of £46.94 per pair and overall all total estimated design and fabrication cost of £104.94 per pair; approximately 36% reduced cost per pair in comparison to cost of £143.34 per pair in “best case” operating model in SLS based system.

- **Actual and assumed projected material cost.**

As discussed that cost of the material in SLS based is the major cost incurring element which makes the total cost per pair higher in the model. However, the commercialisation of rapid manufacturing techniques and materials are progressing at rapid rate with respect to improvements in the processing technique and materials which may subsequently bring down the costs of systems and materials. Table 7.12 shows actual cost of material and assumed reduced cost of material showing the projected cost per pair in the SLS based system model.

Actual and assumed projected material cost		Cost form best case SLS model
Actual material cost	@ £64/kg	£85.34 per pair
50% reduced cost	@ £32/kg	Projected cost of £53.34 per pair
60% reduced cost	@ £25.60/kg	Projected cost of £46.94 per pair
70% reduced cost	@ £19.20/kg	Projected cost of £40.54 per pair
80% reduced cost	@ £12.80/kg	Projected cost of £34.14 per pair
70% reduced cost and	60% and 40% mix	Projected cost of £29.25 per pair

Table 7:12 Actual material cost and assumed projected cost giving total estimated cost per pair

The assumed reduction of 50% in material cost from £64/kg to £32/kg gives the fabrication cost of 53.34 per pair. While reduction of 60%, 70% and 80% in material cost per kg give the total estimated fabrication cost of £46.94, £40.54 and £34.14 per pair, respectively which can bring the SLS based orthoses fabrication cost competitive with the orthoses cost per pair fabricated through the conventional techniques based system.

7.5 Key reasons for application of rapid manufacturing techniques in fabrication of custom-made foot orthoses.

Ability of the rapid manufacturing techniques in directly creating the parts from 3D CAD information layer by layer without tooling and moulding offers greater design freedom in fabrication of geometrically complex structure of foot orthoses shell.

Ease in the incorporation of complex orthoses design features from CAD data such as metatarsal pads and domes at specific sites in orthoses shell shown in Section 2.4.3; prescribed for redistributing the planter pressure, fabrication of wedges and medial flanges required at specific sites to control the tilt or severe pronation problem. Conventional fabrication techniques have limitations and difficulties in fabricating orthoses design features and functional elements such as incorporation of local stiffness at specific sites in the shell which subsequently restricting the product range.

7.6 Summary

At present the orthotics industry is predominantly made up of small companies, who do not always have access to large amounts of capital. A low initial capital cost would help industrial uptake. Around £100 million is spent annually on the provision of orthotics services through the NHS, and the bulk of this is for foot related orthoses (Hutton and Hurry, 2009). Orthotic Service in the NHS: Improving Service Provision (York Health Economics Consortium).

The work in this research was on the cost and lead-time modelling and estimation of total cost per pair of orthoses using rapid manufacturing techniques based design and fabrication system. The cost estimations presented in this work are based on a 'full costing' concept and includes labour, machine absorption, production, and administrative overheads and material costs. The indirect costs were assigned to the components on the machines working-time basis. The output from the cost models developed is a scalable production unit, which can be scaled to a specific market demand. Based on the cost modelling estimations in this work, the business models for different rapid manufacturing based design and fabrication systems can be generated. The return on investment (ROI) can be calculated from the business model; however generation of the business model was out of the scope of this research study.

The total market size for additive manufacturing was $1.068 billion by 2009, only accounting for directly associated products and services (Wohlers, 2010). With the recent growth in desktop printer sales nearly 20% increases from 2009- (Wholers 2010) and the constant reduction in materials costs. However there was a significant gap in the literature for the analysis of RM versus conventional processing technologies when it comes to fabricating final-functional parts. Until now adoption of RM was studied from a design perspective highlighting the opportunities of freedom of design; however the factors that ultimately will influence decision makers in the organisations remain purely productive economic-related. The cost and lead-time modelling in this work assessed the productivity considerations for various RM technologies for the fabrication of custom-made foot orthoses.

7.7 Conclusions

1. This thesis has presented the first in-depth analysis of technical and commercial potential for rapid manufacturing techniques to be used for commercial scale fabrication of custom-made foot orthoses.

2. Process modelling of design and fabrication system for custom-made foot orthoses using IDEF0 modelling methodology showed that rapid manufacturing techniques can be integrated in the current orthoses design and fabrication process in order to develop the mass customisation production systems.

3. In digital means of foot geometry capture 3D scanning is the better method for foot geometry capture regardless of the fabrication techniques. The pin-tool based contact digitisers have limitations in capturing the posterior heel of the foot as pin-tool digitising system only captures the geometry of the plantar of the foot in geometry capture process.

4. Analysis and evaluation of the cost and lead-time through cost modelling identified the most appropriate operating models for fabrication of custom-made foot orthoses using rapid manufacturing techniques.

5. From the current commercial rapid manufacturing techniques, selective laser sintering SLS based system is the most competitive for custom-made foot orthoses fabrication among all other rapid manufacturing based systems, having lowest cost per pair and more build capacities and overall productivity.

6. Selective laser sintering SLS fabricated custom-made foot orthoses are estimated to cost more than conventionally fabricated orthoses. On the basis of using 100% virgin powder; SLS based pair of orthoses is estimated to be 233.88% more expensive in terms of total estimated fabrication cost and 71.54% more expensive in terms of total estimated overall cost. On the basis of using 60% reuse of unsintered and 40% virgin powder it is estimated to be 83.64% more

expensive in terms of total estimated fabrication cost and 25.58% in terms of total estimated overall cost.

7. In order to cost the SLS based fabricated orthoses same as conventionally fabricated orthoses, the raw material cost would have to be reduced by 70% at the rate of 19.20/kg and assuming that 40% virgin and 60% unsintered powder were re-used. This gives the total estimated fabrication cost at the rate of £29.25 per pair and overall cost of £87.25 per pair in SLS based design and fabrication system. The fabrication and overall costs are 10% and 4%, respectively expensive in comparison to cost per pair of orthoses produced through conventional techniques.

7.8 Future work

Reuse of unsintered material for fabrication of orthoses may be further investigated in order to determine that material can be used for fabrication without compromising the material properties and quality of the final product.

Duraform PA (Nylon 12) is a suitable material and could be used in the orthoses fabrication as the end use product material. However, beside the other mechanical properties, fatigue behaviour of the material may be investigated for long periods of service time. Fatigue under a large number of cycles could be investigated as materials gets degradation during service life phase over the time.

In SLS based fabricated orthoses, cushioning layer may be required for orthoses shell. Creating a layer over the main body of orthoses shell in order to increases comfort may be investigated. The sole of the shoe in which orthoses shell has to fit in must be considered and investigated for increased resilience in order to promote the gait, improve mobility and over all comfort to the patient. Additionally, large scale clinical trials should be performed for satisfaction of patients and practicing medical personals and orthotist.

References

Ahlstrom P, and R. Westbrook, (1999), Implications of mass customization for operations management: An exploratory survey, International Journal of Operations and Production Management, Volume 19, Number 3, pp 262-274.

Alford D, Sackett P, and Nelder G, (2000). Mass customization an automotive perspective, International Journal of Production Economics, Volume 65, Number 1, pp 99-110.

Ang, C. L., Luo, M, and Gay K L, (1994). Automatic generation of IDEF0 models, Journal of Intelligent Manufacturing, Volume, 5, Number 2, pp 79-92.

Ang C. L.;M. Luo and R. K. L. Gay (1997). A knowledge-based approach to the generation of IDEF0 models, International Journal of Production Research, Volume 35, Number. 5, 1385-1412.

Ang, C. L., Khoo, L. P, and Gay, R. K. L. IDEF, (1999), A comprehensive modelling methodology for the development of manufacturing enterprise systems. International Journal of Production Research, Volume 37, Number 17, pp 3839-3858.

Anthony J, Raymond (1991), Manufacture and Use of the Functional Foot Orthosis - ISBN 3-8055-5298-X, Karger AG, Basle & New York.

Ashley (1993), “Rapid prototyping for artificial body parts”, The Journal of American Society of Mechanical Engineers, Volume 115, Number 5, pp 50-53.

Armillotta, A., Bonhoeffer, P., Dubini, G., Ferragina, S., Migliavacca, F., Sala, G. & Schievano, S. (2007). Use of rapid prototyping models in the planning of percutaneous pulmonary valved stent implantation. Proceedings of the Institution of Mechanical Engineers, Part H, Journal of Engineering in Medicine, Volume 221, Number 4, pp 407-416.

Atzeni Eleonora, Luca Iuliano, Paolo Minetola, Alessandro Salmi, (2010) "Redesign and cost estimation of rapid manufactured plastic parts", Rapid Prototyping Journal, Volume. 16, Number 5, pp. 308-317.

Baldwin, C.Y., Clark, K.B., (1994). Modularity-in-design: an analysis based on the theory of real options. Working Paper, Harvard Business School, Boston, USA.

Bellamy, L. (2007), Exploratory survey of foot orthoses prescribing practices for patients with rheumatoid arthritis British Journal of Podiatry, Volume 10, Number 1, pages 8-11.

Berger, C., Moslein, K., Piller, F. and Reichwald, R. (2005), Co-designing Modes of Cooperation at the Customer Interface: learning from exploratory research. European Management Review, Volume 2, Number 1, pp 70-87.

Berger Christoph (2003), Mass Customization - an adidas perspective, The institution of Electrical Engineers. IEEE, Savoy Place, London, WCPR OBL. UK, pp 2/1-2/4.

Bibb, R., Eggbeer, D, and Williams, R. (2006), Rapid manufacture of removable partial denture frameworks. Rapid Prototyping Journal, Volume 12, Number 2, pp 95-99.

Blais, F., Bisson, J.A., Williams, S., Robertson, N., Rozin, S., Nelson, A., (2000), The shape grabber foot scanner: a low cost high accuracy 3-D system for the acquisition of human feet. In: Corner, B.D., Nurre, J.H. (Eds.), Three-Dimensional Image Capture and Applications, vol. III. Proceedings of the SPIE, Volume, 3958, pp. 178-186.

Boardman Sara (2007): The economic case for CAD/CAM custom foot orthoses, Podiatry Now, April 2007.

Brown George A., Keikhosrow Firoozbakhsh, Thomas A. DeCoster, Jose R. Reyna, Jr., and Moheb Moneim, (2003), Rapid Prototyping: The Future of Trauma Surgery? The American Journal of Bone and Joint Surgery, Volume 85: Number 4, pp 49-55.

Brocklesby S, Wooles C. (2009). Cost comparison: Orthoses an audit. In-house manufacture from sheet materials vs prefabricated orthoses. Podiatry Now, Volume 6, pp 17-23.

Buonomo L, Klein J, and Keiper T. (2001), Custom-made, pre-fabricated and material selection. Foot and Ankle Clinics, Volume 6, Number 2, pp 249-252.

Bus SA, Ulbrecht JS, Cavanagh PR. (2004), Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity, Clinical Biomechanical, Volume.19, Number 6, pp 629-38.

Buswell R.A., R.C. Soar, A.G.F. Gibb, and A. Thorpe, (2007), Freeform Construction: Mega-scale Rapid Manufacturing for construction, Automation in Construction, Volume 16, Number 2, pp 224–231.

Caselli MA (2004). Orthoses, materials, and foot function. Podiatry Management, Volume 23, Number 7, pp 131-138.

Cee Kai, Chua, K. F. Leong, C.S., Lim. (2003). Rapid Prototyping: Principles and Applications. New Jersey, World Scientific.

Chalmers AC, Busby C, Goyert J, Porter B and Schulzer M, (2000), "Metatarsalgia and rheumatoid arthritis- A randomized, single blind, sequential trial comparing 2 types of foot orthoses and supportive shoes". Journal of Rheumatolog, Volume 27, Number 7, pp 1643-1647.

Chen Y. H., Ng C. T. and Wang Y. Z. (1999), Generation of an STL File from 3D Measurement Data with User-Controlled Data Reduction, International Journal of Advance Manufacturing Technology, Volume 15, Number 2, pp 127-131.

Cheng Tan Kim, Peter Lee Vee Sin, Tam Kock Fye and Lye Sau Lin, (1998), Automation of Prosthetic socket design and fabrication using computer aided-design/computer-aided Engineering and rapid prototype techniques, First National symposium of prosthetic and orthotics, Singapore.

Chinnaiah, P.S.S., Kamarthi, S.V. and Cullinane, T.P., (1995) Characterization and Analysis of Mass-customized Production Systems - submitted to IEEE Trans. on Eng. Management.

Coates, J. F. and Wolff, M. F. (1995), "Customization promises sharp competitive edge", Research Technology Management, Volume 38, Number 6, pp. 6-7.

Colombo Giorgio , Stefano Filipp, Caterina Rizzi and Federico Rotini, (2010). A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses Computers in Industry, Volume 61, Number 6, pp 513-523.

Cormier Denis, Ola Harrison and Tushar Mahale (2003) Rapid Manufacturing in the 21st Century, Journal of the Chinese Institute of Industrial Engineers, Volume. 20, Number 3, pp. 193-202.

Cortex, R., Dinulescu, N., Skafte, K., Olson, B., Keenan, D., and Kuk, F., (2004) Changing with the Times: Applying Digital Technology to Hearing Aid Shell Manufacturing. Hearing Review, Volume 11, Number 3, pp. 30-38.

Cullinane, Thomas P, Pratap S. S. Chinnaiah, Naken Wongvasu and Saga V. Kamarthi (1997) A Generic IDEFO Model of a Production System for Mass Customization, Innovation in Technology Management - The Key to Global Leadership. PICMET: Portland International Conference on Management and Technology.

Czajkiewicz Zbigniew J. (2008) Direct Digital Manufacturing, New Product Development and Production Technology, Economics and Organization of Enterprise, Volume 2 Number 2, pp. 29-37.

Dalgarno, K. W, J. H. Pallari, J. Woodburn, K. Xiao, D. J. Wood, R. D. Goodridge and C. Ohtsuki, (2006), Mass customization of medical devices and implants: state of the art and future directions. Virtual and Physical Prototyping, Volume. 1, Number 3, pp 137-145.

Davis Stanley, (1989), From future perfect: Mass customizing, Planning Review, Volume 17, Number 2, pp 16-21.

Davis Frank M, (1993), In-office computerized fabrication of custom foot supports: The Amfit system, Journal of Clinics in podiatry Medicine and Surgery, Volume 10, Number, 3 pp 393-401.

DeMarco, T., (1979), Structured Analysis and System Specification (New York: Yourdon Computing Series: Yourdon Press).

Dimitrov D., K. Schreve, N. de Beer, (2006) "Advances in three dimensional printing – state of the art and future perspectives", Rapid Prototyping Journal, Volume 12, Number 3, pp.136-147.

Dotchev Krassimir, Ivan Popov, Daniel Eyers, (2009), Rapid Manufacturing and Reverse Engineering: Key Issues For Mass Customisation, International Conference General Machine Design October 15-th – 16-th, University of Ruse.

Doxey, Gordon E. (1985) Clinical Use and Fabrication of Molded Thermoplastic Foot Orthotic Devices Volume 65, Number 11, pp 1679-1682.

Duray R, Ward P.T, Milligan G.W, Berry W.L (2000) Approaches to mass customization: configurations and empirical validation, Journal of Operations Management, Volume 18, Number 6, pp 605-625.

Duray Rebecca, (2002) Mass customization origins: mass or custom manufacturing International Journal of Operations & Production Management Volume 22, Number 3, pp 314-328.

Eastwood M, (1996) Implementing mass customization, Computers in Industry, Volume 30, Number 3, pp 171-174.

Faustini MC, Neptune RR, Crawford RM, Rogers WE and Bosker G. (2005), “Selective laser sintering of passive dynamic ankle-foot orthoses”, Transactions of the ASME 946 / Volume. 127, November 2005.

Frank Matthew, Sanjay b. Joshi and Richard A. Wysk (2003) Rapid prototyping as an integrated product/process development tool an overview of issues and economics journal of the Chinese institute of industrial engineers, Volume. 20, umber. 3, pp. 240-246.

Freeman Donald and Leslie Wontrorcik, (1998) Stereolithography and Prosthetic test socket manufacture: A cost benefit analysis, Journal of Prosthetic and Orthotics, Volume 10, Number. 1 pp 17-20

Frykberg RG, Zgonis T, Armstrong DG, (2006), Diabetic foot disorders, A clinical practice guideline revision. J Foot Ankle Surg. Sep-Oct 45 (Suppl): S1-66.

Gartner, H., Lavoie, J.F., Vermette, E., Houle, P.S., (1999). Multiple structured light system for the 3D-measurement of feet. In: Proceedings of Three-dimensional Image Capture and Applications II (IS&T/ SPIE) Conference, San Jose, CA, January 1999, SPIE, Volume, 3640, pp. 104-114.

Giannatsis J., Dedoussis V, D. Karalekas (2002). Architectural scale modelling using stereolithography, Rapid Prototyping Journal, Volume 3, Number 3, pp 200-207.

Gibson I (2005), Rapid Prototyping: A Tool for Product Development Computer-Aided Design & Applications, Volume. 2, Number. 6, pp 785-793.

Gibson I, (2006) Rapid prototyping: from product development to medicine and beyond, Journal of Virtual and Physical Prootyping, Volume, 1, Number, 1 pp 31-42.

Gibson I., L.K. Cheung, S.P. Chow, W.L. Cheung, S.L. Beh, M. Savalani, S.H. Lee, (2006) "The use of rapid prototyping to assist medical applications", Rapid Prototyping Journal, Volume. 12, Number 1, pp.53-58.

Gibson l D. W. Rosen l B. Stucker, (2010), Additive Manufacturing Technologies Rapid Prototyping to Direct Digital Manufacturing, Springer.

Gilmore J., and Pine J., (1997), The four faces of mass customization, Harvard Business Review, Volume 75, Number 1, pp 91-101.

Goodman, Ashley, (2004), Foot Orthoses in Sports MedicineSouthern Medical Journal: Volume 97 - Issue 9 - pp 867-870

Godwin, A., Gleeson, J. and Gwillian, D. (1989). An assessment of the IDEF notations as descriptive tools. Information Systems, Volume 14, number 1, pp 13-28.

Grimm, T. and Terry Wohlers, The real cost of RP, Time compression technologies, March/April, 2002.

Grumbine N. (1993). Computer-generated orthoses. A review. Clinical Podiatry Medicine Surgery, Volume 10, Number 3, pp 377-391.

Hague R, Campbell I, and Dickens P, (2003) “Implications on design of rapid manufacturing”, Journal of Mechanical Engineering Science, Part C, Proc. Inst Mech. Engrs, Volume 217, Part c.

Hammer M., and J. Champy. (1993) Reengineering the Corporation, New York Harper Collins.

Hart, C. (1995) Mass Customization: Conceptual Underpinnings, Opportunities and Limits. International Journal of Service Industry Management, Volume 6, Number 2, pp 36-45.

Hearon, K., Lee, J., and Marich, K. (2008). Comparison of 3D digital contact casting versus manual foam casting of the feet for the design and fabrication of custom foot orthoses. Journal of Vertebral Subluxation Research, Volume 10 Number 1, pp 1-5.

Helliwell P, Woodburn J, Redmond A, Turner D and Davys H, (2007) “The Foot and Ankle in Rheumatoid Arthritis – A Comprehensive guide”, Churchill Livingstone Elsevier, 2007, ISBN 0443101108.

Herbert Nicholas, David Simpson, William D Spence and William Ion, (2005), A preliminary investigation into the development of 3-D printing of prosthetic sockets, Journal of Rehabilitation Research and Development, Volume 42, Number 2, pp 141-146.

Hieu, L.C., Bohez, E., Vander Sloten, J., Phien, H.N., Vatcharaporn, E., Binh, P.H., An, P.V. & Oris, P. (2003). Case Study: Design for medical rapid prototyping of cranioplasty implants. Rapid Prototyp Journal, Volume 9, Number 3, pp. 175-186.

Hollister, S. (2005). Porous scaffold design for tissue engineering. Nature Materials, Volume 4, Number 7, pp 518-524.

Hopkinson, N and Dickens, P. (2001). Rapid prototyping for direct manufacture, Rapid Prototyping Journal, Volume 7, Number 4, pp 197-202.

Hopkinson, N. and P. Dickens (2003). "Analysis of rapid manufacturing-using layer manufacturing process for production." Proceedings of IMechE, Part C, Journal of Mechanical Engineering Science 217, Number 1, pp 31-39.

Hopkinson, N., Hague, R., Dickens, P. (2006). "Introduction to Rapid Manufacturing" in Rapid manufacturing: an industrial revolution for the digital age, editors: Hopkinson, N., Hague R. J. M., Dickens, P.M., Chichester, England, John Wiley.

Houle, P.S., Beaulieu, E., Liu, Z., (1997). Novel fully integrated computer system for custom footwear: from 3D digitization to manufacturing. Proceedings of Three-dimensional Image Capture and Applications, SPIE, Volume. 3313, San Jose, CA, pp. 65-73.

Hutmacher, D.W., Sittinger, M. & Risbud M.V. (2004). Scaffold-based tissue engineering: rationale for computer-aided design and solid free-form fabrication systems. Trends in Biotechnology, Volume 22, Number 7, pp 354-362.

Hunt,V.D., (1996), Process Mapping: How to Reengineer Your Business Processes (Wiley).

Hunter S, Dolan MG, Davis JM. (1995) Foot orthotics in therapy and sport, Champaign, IL: Human Kinetics.

Huppin Larry, (2009), Technology: Choosing a digital foot scanner, Lower Extremity review, August 2009.

J. M. Saleh and K. W. Dalgarno (2009), “Cost and benefit analysis of fused deposition modelling (FDM) technique and selective laser sintering (SLS) for fabrication of customised foot orthoses,” in Proc. 4th Int. Conf. Adv. Res. Virtual Rapid Manuf., Innovative Dev. Des. Manuf., Leiria, Portugal, Oct. 6–10, 2009, pp. 187–192, ISBN 978-0-415-87307-9.

Kennedy Séamus (2008), Material Choices in Foot Orthotic Design, The O&P EDGE February 2008.

Kotha, S. (1995), Mass customization: implementing the emerging paradigm for competitive advantage, Strategic Management Journal, Volume. 16, Number 1, pp 21-42.

Kotha, S. (1996), From mass production to mass customization: The case of the National Industrial Bicycle Company of Japan, European Management Journal, Volume 14, Number 5, .pp 442-450.

Kraemer Kenneth L., Dedrick Jason, and Yamashiro Sandra (2000). Refning and extending the business model with Information Technology: Dell Computer Corporation, International Journal of Information Society, Volume 16, Number,1, pp 5–21.

Kruth, J. P., Leu, M.C., Nakawa, T. (1998). "Progress in Additive Manufacturing and Rapid Prototyping." CIRP Annals - Manufacturing Technology, Volume 47 Number 2, pp 525-540.

Kruth J.P., B. Vandenbroucke, J. Van Vaerenbergh, and I. Naert (2005). Digital manufacturing of biocompatible metal frameworks for complex dental prostheses by means of SLS/SLM In Virtual Prototyping and Rapid Manufacturing, Advanced research in virtual and Rapid Prototyping, Taylor & Francis, London, pp 139–146.

Kumar Vijay, Ruzena Bajcsy, William Harwin, and Patrick Harker (1996) Rapid Design and Prototyping of Customized Rehabilitation Aids, Communications of the Acm, Volume. 39, Number 2, pp 55-61.

Lampel, J., and Mintzberg, H., (1996) Customizing customization. Sloan Management

Review, Volume 38, Number 1, pp 21-30.

Lau R., (1995), Mass customization: The next industrial revolution, Industrial Management, Volume 37, Number 5, pp18-19.

Laughton C, McClay Davis I, Williams DS: (2002), A comparison of four methods of obtaining a negative impression of the foot. Journal of American Podiatric Med Assoc, Volume 92, Number 5, pp 261-268.

Leber C. and P. M. Evanski, (1986), A comparison of shoe insole materials in plantar pressure relief, Prosthetics and Orthotics International, Volume10, Number 3, pp135-138.

Lebovitz Richard and Graban Mark (2001), The Journey Toward Demand Driven Manufacturing, Proceedings 2nd International Workshop on Engineering Management for Applied Technology, 2001. EMAT 2001. Pp 29-35.

Lee Chang, C.C., M.Y., Wang, S.H. (2006), Digital denture manufacturing- An integrated technologies of abrasive computer tomography, CNC machining and rapid prototyping. International Journal of Advance Manufacturing Technology, Volume 31, Number 1-2, pp 41-49.

Leong, K.F., Chua, C.K., Gui, W.S. & Verani (2006), Building porous biopolymeric microstructures for controlled drug delivery devices using selective laser sintering. International Journal of Advanced Manufacturing Technologies, Volume 31, Number 5-6, pp 483-489.

Leung A. K. L., Cheng J. C. Y. and Mak A. F. T. (2004), Orthotic design and foot impression procedures to control foot alignment, Prosthetics and Orthotics International, Volume 28, Number 3, pp 254-262.

Leung Ki SW, AK, Li AN. (2008), Comparison of plantar pressure distribution patterns between foot orthosis provided by the CAD-CAM and foam impression methods. Prosthetics and Orthotics International, Volume 32, Number 3, pp 356-362.

Levy, G. N., Schindel, R. (2002). "Overview of layer manufacturing technologies, opportunities, options and applications for rapid tooling". Proc. Inst. Mech. Engrs Part B: Journal Engineering Manufacture, Volume 216, Number 12, pp 1621-1634.

Lockard MA. (1998), Foot orthoses, Physical therapy, Volume 68, Number 12, pp 1866-73.

Lusardi, M.M, & Nielsen, (2000) C.C, “Orthotics and prosthetics in rehabilitation”, Butterworth- Heinmann, 2000, ISBN 0750698071.

Mandel, K, (1990), Graphical process description views and diagrams. International Journal of Computer Integrated Manufacturing Systems, Volume 3, Number 5, pp 314-327.

McCarthy, (2003), Understanding Customization in Mass Customization The Institution of Electrical Engineers, IEE, Savoy Place, London,

McCarthy, Barbazon and Bramham, (2003), Fundamental modes of operation for mass customisation, International Journal of Production Economics, 3, Volume 85, Number 3, pp 289-304.

MacCarthy and Philip Brabazon: In the business of mass customization, (2003), IEE Manufacturing Engineer August/September, pp 30-33.

McPoil TG, Schuit D, Knecht HG. (1989), Comparison of three methods used to obtain a neutral plaster foot impression. Physical Therapy, Volume 69, Number 6, pp 448-52.

Madazhy Rajeev, (2004), Automated Capture of 3D Foot Geometry For Custom Orthoses, 2004 ME Graduate Student Conference, Louisiana State University, USA.

Magalhaes ED, Davitt M, Filho DJ, Battistella LR, Bertolo MB. (2006), The effect of foot orthoses in rheumatoid arthritis. Rheumatology, Volume 45, Number 4, pp 449-553.

Maslowski, E. and Heise, S. (2002), “President’s house 3D model”, available at: http://mu3d.ummu.umich.edu/ projects/president house/index.html

McCutcheon, D.M., Raturi, A.S., Meredith, J.R., (1994), The customization responsiveness squeeze. Sloan Management Review, Volume 35, Number 2, pp 89-99.

Milovanovic J, M. Trajanović, (2007), Medical Applications of Rapid Prototyping, Facta Universitatis Series: Mechanical Engineering, Volume. 5, Number 1, pp. 79-85

Moser, K., Muller, M. and Piller, F.T., (2006), Transforming mass customisation from a marketing instrument to a sustainable business model at Adidas, International Journal of Mass Customisation, Volume 1, Number 4, pp 463- 479

Mueller, M.J., Lott, D.J., Hastings, M.K., Commean, P.K., Smith, K.EPilgram, T.K., (2006), Efficacy and mechanism of orthotic devices to unload the metatarsal heads in people with diabetes and a history of plantar ulcer. Physical Therapy Volume 86, Number 6, pp 833-842.

Nicolopoulos C. S, J. Black, E. and G. Anderson (2000), Foot orthoses materials, The Foot, Volume 10, Number 1, pp 1-3.

Ng P., P.S.V. Lee, J.C.H. Goh, (2002), "Prosthetic sockets fabrication using rapid prototyping technology", Rapid Prototyping Journal, Volume. 8, Number 1, pp.53-59

Nigg BM, Nurse MA, and Stefanyshyn DJ. (1999), Shoe inserts and orthotics for sport and physical applications, Journal of Medicine and Science in Sports and Exercise, Volume 21, Number 7, pp 421-8.

Nookabadi A. S. and John E. Middle, (1996), A Generic IDEF0 Model of Quality Assurance information systems for the design to order manufacturing environments, IEEE Transactions on Components, Packaging, and Manufacturing Technology-part c, Volume. 19, Number. 2, pp 78-84.

Noorani, Rafiq (2006), Rapid prototyping Principles and Applications New Jersey: John Wiley & sons, Inc.

Obrovac, Karlo; Udiljak, Toma; and Mihoci, Kristijan. (2005), CAD/ CAM in Production of the Foot Orthoses Transactions of FAMENA, Volume 29, Number 1, pp 49-60.

OSullivan, (1991), Project management in manufacturing using IDEFO, International Journal of Project Management, Volume 9, Number 3, pp 162-168.

Otto J. P.. (2008, Sep.), A Good CAD-CAM Education is Hard to Find [Online]. Gainesville, FL: The O&P Edge. Available: http://www.oandp.com/articles/2008-09-13.asp.

Pallari J., (2008) “Mass customisation of foot orthoses for rheumatoid arthritis,” Ph.D. Thesis, Dept. Mech. Eng., Univ. Leeds, Leeds, U.K., Pallari Jari H. P., Kenneth W. Dalgarno, and James Woodburn (2010) Mass Customization of Foot Orthoses for Rheumatoid Arthritis Using Selective Laser Sintering, IEEE Transactions on Biomedical Engineering, Volume 57, Number 7, pp 1750-56

Paton, J. (2007), The physical characteristics of materials used in the manufacture of orthoses for patient with diabetes. Foot & Ankle International, 28 (10), 1057–1063.

Payne CB. (2007), Cost benefit comparison of plaster casts and optical scans of the foot for the manufacture of foot orthoses. Australian Journal of Podiatric Medicine, Volume 41, Issue 2, pp 29-31.

Peltola Sanna M., Ferry P. W. Melchels, Dirk W. Grijpma Minna Kelloma Ki, (2008), A Review of Rapid Prototyping Techniques for Tissue Engineering Purposes, Annals of Medicine, Volume 40, Number 4, pp 268-280.

Pham D.T and R.S Gault (1998), A comparison of rapid prototyping technologies, International Journal of Machine Tools and Manufacture Volume 38, Number 10-11, pp 1257-1287

Pham, D. T. and S. S. Dimov (2001), Rapid manufacturing : the technologies and applications of rapid prototyping and rapid tooling. London, Berlin, Heidelberg, Springer.

Pham, D. T. and S. S. Dimov (2003), Rapid prototyping and rapid tooling- the key enablers for rapid manufacturing, Proceedings of the Institution of Mechanical Engineers, Part C: Journal of Mechanical Engineering Science, Volume 217, Number, 1 pp 1-23.

Phillip W. Balsmeier, Wendell J. Voisin (1997), Rapid prototyping: State-of-the-art manufacturing, Industrial Management, Volume. 39, Number 1.

Phillips J W (1990), The Functional Foot Orthoses, New York: Chrchilhill Livingstone.

Piller FT and Stotko CM (2002), Mass customization: four approaches to deliver customized products and services with mass production efficiency, in TS Durrani, ed., Proceedings of the IEEE International Engineering Management Conference (IEMC-2002). Cambridge University, UK, pp 773-778

Piller (2003), The customer as co-designer: how to master mass customization's most demanding challenge Mass Customization: Turning Customer Differences into Business Advantages, IEE Seminar, pp 6/1-6/5

Piller FT, Moeslein K, Stotko CM (2004), Does mass customization pay? An economic approach to evaluate customer integration, Production Planning and Control, Volume 15, number 4, pp 435-444

Pine, B.J. Mass Customization: (1993), The New Frontier in Business Competition, Harvard Business School Press, Boston, MA.

Pine J., (1993), Mass customizing products and services, Planning Review, Volume 21, Number 4, pp 6-55.

Pine, B.J. II, Victor, B., Boyton, A.C., (1993), Making mass customization work. Harvard Business Review 71, pp 108-119

Pine, B.J. II, Peppers, D., and Rogers, M., (1995), Do you want to keep your customers forever? Harvard Business Review, 72, pp 103-114.

Pine J, and J. Gilmore, (1997), The four faces of mass customization, Harvard Business Review, Volume 75, Number 1, pp 91-101.

Pollard Dennis, Shirley Chuo Fullerton and Lee Brian (2008), Strategies for Mass Customization, Journal of Business and Economics Research, Volume 6, Number 7, pp 77-84

Pratt, DJ (2000 a), A critical review of the literature on foot orthoses Journal of the American Podiatric Medical Association, Volume 90, Number 7, pp. 339-341.

Pratt DJ (2000 b), Dynamic foot orthoses, Principles and applications, Journal of the American Podiatric Medical Association, Volume 90, Number 1, pp 24-29.

Pratt D J, (1994), Some aspects of modern orthotics, Physiological Measurements, Volume 15, Number 1, pp 1-27.

Pratt D J (1995), Functional foot orthoses, The Foot, Volume 5, pp 101-110

Qingbin Liu, Ming C. Leu, Stephen and M. Schmitt, (2006), Rapid prototyping in dentistry: technology and application, International Journal of Advance Manufacturing Technology, Volume 29, Number 3-4, pp 317-335.

Rajala Mikko and Tapani Savolainen (1996), A framework for customer oriented business process modeling Computer oriented manufacturing systems, Volume 9, Number 3, pp 127-135

Redford JB, Basmajian JV, and Trautman P, "Orthotics (1995), clinical practice and rehabilitation technology", Churchill Livingstone, ISBN 0443089922.

Rogers Bill , Gordon W. Bosker, Richard H. Crawford, Mario c. Faustini Richard R. Neptune, Gail Walden, and Andrew J. Gitter , (2007), Advanced trans-tibial socket fabrication using selective laser sintering International Journal of Prosthetics and Orthotics, Volume 3, Number 1, pp 88-100

Rome K: (1990), Behaviour of orthotic materials in chiropody. Journal of the American Podiatric Medical Association Volume 80, Number 9, pp 471-478.

Rome, K., (1991), A study of the properties of materials used in podiatry. Journal of the American Podiatric Medical Association, Volume 81, number 2, pp 73–83.

Ross A (1996), Selling Uniqueness, Manufacturing Engineering, Volume 75, Number 6, pp 260-263

Ross, T.R. (1985), Applications and extensions of SADT, IEEE Computer, pp. 25-34

Rosochowski A, and Matuszak A, (2000), Rapid tooling: the state of the art, Journal of Materials Processing Technology, Volume 106, Number 1, pp 191-198.

Ruffo M, C Tuck, and R Hague, (2006), Cost estimation for rapid manufacturing – laser sintering production for low to medium volumes, Proc. IMechE, Volume. 220 Part B: Journal of Engineering Manufacture.

Saraswathy G., Gautham Gopalakrishna, B.N. Das, (2004) New material for recording impression of foot for customized footwear applications, The Foot, Volume 14, Number 4, pp 192-197

Saven Aguilar, R.S, (2004), Business process modeling: review and framework, International Journal of Production Economics, Volume 90, Number, 2, pp 129-149

Schwartz, R. (1991), Foot orthoses and materials. In M. Jahss (Ed.), Disorders of the foot and ankle (pp. 2866-2878). Philadelphia: Saunders

Selldurai R S (2004), Mass customization in operations management: oxymoron or reality? Omega, Volume 32, Number 4, pp 295-300.

Sewell, N. T., M. Felstead, M. R. Sloan and M. A. Jenkins, (2008), "A Study of the Degradation of Duraform PA Due to Cyclic Processing," International Conference on Advanced Research in Virtual and Rapid Prototyping, Leiria, Portugal, pp. 299-304.

Silveira, Borenstien, and Fogliatto, (2001), Mass customization: Literature review and research directions International Journal of Production Economics, Volume 72, Number 1, pp 1-13.

Skipworth and A. Harrison, (2004), Implications of form postponement to manufacturing a customised product, International Journal of Production Research, Volume. 44, Number 8, pp1627-1652.

Slack, N., Chambers, S., Johnston, R. (2001), Operations Management, 3rd edition, Pearson Education Limited, U.K., ISBN 0273-64657-5.

Smith D and Burgess EM, (2001) “The use of CAD/CAM technology in prosthetics and orthotics – Current clinical models and a view to the future”, Journal of Rehabilitation Research and Development, Volume 38, Number 3, pp 327-334.

Spira J, (1993), Mass customization through training at Lutron Electronics, Strategy and Leadership, Volume 21, Number 4, pp 23-24.

Squire, Brown, Readman and Bessant, (2006), The impact of Mass Customisation on Manufacturing trade-offs, Production and Operations Management, Volume 15, Number 1, pp 10-21.

Staats Timothy B and Kriechbaum Michael P, (1989), Computer Aided Design and Computer Aided Manufacturing of Foot Orthosis. Journal of Prosthetic and Orthotics, Volume 1, Number 3, pp 182-186.

Steven J. Levitz., and Ellen Sobel, (2002), Prescribing Foot Orthoses, Podiatry Management, pp 103-116

Strub Joerg R, Rekow E. Dianne and Witkowski Siegbert, (2006), Computer-aided design and fabrication of dental restorations: Current systems and future possibilities, Journal of American Dental Association, Voulme 137, Number 9, pp1289-1296

Tangen, S. (2003), “An overview of frequently used performance measures”, Work Study, Volume 52, Number. 7, pp. 347-54.

Tangen Stefan (2004), Performance measurement: from philosophy to practice, International Journal of Productivity and Performance Management, Volume 53, Number. 8, pp. 726-737

Tay Francis E.H., M.A. Manna, L.X. Liu, (2002), "A CASD/CASM method for prosthetic socket fabrication using the FDM technology", Rapid Prototyping Journal, Volume. 8, Number: 4, pp.258-262.

Toffler, A. (1970), Future Shock, Random House, New York

Tognola G, Parazzini M, Svelto C, Ravazzani P and Grandori F, (2003), “Three-dimensional laser scanning and reconstruction of ear canal impressions for optimal design of hearing aid shells”, Proc. SPIE, Volume. 5009, pp 19-26.

Tseng Mitchell M. and Piller Frank T (2003), The Customer Centric Enterprises: Advances in mass customization and personalization, Springer.

Tuck C.J., Hague R.J.M (2006), The pivotal role of rapid manufacturing in the production of cost-effective customised products, International Journal of Mass Customisation, Volume.1, Number. 2/3, pp 360-373.

Tuck C.J., Hague R.J.M., Ruffo, M. Ransley M. and Adams P., (2008), Rapid manufacturing facilitated customisation, International Journal of Computer Integrated Manufacturing, Volume 21, Number 3, pp 245 - 258

Tukuru Nagarjan, Shivalinge Gowda KP, Syed Mansoor Ahmed and S Badami, (2008), Rapid Prototype Technique in Medical Field, Research Journal of Pharm. and Tech. Volume 1, Number 4, pp 341-344.

Ulrich, K. and Tung, K., (1991), Fundamentals of product modularity, Proceedings of ASME Winter Annual Meeting Symposium on Design and Manufacturing Integration, Atlanta, USA,

Ulrich, K., (1995), The role of product architecture in the manufacturing firm, Journal of Research Policy, Volume 24, pp 419-440.

Ulrich, K., Eppinger, S., 1995. Product Design and Development, McGraw-Hill, New York, USA.

Vaupotic B., M. Brezocnik, J. Balic (2006), Use of PolyJet technology in manufacture of new product. Journal of Achievements in Materials and Manufacturing Engineering Volume 18, Number 1-2, pp 319-322.

Walter, M., Holmstrom, J., and Tuomi, H., (2002), Rapid manufacturing and its impact on supply chain management, Proceedings of the Logistics Research Networks, Annual conference, Dublin, Ireland.

Ward P T and Mellor S J, (1985), Structured development of Real-Time Systems, Prentice-Hall Inc, USA.

Webb P A., (2000), A review of rapid prototyping (RP) techniques in the medical and biomedical sector, Journal of Medical Engineering & Technology, Volume 24, Number 4, pp 149-153.

Williams Bruce (2010), Key Insights on Digital Casting Techniques, Volume: 23, Number 1, pp 11-15.

Winder and Bib (2005), Medical Rapid Prototyping Technologies: State of the Art and Current Limitations for Application in Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery Volume, 63, Number 7, pp 1006-1015

Woodburn J, Helliwell PS, and Barker S, (2002), “A randomized controlled trial of foot orthoses in rheumatoid arthritis”, Journal of Rheumatology, Volume 29, Number 7, pp 1377-1383.

Wohlers Terry, (2006), Rapid Prototyping and Manufacturing: State of the Industry, Annual worldwide progress report, Wohlers associates Inc, USA

Wohlers Terry, (2010), Additive Manufacturing: State of the Industry, Wohlers associates Inc, USA.

Wong Hartanto and Daniel Eyers (2010), Enhancing Responsiveness for Mass Customization Strategies through the Use of Rapid Manufacturing Technologies, International Handbooks on Information Systems, Springer-Verlag Berlin Heidelberg, pp 205-226.

Xiao Yan-ling Xu Fu-Yxi Hu Wen-bo, (2004), Business Process Reengineering Based on IDEF Methods, Information Reuse and Integration, 2004. IRI 2004. Proceedings of IEEE International Conference 8-10 Noveber 2004, pp 265-270.

Yan Xue and P Gu (1996), A review of rapid prototyping technologies and systems Journal of Computer-Aided Design, Volume 28, Number 4, pp 307-318.

Yang, S., Leong, K. F., Du, Z. H., and Chua, C. K. (2002), Design of scaffolds for use in tissue engineering. Part II: Tissue Engineering, Volume 8, Number 1, pp 1-11.

Yusuf KO and Smith NJ, (1996), Modeling business processes in steel fabrication, International Journal of Project Management, Volume 14, Number 6, pp 367-371.

Zhang Ren-qian, (2000), "Analysis of Business Cost in the BPR", Industry Engineering, China, Volume 3, Number.4, pp. 15-19.

Weblink resources

http://www.additive3d.com/sla_int.htm [accessed July, 2010]

http://www.additive3d.com/fdm_int.htm [accessed July, 2010]

http://www.additive3d.com/3dp_int.htm

http://www.additive3d.com/sls_int.htm

http://www.algeos.com/acatalog/Algeos_Online_Foot_Orthotics Insoles_28.html

http://www.alimed.com/Alimed/catalog/Orthopedics,249.htm

http://www.aligntech.com/Pages/Home.aspx

http://www.amfit.com/

http://www.dimensionprinting.com/

http://www.footdynamics.com/

http://www.footcraft.com.au/

http://www.hearing.siemens.com/en/03-home/index-en.jsp

http://www.insolepro.co.uk/

http://www.invisalign.com/Pages/default.aspx

http://www.klmlabs.com/

http://www.londonorthotics.co.uk/

http://www.precision3d.co.uk/index.htm

http://www.pedag.co.uk/index1.htm

http://www.phonak.com/uk/b2c/en/home.htmlw.objet.com/PRODUCTS/PolyJet_Technology

http://www.shapeways.com/

http://www.saumadesign.net/P2Lshoe.htm

http://www.theorthoticgroup.com/

http://www.stssox.com/

http://www.printin3d.com/3d-printers/v-flash-personal-3d-printer

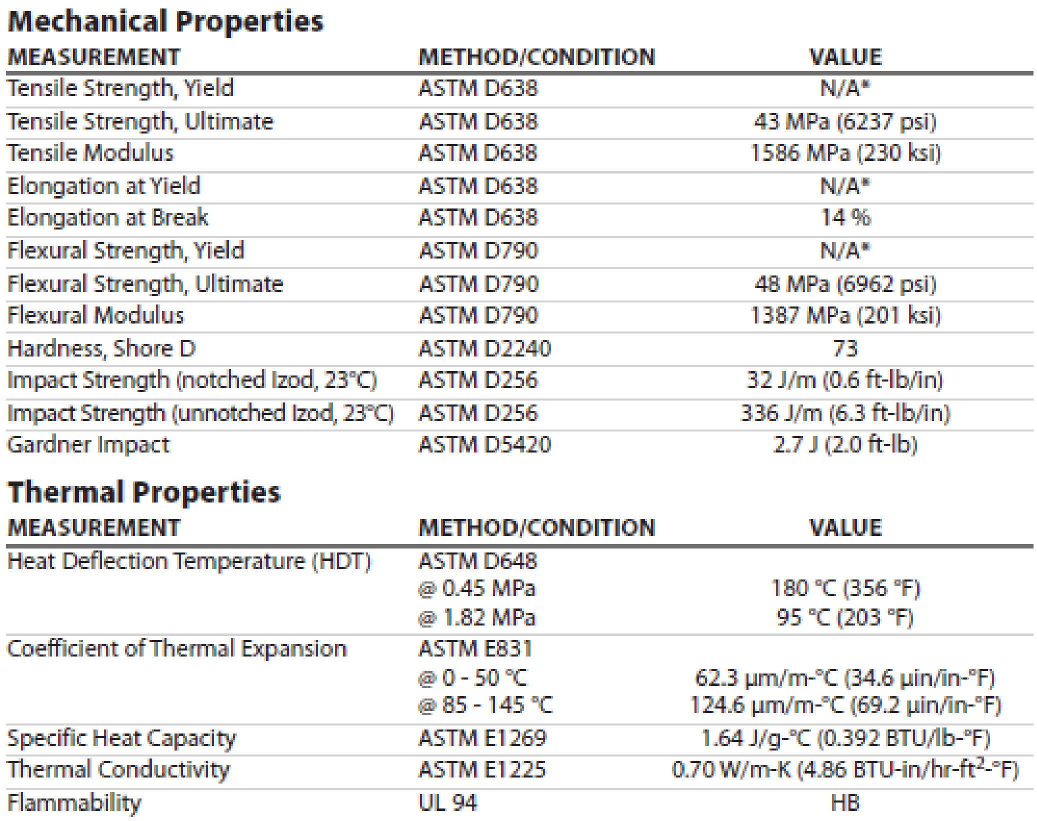
http://www.3dsystems.com/products/sla/iPro/index.asp

http://www.3dsystems.com/products/sls/index.asp

Appendix

Properties of materials

1. Properties of Duraform PA (Nylon 12) material used in *spro* SLS system



Mechanical Properties

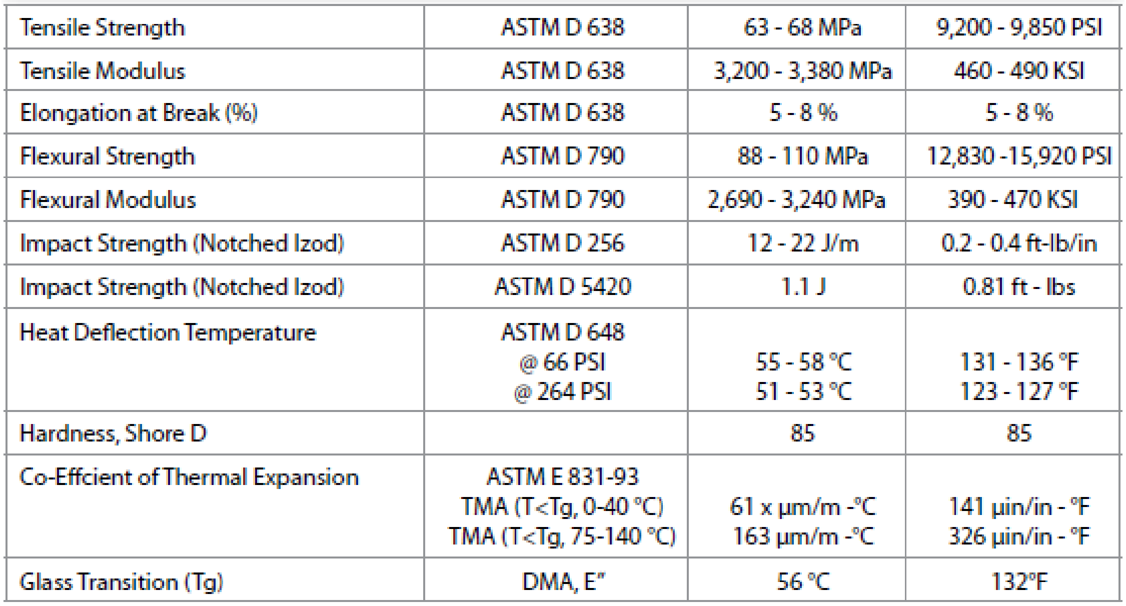
MEASUREMENT	METHOD/CONDITION	VALUE
Tensile Strength, Yield	ASTM D638	N/A*
Tensile Strength, Ultimate	ASTM D638	43 MPa (6237 psi)
Tensile Modulus	ASTM D638	1586 MPa (230 ksi)
Elongation at Yield	ASTM D638	N/A*
Elongation at Break	ASTM D638	14 %
Flexural Strength, Yield	ASTM D790	N/A*
Flexural Strength, Ultimate	ASTM D790	48 MPa (6962 psi)
Flexural Modulus	ASTM D790	1387 MPa (201 ksi)
Hardness, Shore D	ASTM D2240	73
Impact Strength (notched Izod, 23°C)	ASTM D256	32 J/m (0.6 ft-lb/in)
Impact Strength (unnotched Izod, 23°C)	ASTM D256	336 J/m (6.3 ft-lb/in)
Gardner Impact	ASTM D5420	2.7 J (2.0 ft-lb)

Thermal Properties

MEASUREMENT	METHOD/CONDITION	VALUE
Heat Deflection Temperature (HDT)	ASTM D648	
	@ 0.45 MPa	180 °C (356 °F)
	@ 1.82 MPa	95 °C (203 °F)
Coefficient of Thermal Expansion	ASTM E831	
	@ 0 - 50 °C	62.3 µm/m-°C (34.6 µin/in-°F)
	@ 85 - 145 °C	124.6 µm/m-°C (69.2 µin/in-°F)
Specific Heat Capacity	ASTM E1269	1.64 J/g-°C (0.392 BTU/lb-°F)
Thermal Conductivity	ASTM E1225	0.70 W/m-K (4.86 BTU-in/hr-ft^2-°F)
Flammability	UL 94	HB

Table 1: Material properties of Duraform PA Nylon 12, (3D systems.com, 2010)

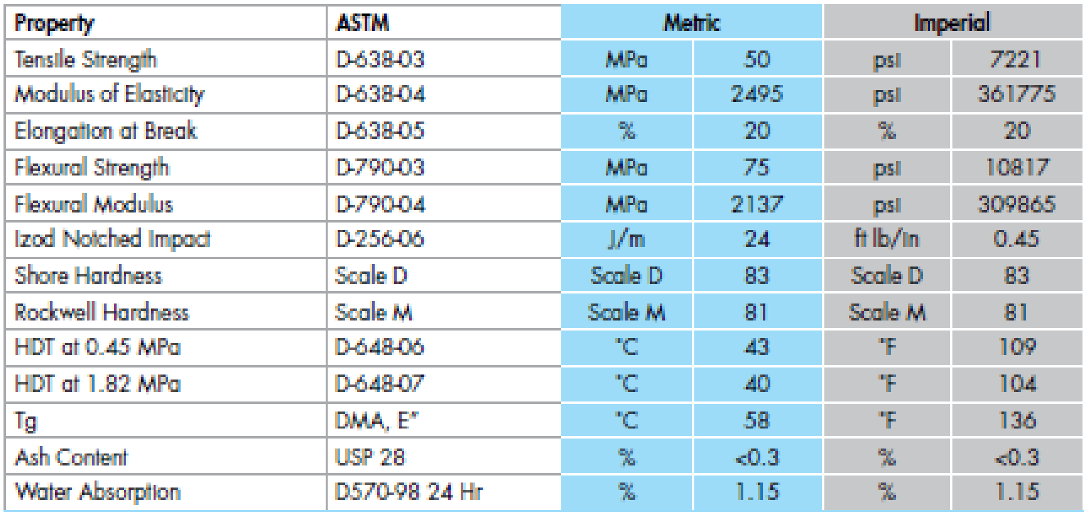
2. Properties of Acura 55 material used in *ipro* SLA system



Tensile Strength	ASTM D 638	63 - 68 MPa	9,200 - 9,850 PSI
Tensile Modulus	ASTM D 638	3,200 - 3,380 MPa	460 - 490 KSI
Elongation at Break (%)	ASTM D 638	5 - 8 %	5 - 8 %
Flexural Strength	ASTM D 790	88 - 110 MPa	12,830 -15,920 PSI
Flexural Modulus	ASTM D 790	2,690 - 3,240 MPa	390 - 470 KSI
Impact Strength (Notched Izod)	ASTM D 256	12 - 22 J/m	0.2 - 0.4 ft-lb/in
Impact Strength (Notched Izod)	ASTM D 5420	1.1 J	0.81 ft - lbs
Heat Deflection Temperature	ASTM D 648 @ 66 PSI @ 264 PSI	 55 - 58 °C 51 - 53 °C	 131 - 136 °F 123 - 127 °F
Hardness, Shore D		85	85
Co-Effcient of Thermal Expansion	ASTM E 831-93 TMA (T<Tg, 0-40 °C) TMA (T<Tg, 75-140 °C)	 61 x µm/m -°C 163 µm/m -°C	 141 µin/in - °F 326 µin/in - °F
Glass Transition (Tg)	DMA, E"	56 °C	132°F

Table 2: Material properties of Acura 55 resin (3D systems.com, 2010)

3. Properties of Vero white full cure 830 material used in Connex 500 system



Property	ASTM	Metric		Imperial	
Tensile Strength	D-638-03	MPa	50	psi	7221
Modulus of Elasticity	D-638-04	MPa	2495	psi	361775
Elongation at Break	D-638-05	%	20	%	20
Flexural Strength	D-790-03	MPa	75	psi	10817
Flexural Modulus	D-790-04	MPa	2137	psi	309865
Izod Notched Impact	D-256-06	J/m	24	ft lb/in	0.45
Shore Hardness	Scale D	Scale D	83	Scale D	83
Rockwell Hardness	Scale M	Scale M	81	Scale M	81
HDT at 0.45 MPa	D-648-06	°C	43	°F	109
HDT at 1.82 MPa	D-648-07	°C	40	°F	104
Tg	DMA, E"	°C	58	°F	136
Ash Content	USP 28	%	<0.3	%	<0.3
Water Absorption	D570-98 24 Hr	%	1.15	%	1.15

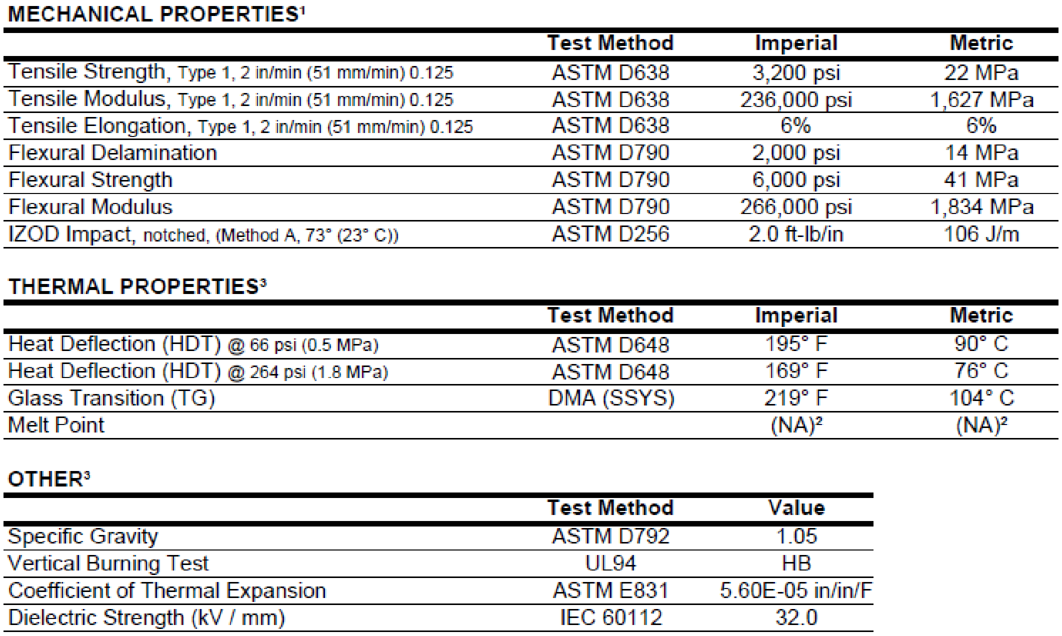
Table 3: Material properties of Vero white full cure 830 (Objet.com, 2010)

4. Material properties of V-Flash ^{R} FTI material used in V-Flash system

Properties	**Values**	**Units**
Density	1.11	g/cm^3
Tensile strength	33	mpa
Tensile modulus	1550	mpa
Elongation	5.0	%
Flexural strength	35	mpa
Flexural modulus	1700	mpa

Table 4: Material properties of V-Flash ^{R} FTI material (3D systems.com, 2010)

5. Properties of ABS P400 material used in Dimension FDM 768 system



MECHANICAL PROPERTIES[1]

	Test Method	**Imperial**	**Metric**
Tensile Strength, Type 1, 2 in/min (51 mm/min) 0.125	ASTM D638	3,200 psi	22 MPa
Tensile Modulus, Type 1, 2 in/min (51 mm/min) 0.125	ASTM D638	236,000 psi	1,627 MPa
Tensile Elongation, Type 1, 2 in/min (51 mm/min) 0.125	ASTM D638	6%	6%
Flexural Delamination	ASTM D790	2,000 psi	14 MPa
Flexural Strength	ASTM D790	6,000 psi	41 MPa
Flexural Modulus	ASTM D790	266,000 psi	1,834 MPa
IZOD Impact, notched, (Method A, 73° (23° C))	ASTM D256	2.0 ft-lb/in	106 J/m

THERMAL PROPERTIES[3]

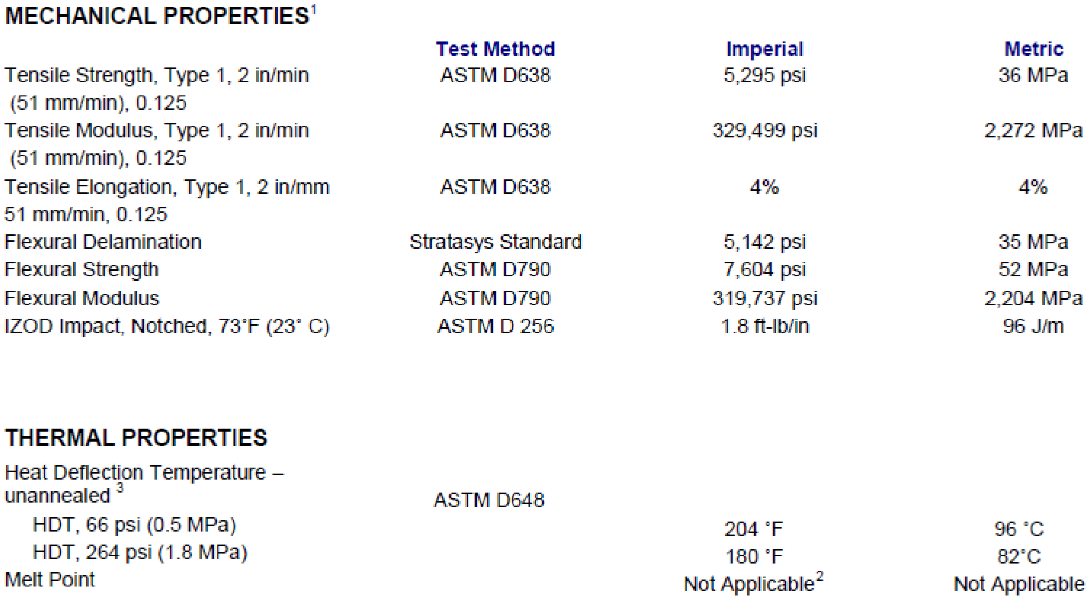
	Test Method	**Imperial**	**Metric**
Heat Deflection (HDT) @ 66 psi (0.5 MPa)	ASTM D648	195° F	90° C
Heat Deflection (HDT) @ 264 psi (1.8 MPa)	ASTM D648	169° F	76° C
Glass Transition (TG)	DMA (SSYS)	219° F	104° C
Melt Point		(NA)[2]	(NA)[2]

OTHER[3]

	Test Method	**Value**
Specific Gravity	ASTM D792	1.05
Vertical Burning Test	UL94	HB
Coefficient of Thermal Expansion	ASTM E831	5.60E-05 in/in/F
Dielectric Strength (kV / mm)	IEC 60112	32.0

Table 5: Material properties of ABS P400 (Dimension printing.com, 2010)

6. Properties of ABS P430 material used in Dimension uPrint system



MECHANICAL PROPERTIES[1]

	Test Method	Imperial	Metric
Tensile Strength, Type 1, 2 in/min (51 mm/min), 0.125	ASTM D638	5,295 psi	36 MPa
Tensile Modulus, Type 1, 2 in/min (51 mm/min), 0.125	ASTM D638	329,499 psi	2,272 MPa
Tensile Elongation, Type 1, 2 in/mm 51 mm/min, 0.125	ASTM D638	4%	4%
Flexural Delamination	Stratasys Standard	5,142 psi	35 MPa
Flexural Strength	ASTM D790	7,604 psi	52 MPa
Flexural Modulus	ASTM D790	319,737 psi	2,204 MPa
IZOD Impact, Notched, 73°F (23° C)	ASTM D 256	1.8 ft-lb/in	96 J/m

THERMAL PROPERTIES

Heat Deflection Temperature – unannealed [3]	ASTM D648		
HDT, 66 psi (0.5 MPa)		204 °F	96 °C
HDT, 264 psi (1.8 MPa)		180 °F	82°C
Melt Point		Not Applicable[2]	Not Applicable

Table 6: Material properties of ABS P430 (Dimension printing.com, 2010)

Papers presented in international conferences.

1. J.M. Saleh and K. W. Dalgarno (2009), “Cost and benefit analysis of fused deposition modelling (FDM) technique and selective laser sintering (SLS) for fabrication of customised foot orthoses,” in Proc. 4th Int. Conf. Adv. Res. Virtual Rapid Manuf., Innovative Dev. Des. Manuf., Leiria, Portugal, Oct. 6–10, 2009, pp. 187–192, ISBN 978-0-415-87307-9.

2. J.M. Saleh and K. W. Dalgarno (2009), Fused deposition modelling technique in foot orthoses fabrication: A cost benefit analysis, 33 Japan Rapid Prototyping symposium, Tokyo Japan, June (2009).

3. Jari Pallari, Muhammad Jumani, Kenny Dalgarno and Jim Woodburn (2009) Rapid manufacturing of orthotics and prosthetics – is it a good idea? The 5th International Conference on Mass Customization and Personalization - Match Making, Helsinki, Finland, October, (2009).

4. J.M. Saleh and K. W. Dalgarno (2008), Development of Rapid Manufacturing Based Mass Customisation System for Foot Orthoses, 32nd Japan Rapid Prototyping Symposium, Tokyo, Japan, June (2008).

5. J.M Saleh and K W Dalgarno (2008), Process modelling of rapid manufacturing based mass customisation system for foot orthoses, 9th National Conference on Rapid Design, Prototyping, and Manufacturing (RDPM), Lancaster Product Development Unit, Lancaster University, UK, June (2008).