Process Modelling of Rapid Manufacturing Based Mass Customisation System for Fabrication of Custom Foot Orthoses: Review Paper

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ABSTRACT

The need for custom-made devices, rehabilitation aids and treatments is explicit in the medical sector. Applications of rapid manufacturing techniques based on additive fabrication processes combined with medical digitising technologies can generate high quality solutions in situations where the need for custom-made devices and rehabilitation aids and low-lead times are very important factors. Foot orthoses are medical devices applied in the treatment of biomechanical foot disorders, foot injuries and foot diseases including rheumatoid arthritis and diabetes. The significant challenge in the treatment of foot related diseases is progressing pathological deterioration in the affected sites of the foot which requires quick provision of the orthoses. A process model is developed using the IDEF0 modelling technique in which a rapid manufacturing approach is integrated in the design and fabrication process of custom foot orthoses. The process model will be used in the development of rapid manufacturing based design and fabrication system for mass customisation of foot orthoses. The developed system is aimed at mass scale production of custom foot orthoses with the advantages of reduced cost, reduced lead-time and improved product in terms of increased fit, consistency and accuracy in the final product.

Key Words: **Mass Customisation, Rapid Manufacturing, Process Modelling, IDEF0 Modelling, Foot Orthoses.**

1. INTRODUCTION

In modern manufacturing engineering, application of new approaches such as agile manufacturing, lean manufacturing, rapid manufacturing and mass customisation have received much attention in the literature. Mass customisation is an approach which is believed to offer solutions for provision of individualisation and customisation of the products at a mass scale, [1-2]. 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, [3-5]. In the medical sector, the need for custom-made products,

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rehabilitation devices/aids and treatments is explicit. The production of custom-made devices, implants and tailored treatments in medical sector can be broadly classified into two groups. The first group is concerned with medical devices and instruments for diagnosis and therapy purposes and the second group is associated with implantable parts or devices and aids for long-term patient use, [6-7.

Applications of rapid manufacturing techniques combined with advanced medical digitising technologies such as CT (Computerized Tomography) scanning) and MRI (Magnetic Resonance Imaging) can generate effective solutions in providing custom-made devices within minimum lead-time. These techniques have significantly increased their role in the medical sector for production of custom-made devices and implants, [8-12]. Applications of these techniques have shown successful commercial scale examples of mass customisation of personalised in-the-ear hearing aids and dental braces, [13]. Production of custom-made hearing aids by Phonak and Siemens, [13], custom-made dental braces by Align Technology Inc, USA and custom-made dental bridges and crowns by Sirona Dental Systems GMBH, Germany, [14] have shown key advantages and benefits of these techniques in terms of improved fit product, easy repeatable fabrication and increased product performance and comfort.

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 in the treatment of medical conditions developed during rheumatoid arthritis, [15-21], 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, [22-25]. The significant challenges in foot related ailment and problems are growing deterioration in the pathological conditions such as pain and joint destruction in rheumatoid arthritis, [26] and progressing foot ulceration in diabetes which quickly changes the state of diseases, [18]. In order to prevent these progressing problems, custom foot orthoses are prescribed in order to correct the foot alignment and to support abnormal foot structure by transferring and redistributing the mechanical stresses and loads on the foot tissues in the affected parts of foot, [27]. Fig. 1 shows the images of the foot orthoses.

The fabrication of custom foot orthoses is primarily based on labour intensive craft-based manual techniques involving lengthy design and fabrication processes, [24-25,27-29]. Computer based fabrication methods were introduced in 1960s for custom foot orthoses using NC (Numerically Controlled) milling machines, [28]. The NC milling techniques require a 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, [30-31].

Rapid manufacturing techniques offer advantages in fabrication of custom foot orthoses especially in terms of increased design freedom, the ability to create the complex geometrical features, accuracy, cost efficiency, lead-time and overall improved product quality. In production of mass scale production of custom foot orthoses these techniques have advantages over conventional manufacturing techniques in terms of increased design freedom, ability to create complex geometrical design features, accuracy, cost efficiency, lead-time and overall

improved product quality. To achieve this, application of rapid manufacturing techniques combined with medical digitising technologies is required to create a digital design and fabrication process for the production of custom-made foot orthoses at mass scale.

In this paper, an IDEF0 process model is developed in order to integrate rapid manufacturing approach in the current design and fabrication process of custom foot orthoses for the development of a rapid manufacturing based mass customisation systems for foot orthoses.

2. FABRICATION OF CUSTOM FOOT ORTHOSES

The traditional process of foot orthoses fabrication begins with taking measurements and an impression of the foot. The next step is to develop a positive mould of the foot using plaster of Paris or fiber resin tape, [32]. Once the mould is developed it is modified to incorporate the required design features. The orthoses is then created around the corrected and developed mould. Finally the orthoses is fitted to the patient, [24].

Computer-based manufacturing of custom foot orthoses first started in 1960 with the application of stereo photography and NC machines in the fabrication process. Recent developments in computer technology and its applications such as CAD (Computer Aided Design) and CAM (Computer Aided Manufacturing) have replaced most of the conventional manufacturing methods for fabrication of custom foot orthoses, [28,33]. The orthosis fabrication process starts with taking the impression of the foot using a foam impression box or plaster of Paris. The captured impression information is then transferred through a sensor probe into to a CAD-based system where the data is expanded and corrected using orthoses designing software. After that, an NC machine is used to fabricate the orthoses. Fig. 2 illustrates the conventional foot orthosis fabrication process using a CNC milling technique.

Currently, CAD/CAM orthoses fabrication systems ranges from office based manufacturing systems to factory-based systems and have replaced the craft based practices in the orthotics and prosthetics manufacturing industry, [34]. However, milling process limitations in CAD/CAM for

FIG. 1. FOOT ORTHOSES

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, [35]. Additionally, experts in the prosthetics and orthotics industry have raised significant training issues for applications and use of CAD/CAM in prosthetic and orthotics manufacturing industry, [36].

3. IDEF0 MODELING METHODOLOGY

IDEF (Integrated DEFinition) is a group of modelling techniques to represent and describe the functions and operations in the systems. There are sixteen IDEF versions developed for specific purposes to accumulate information through modelling processes. An IDEF0 model is comprised of a graphical representation of a series of related diagrams organised in a hierarchy, showing graphically the complex functional relationships and identifying information and objects that are interrelated, [37-38]. An IDEF0 diagram has four important characteristics which make IDEF0 a powerful modelling tool; differentiation between organisation and function, simple graphics, data abstraction and precision, [39-40].

An IDEF0 diagram consists of four elements and is abbreviated as ICOMs (Inputs, Controls, Output and Mechanisms). Fig. 3 shows IDEF0 diagram in which inputs and outputs are the information or physical objects used in a system, while the controls are activating or regulating the function inside the boxes and mechanisms 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 the functions and objectives required. IDEF0 modelling provides a tangible basis for redesigning the processes and further simulations can be performed to improve them.

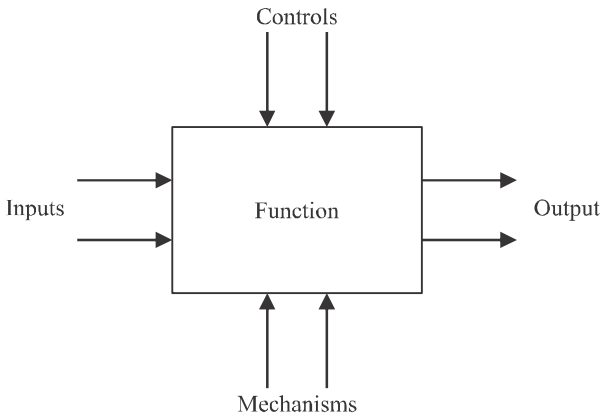

FIG. 3. IDEF0 DIAGRAM

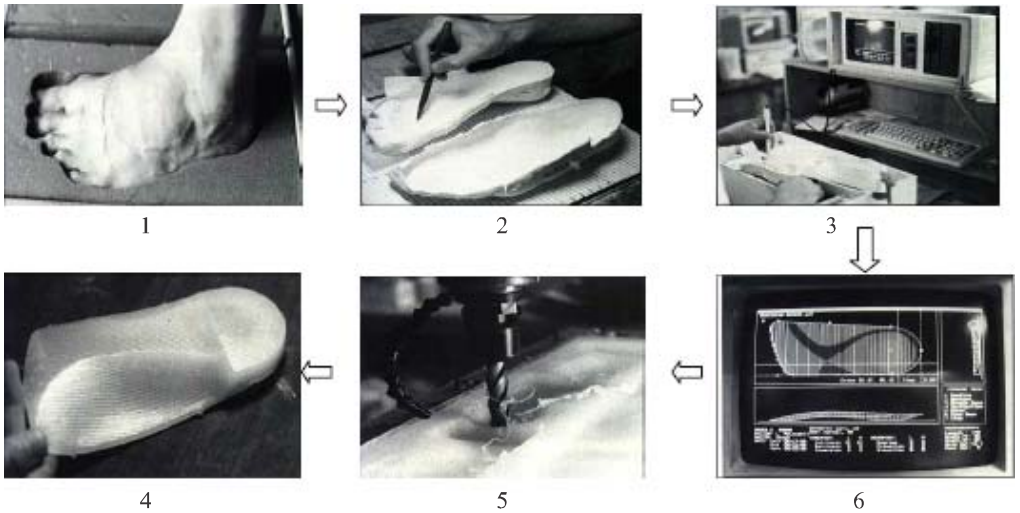

FIG. 2. COMPUTER AIDED DESIGN AND MANUFACTURING OF FOOT ORTHOSIS [33]

IDEF0 modelling methodology works on hierarchical principles, where the modelling process starts with the 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" model. The "A-0" is a one box diagram which determines the subject of the model and defines the scope of the analysis to be included in the model, [41].

The developed context or reference model is then decomposed to generate the details of the model at the required level which is then marked as "as-is" (A0) model. The "as-is" (A0) model contains three to six boxes, representing the functions and activities in the system, [42]. The justification of recommendation of limits of the boxes, in case of less than three boxes is given that the model does not constitute sufficient detail for useful decomposition; whereas the boxes more than six contain details that should be suppressed within the diagram and unpacked during 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 further analysed and evaluated in order to improve the models or systems from where the new "as-to" (A-0) be models are developed; aiming at modifying or improving the efficiency of the systems, [43].

Some of the examples of applications of IDEF0 modelling in companies include the National Bicycle Company of Japan that has implemented IDEF0 modelling methodology for production of custom-made bicycles and is producing more than 11 million variations of the custom-made bicycles, [44-45] used the IDEF0 modelling technique in the development of a process model for design and fabrication of custom-specific conformal products. Colombo, et. al. [46] modelled the design and fabrication process using IDEF0 technique for the production of custom-fit socket for lower limb prosthesis. Alveres & Ferreria, [47] is using the IDEF0 process modelling in Tele operation web-turning activities [47]. A Finland based company, NAPS is selling photovoltaic and solar power products using the IDEF0 technique in sales order process, [48].

4. DEVELOPMENT OF THE PROCESS MODEL

A process model is developed for a design and manufacturing system of custom-foot orthoses. The methodology in the development of model is adopted from the IDEF0 modelling approach.

4.1 Development of Generic Model (A-0) of the System

The first and important step in the construction of IDEF0 model is the "identification" of the perspective from which it is being made generally called as "viewpoint". Similarly, the "purpose" of constructing the model of the system must also be clarified on the context or reference diagram; since the purpose will influence the level of detail the model is to show and is thus the reason for determining when to stop decomposing the model, [49]. The generic model serves an example of the capability of IDEF0 as a general purpose functional modelling technique which provides a clear picture of a complex aspect of any manufacturing system or an organisation, [50].

In the first step in modelling the context model for design and fabrication of custom foot orthoses, a context or reference model (A-0) is developed in which the purpose of the system is stated. The context model

(A-0) presents the generic view of the entire system. The context model is then decomposed to a required level for capturing more detail of the system and construction of a detailed model of the system. Decomposition is a starting point in the construction of more detailed models called "as-is" (A0) models of the systems. An "as-is" model (A0) represents the system in its existing state and provides basis for functional analysis of the activities and functions involved in the systems, [43].

Fig. 4 represents the context or generic model (A-0) of design and fabrication of custom- foot orthoses which shows inputs, outputs, controls and mechanisms involved in the system. This is followed by development of an "as-is" model (A0) of the system shown in Fig. 5. All the functions and processes involved in the system are exposed with more detail in "as-is" (A0) model and the system is represented in the existing operate-base state.

4.2 Development of "as-is" Model (A0) of the System

In the development of the "as-is" model (A0) of the system, the context model shown in the Fig. 4 is decomposed and the detail of the system is generated. The main objective of developing "as-is" model (A0) of the system is to understand the existing state of the system and carryout functional analysis and evaluation of the functions and functions in order to improve the system.

In the "as-is" model (A0), all the functions shown in the system turn the inputs into outputs through mechanisms under the guidelines of the controls in the system. The functions in the systems 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, [51-52]. The performance of a function is generally stated in terms of

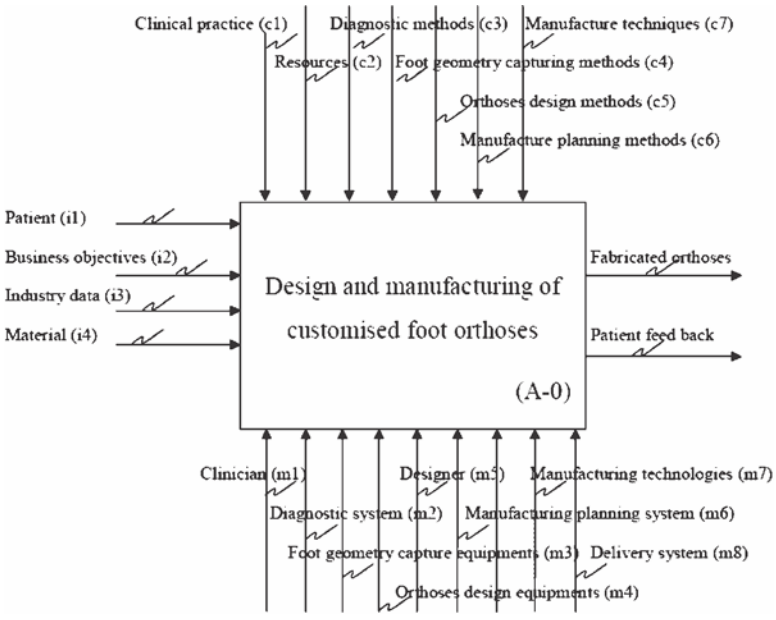

FIG. 4. CONTEXT MODEL (A-0) OF SYSTEM FOR DESIGN AND MANUFACTURING FOR CUSTOM FOOT ORTHOSES

cost, time, speed, quality, satisfaction and additional value, [53]. The level of the performance of a function is a key factor in decision making for redesigning or replacing the function in order to improve the overall performance of the system, [54].

The developed "as-is" model (A0) of the system in Fig. 5 represents the core functions in more detail which provides the basis for understanding the systems so as to improve the existing system and redesign the process model of the system with "as-to-be" model (A-0) of the system.

4.3 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 into the system of design and fabrication of custom-made foot orthoses. A potential rapid manufacturing based "as-to" be model (A-1) is developed which shows the applications of rapid manufacturing approach in the system. Fig. 6 shows the developed potential rapid manufacturing based "as-to" be model (A-1) of the system.

The application of the rapid manufacturing approach has changed the system for design and manufacturing of custom foot orthoses. Rapid manufacturing techniques use digital data in the fabrication process and require the orthoses design in the digital format. For this purpose a digital foot scanning system (m5) and a CAD system (m6) respectively are included as the mechanisms for capturing the foot geometry and designing the orthoses. The foot scanning software (c4) and CAD based orthoses designing software (c5) work as the controls in the system and regulate and guide the digital impression capturing and CAD based orthoses designing functions in the system.

The developed process model in Figs. 5-6 represent the "as-is" model (A0) and "as-to-be" model (A-1) of the

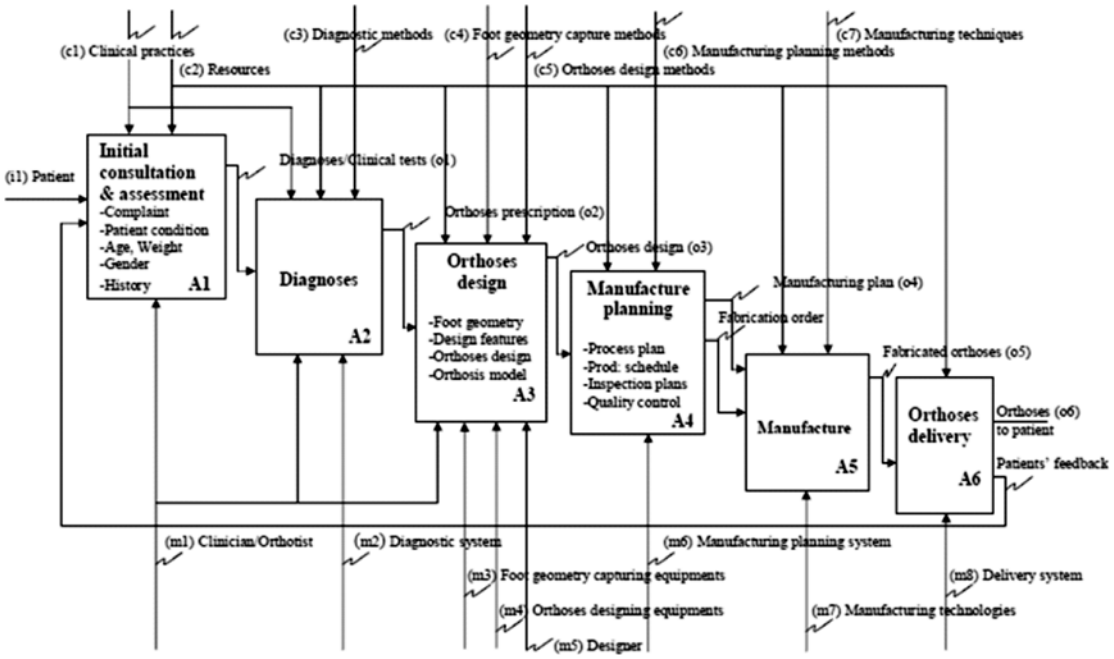

FIG. 5. "AS-IS" MODEL (A0) OF THE SYSTEM THE IN THE EXISTING OPERATE-BASE STATE

system. In both models, step (i) and step (ii) involve same functions. However, in the "as-to-be" model (A-1), application of rapid the manufacturing approach has changed the step (iii) and step (iv) in the system.

Step (iii) is function of designing the orthoses (A3) in the "as-is" model (A-0) where the traditional foot geometry capturing activities are replaced by the digital geometry capture technique in which 3D digital foot scanner is used for capturing the foot geometry. The orthoses design activity 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 activities in the functions of foot geometry capture and orthoses design.

In step (iv) in the "as-is" process model (A-0), the applications of rapid manufacturing approach has replaced the function of planning for the manufacturing (A4). The function involves process planning, sequencing and scheduling the manufacturing activities and requires production schedule plans and synchronisation of the manufacturing activities in the system. This is coupled with additional activities quality control and inspection which requires resources such as systems and labour in organising and planning the function of planning for manufacturing (A3) in the system.

As rapid manufacturing techniques directly fabricate the parts designed through CAD based systems. The manufacturing processes in the rapid manufacturing approach are simple and straightforward. The rapid manufacturing approach consists one stage process chain; from product design through CAD system to final product. This removes the need for traditional work required in the function of planning for the manufacturing in the system.

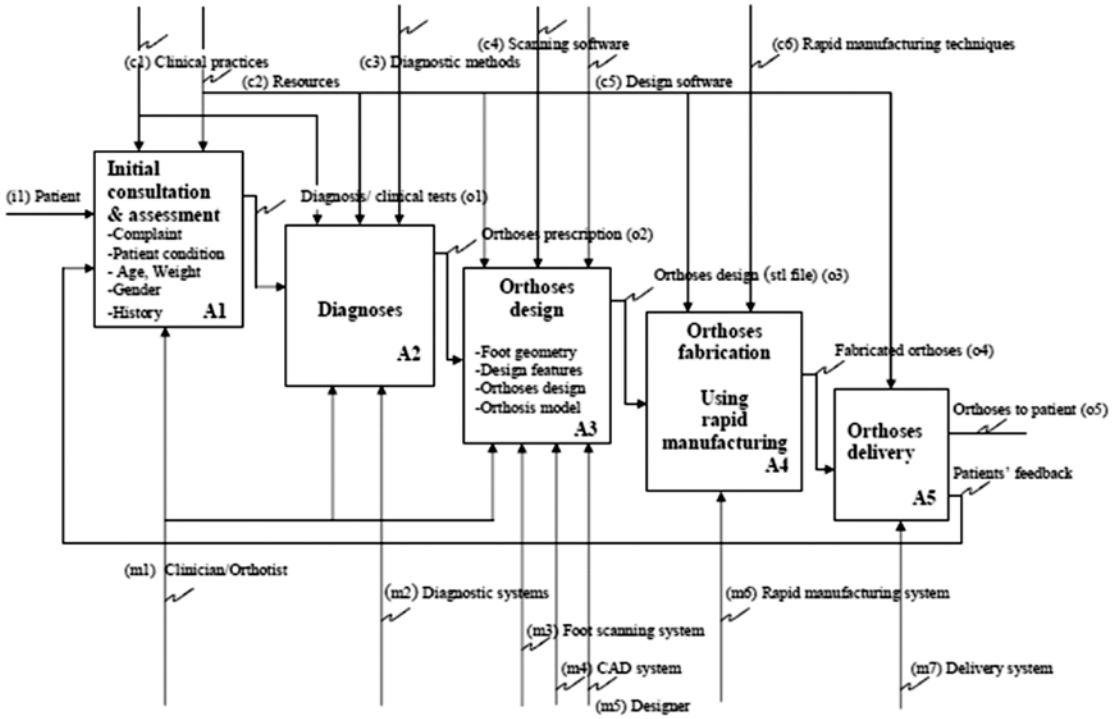

FIG. 6. "AS-TO" BE MODEL (A-1) WITH RAPID MANUFACTURING INTEGRATED IN THE SYSTEM

The step (v) in "as-is" model (A-0), rapid manufacturing approach replaces conventional manufacturing techniques using CNC systems for the function of manufacturing 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 s ank, et. al. [30]. Besides, the techniques require amount of set-up time and re-setting of tool path for adjusting the different shapes and dimensions of the orthoses. Another disadvantage in the current manufacturing techniques is the complexity in the operations and running of the machines which require highly skilled operators in the selection and setting of proper tool path, and setting of cutting parameters in the fabrication of custom foot orthoses.

The application of the rapid manufacturing approach in the system has several advantages in improving the design and manufacturing process for fabrication of custom foot orthoses. The techniques are based on 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, [12,45,55-56]. In conventional manufacturing techniques, there is a direct link between complexity of the part and its manufacturing cost. The ability of rapid manufacturing techniques in the fabrication of complex geometrical parts reduces the manufacturing cost of complex structured parts. Rapid manufacturing techniques require raw material and digital design of parts for the fabrication which also minimises the requirements of highly skilled workers in the process, [45].

5. ADVANTAGES OF THE RAPID MANUFACTURING APPROACH IN THE PROCESS

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

- Reduced cost.
- Reduced lead-time.
- Improved fit and quality.
- Reduced cost

The rapid manufacturing approach in the system creates the digital design and manufacturing process for the fabrication of custom foot orthoses. The use of various equipment, tooling and materials combined with extensive labour 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 the foot geometry capture step, the process involves digital foot geometry capture in the system which removes labour and cost in traditional geometry capturing processes. The cost benefit analysis studies conducted by Payne [57] for foot impression capturing using plaster of Paris and optical scanning has shown significant reduction in the impression capturing cost through optical scanning. Additionally, digital scanning of the foot impressions saves the cost for handling and storage of the foot impressions for future use as compared to traditional methods of storage of plaster of Paris casts and other types of impression casts.

In the design step of foot orthoses, the process involves CAD based designing system which reduces the designing cost and time. The CAD based designing system replaces the traditional methods of designing the orthoses where the positive moulds of the orthoses are developed from the negative casts involving labour work, equipment, tooling and materials. The traditional method involves manual corrections, modifications in designing the orthoses positive moulds. The manual corrections and modifications process is replaced by CAD design system.

In the fabrication stage, conventional fabrication techniques require high skill labour which increases the manufacturing cost of the parts. However, in rapid manufacturing techniques, the burden of labour cost is transferred to the technology itself i.e. the rapid manufacturing systems, [45]. The rapid manufacturing systems involve minimum human interferences during the fabrication 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, [13].

5.1 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 main advantage of the digital scanning process is increased accuracy and repeatability in the foot impression capturing process, [57-59]. Additionally, the foot scanning technique generates the 3D foot impressions in the digital format which can be easily stored in a database and transferred electronically to different places for the fabrication.

The designing of orthoses in the CAD based systems is another advantage which improves the efficiency of the process and reduces the lead-time in the system. The orthoses corrections and modifications can be digitally incorporated through a CAD based designing system. One of the main advantages of a 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 of the required design prescription, [58-59].

5.2 Improved Fit Orthoses

The process involve digital techniques and digital systems in design and manufacturing process which will result in (i) increased accuracy in measurements of the foot geometry, (ii) digital incorporation of orthoses features reduces errors during the correction and modifications process and (iii) digital fabrication processes minimise the part errors are the subsequent advantages in production of accurate and improved fit foot orthoses. The commercial examples of rapid manufacturing techniques in production of custom made products mentioned earlier in section 1 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.

6. CONCLUSIONS AND FUTURE WORK

Process modelling through IDEF0 methodology showed that rapid manufacturing techniques are compatible and can be integrated in current design and fabrication process

in development of a mass customisation production system. The digital means of foot geometry capture is a better method for foot geometry which results in increased product accuracy and consistency in the final product. 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.

The designed IDEF0 rapid manufacturing based design and fabrication process model will be used to integrate and investigate the rapid manufacturing based mass customisation systems for foot orthoses using different rapid manufacturing techniques. The efficiency of the different techniques will be evaluated in terms of variables and parameters such as production efficiency of the different techniques, cost and the lead-time involved in foot orthoses fabrication.

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