A new method of digital manufacturing of orthoses

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Received 1 March, 2014, www.tsi.lv

Abstract

The proportion of disabled people is rising and now represents 1 billion people–15% of the global population, which leads to increasingly demand for orthotic device. However, moulds for orthoses manufacturing through traditionally manual technique are often dedicated, and this causes problems such as long lead time, lack of flexibility, low-efficiency and material waste, further leading to serious financial burns and environmental pollution as well. In this paper, an innovative method is proposed to replace traditionally dedicated moulds with reconfigurable moulds utilizing screw-pins that are directly transferred to the vacuum forming of thermoplastic material at low cost for the fabrication of orthoses. In the developed system, the fast reconstruction of human body anatomy based on the 3D digital scanning, is introduced firstly, the reconfigurable mould utilizing screw-pins is then generated and machined based on the reconstructed human body anatomy. After this, vacuum forming is performed on the reconfigurable mould, which could be reused for different anatomical shape variations by adjusting screw-pins. Additionally, an intelligent database is developed and a lot of reconstructed anatomies, the best practices of experienced orthotists, optimal parameters for 3D digital scanning, reconfigurable mould generation and machining and vacuum forming are stored, which will allow rapid recall of the stored information to reduce too much man-machine interaction and expertise dramatically.

Keywords: Orthoses, Digital manufacturing, Reconfigurable moulds, Fast reconstruction

1 Introduction

For the disabled and elderly, orthoses are important tools to help them recover in the clinical environment and live independently, especially for the population ageing and the rapid spread of chronic diseases. According to the United States Census Bureau report [1], global population will reach 9.3 billion in 2040, of which over 65-year-old population will be twice from 7% to 14%. Moreover, the proportion of disabled people is rising and now represents 1 billion people–15% of the global population [2]. All these demographic changing are expected to underpin a rise in the incidence of orthopaedic problems triggering significant demands for orthoses. Nowadays the conventional fabrication technique of orthoses by repairing plaster cast manually plays a dominant role in orthotics industry, which means that the quality of orthoses mainly depends on operators' experience and skills [3]. Since orthses are generally personalized products for individual patients, thus, the manufacturing process needs one or more dedicated moulds, which can only be used once. Taking the traditional fabrication of foot orthoses as an example, the whole process is time and labour intensive, dirty and messy [4], with the making of the plaster cast (the negative cast and the positive cast), as shown in Fig.. Moreover, the natural plaster as the material of cast can only be used once and then thrown away, leading to natural resource depletion and environmental pollution. Recent advances in computer technology, especially Reverse Engineering (RE), Computer Aided Design and Manufacture (CAD/CAM), Motion Simulation and Rapid Prototyping have been introduced into orthotics and have significantly reduced the manual work and shortened production time recently [5, 6, 7, 8, 9, 10, 11, 12]. However, the problems associated with dedicated moulds including lack of flexibility, long lead-time, material waste and low-efficiency, still remain.

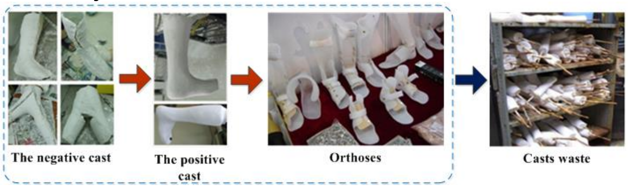

FIGURE 1 Traditional manufacturing of foot orthoses

In order to improve the efficiency of moulds, the reconfigurable moulds were presented in several patents recently [13, 14, 15, 16]. Nevertheless, most of the reconfigurable moulds are only applied in forming some simple geometries and high-end products, such as the shell of aviation aircraft and the panels for a high-speed train [17, 18]. This research aims at replacing traditionally dedicated moulds with reconfigurable moulds utilising screw-pins [19, 20, 21, 22, 23] that are directly transferred to the vacuum forming of thermoplastic materials at low cost for the manufacturing

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of low-end mass customization products by using orthoses as examples, which eliminates the plaster cast making process. An example of the screw-pin reconfigurable mould applied in other field is shown in Fig.2 [19, 20, 21, 22, 23], in which mesh screw pins were adjusted in vertical direction to represent the component geometry and were then machined to make the contact surface of screw-pins be conformable for the vacuum forming purpose.

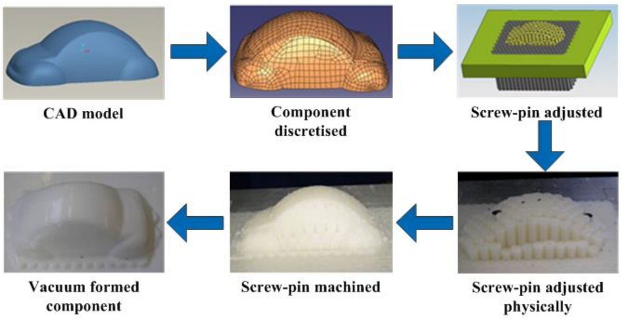

FIGURE 2 Concept of reconfigurable moulds using screw pins

The purpose of this paper is to propose a novel method of orthoses manufacturing based on 3D digital scanning, CAD/CAM/RE and the screw pin reconfigurable moulding technology. The whole process of orthoses manufacturing using reconfigurable moulds method is clean, fast and convenient, and environmental problems caused by plaster cast are minimized to realize the digital manufacturing.

2 The Research Framework

In order to reduce man-machine interaction and expertise demanding, a digital manufacturing system for orthoses is developed based on PowerSHAPE, one of the famous reverse engineering software. The system is comprised of four parts: 3D digital scanning and fast reconstruction, generation and machining of reconfigurable moulds, vacuum forming of orthoses, and intelligent database of human anatomy. The overall framework of the methodology is depicted in Fig. 3 and each part will be explained in detail in this paper.

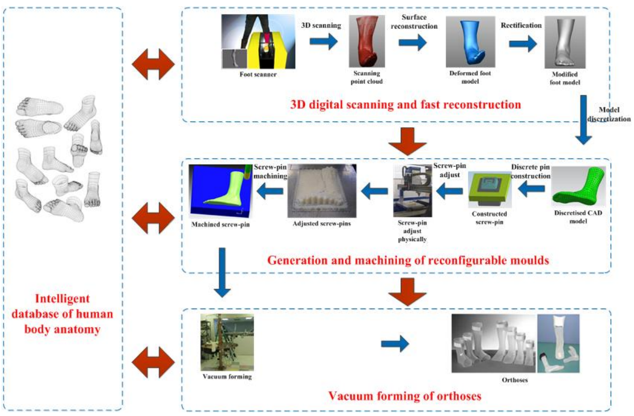

FIGURE 3 Research framework

2.1 3D DIGITAL SCANNING AND FAST RECONSTRUCTION

A specialized 3D scanner for the human anatomy, which can be available on the market, is used to scan patient's body region to be rectified by using orthopedics, and the contour is recorded by the 3D image in form of scanning point cloud. The scanned data is then processed to reconstruct the human anatomy CAD model after point cloud pre-processing within the reverse engineering environment. The reconstruction of the CAD model is a complex process, which involves much man-machine interaction and expertise. Since the system is operated by prosthetists/orthotists/technicians who has only medical or technical background, a friendly user interface for the rapid reconstruction of the human anatomy is provided. After that, the CAD model of human body anatomy should be rectified before generation of reconfigurable moulds, which is achieved by manual adding or removing material on the plaster in traditional manufacturing of orthoses. In this system, the obtained 3D geometric model, which is used as the positive cast is rectified through the developed tools in the principle, which is the same as that of the conventional manual method. Optimized scanning parameters for the generation of high quality point cloud are also embedded into the system, which is important for the reconstruction and rectification.

2.2 GENERATION AND MACHINING OF RECONFIGURABLE MOULDS

After the rectified CAD model of human body anatomy is done, it will be used to generate the corresponding reconfigurable moulds using screw-pin. Generation and machining of reconfigurable moulds consist of three steps: discrete screw-pin construction, adjustment of screw pins and machining of the adjusted screw-pins.

Since the size and the number of screw-pins have an influence on the process of pin adjustment, the tooling time, and representing accuracy of the human anatomy model, they should be set and optimized according to the discretized CAD model. The discrete screw-pin matrix is then constructed to be adjusted based on the input parameters. The amount of adjustment from the existed position of each screw-pin to the position representing the contour surface of human anatomy model is calculated firstly. In order to generate adjusting every screw-pin into certain position, the amount of adjustment is converted into the number of required adjusting turns of every screw-pin in constructed screw-pin matrix according to the screw-pins' parameters (diameter and pitch, etc.). The position and the required adjusting turns are recorded in G code [19, 20, 21, 22, 23], which is same as the NC code to control the cutter. The obtained G codes are input into the CNC system in the machine tool, which uses the screwdriver as the ordinary cutter to adjust every screw-pin into required position. The adjusted screw-pin matrix is representation for the rectified human anatomy model.

Due to steps existed between the screw-pins in the adjusted screw-pin matrix, screw-pins are required to be machined so that the contact surface of screw-pins is conformable with that of the part. In NC programming, the machining parameters are similar for similar geometry, such as human body anatomy model, which provides convenience for the exploration of optimized machining parameters. The optimized machining parameters such as size of the cutter, cutting speed, cutting depth, feed rate, type of tool path etc. for each of the human anatomy are explored and embedded in the system. Moreover, it allows minor correction for the users to generate NC codes rapidly. The screw-pins are machined in the CNC machining tool after input the generated NC codes.

2.3 VACUUM FORMING OF ORTHOSES

The reconfigurable moulds representing the CAD model of human body anatomy can be used as the positive plaster in conventional method for vacuum forming of thermoplastic material to manufacture orthoses. Vacuum forming parameters (heating temperature, time, vacuum pressure setting, etc.) are related with the shape and size of human body anatomy, matrix materials and thickness of the material. The optimal material properties and vacuum forming parameters are identified through Finite Element Analysis and experiments. After that, the orthosis is cut from the formed thermoplastic material. And then it is trimmed, polished and attached accessories for trying on.

2.4 INTELLIGENT DATABASE OF HUMAN BODY ANATOMY

As illustrated in Fig.3, the fabrication of orthoses can be completed through the above three parts. However, this system is developed for prosthetists/orthotists/technicians who has only medical or technical background. Moreover, the main purpose of the system is to render the manufacturing process of orthoses as simple and automated as possible. Therefore, the intelligent database is required.

In the intelligent database, many samples of human body anatomy are stored according to the gender, height and weight, and each of these is associated with the optimal parameters for digital scanning, reconstruction and rectification of the human anatomy, generation and machining reconfigurable moulds and vacuum forming. After input the patient individual information and symptom, the most similar samples will be matched and displayed in the system associated with the optimal parameters as reference, which greatly simplify the process and reduce the manual repeatable work.

By using this intelligent database, the 3D digital scanning to reconstruct human body anatomy can be replaced by manual measurement at clinics where there is no scanner available. Based on the measurement data of cross section of the human body anatomy, the similar model stored in the database is searched out and then modified to the personalized shape which can represent patient’s human body anatomy for fabrication of orthoses. Particularly, the intelligent database is open, and when more people use the system, more samples will be stored, and a better chance that a match will be found. So, the operation of the system becomes more and more simple and intelligent and the quality of the manufactured orthoses improves over time. The whole process of orthoses manufacturing using reconfigurable moulds method is clean, fast convenient and without demanding expertise, and environmental problems caused by plaster cast are minimized to realize the digital manufacturing.

3 Case study

In this part, the valgus was taken to as a case study, as shown in Fig. 4. The point cloud of the deformed crus model was obtained through the scanning of a foot scanner and saved as the common file format (*.asc), and then input into the system which is developed based on PowerSHAPE. The crus 3D CAD model is reconstructed rapidly only through inputting several simple parameters and rectified later. After that, the corresponding reconfigurable mould is generated and machined to be the representation of the rectified model. It is used for vacuum forming of orthosis. The orthosis will be gained and to be tried on by the patient. The 3D digital scanning and fast reconstruction, and the generation and machining of reconfigurable moulds have been done. The vacuum forming of orthoses and the intelligent database of human anatomy are being researched. They will be finished soon.

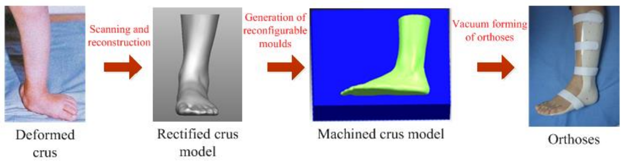

FIGURE 4 The digital manufacturing of orthoses

4 Conclusions

Over a billion people are estimated to live with some form of disability according to the first official global report on disability, which corresponds to about 15% of the world's population. The demand for orthotic devices is growing increasingly. However, the conventional fabrication technique of orthoses plays a dominant role in orthotics industry and the problems associated with which include lack of flexibility, long lead time, low-efficiency and material waste are still existed. An innovative method is proposed in this paper to replace traditionally dedicated moulds with reconfigurable moulds utilising screw-pins that is directly transferred to the vacuum forming of thermoplastic material at low cost for the digital manufacturing of orthosis, and an associated support system is developed. The whole process of orthoses manufacturing using this method is clean, fast convenient and without much man-machine interaction and demanding expertise. The cost and cycle of orthoses manufacturing and environmental pollution are also minimized to realize the digital manufacturing.

Acknowledgements

The authors would like to thank the support from the National Natural Science Foundation of China (Grant No. 51105212), Ningbo International Collaboration Funds (Grant ID: 2009D10016 and 2011D10003) and the Ningbo Natural Science Foundation (Grant ID: No.2011A610152).

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