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Sockets digital design of above–knee prosthetic for mass customization

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ABSTRACT

Aiming at two main problems of designing prosthetic sockets– time consuming and high cost, a digital design method of prosthetic sockets in mass customization for above-knee amputees is presented. Firstly, the numerical data representing the stump were obtained by the coordinate measuring machine (CMM). Then, feature points of the sockets were got by intersecting a set of rays with triangle patches to establish the master models of key modules. With these master models, the primary structure of above-knee prosthetic socket was made up. Finally, corresponding modules can be selected and configured to get a new individual prosthetic socket for an above–knee amputee according to user's specific body parameters information to meet different amputees' requirements. Via this way, traditional individual design can be transfer to modularization design and design time and cost can be saved apparently.

KEYWORDS

Prosthetic socket;
Above-knee amputee;
Digital design;
Master model;
Master structure.

INTRODUCTION

A prosthetic socket is a cavity parts that connects the stump with prosthetic, wraps the stump and contacts with it directly. As a biological interface of mechanical analysis and computer-aided design systems between human and mechanical prosthetic, it connects amputees' body with prosthetics directly. The force between the body and prosthetic stump is transmitted through the contact surface of the stump and the prosthetic socket. So the prosthetic socket is one of the most important and crucial parts of artificial limb[1], and typical above-knee prosthesis is shown in Figure 1.

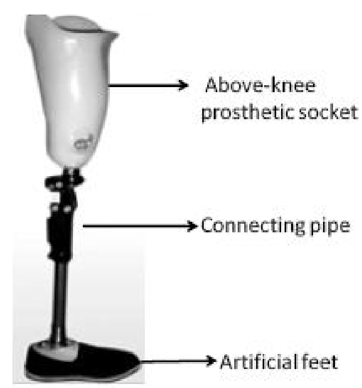

Figure 1 : typical structure of the above-knee prosthesis

The stump shape, strength and other conditions of every amputee are different, so prosthetic socket are non-standard generally, and its structure, shape and size is varying with amputees and their specific conditions[2]. Currently prosthetic socket is usually fabricated complicatedly by hand. Figure 2 shows the traditional fabrication process[3].

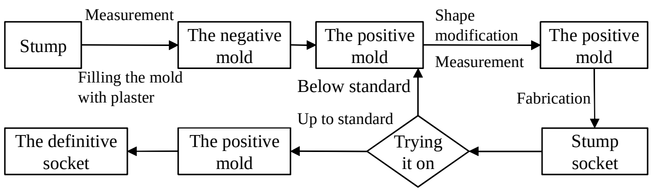

Figure 2 : traditional fabrication process of prosthetic socket

1 Measuring the feature size of the stump and using the brush to tick the feature region on the limb stump;
2 Production of the negative plaster mold by wrapping the stump with plaster, and then making the positive plaster mold;
3 Modifying the positive plaster mold according to the skilled prosthesis;
4 Production of the test socket;
5 Local modifications of uncomfortable place after patients' try on until the user was satisfied;
6 Production of the definitive prosthetic socket.

The Ministry of Civil Affairs and the Institute of Hebei University developed CAD/CAM prototype system of prosthetic sockets by combining theoretical design, the standard port-rings and the actual measurement. The proprietary software was developed and the prosthetic-aided design platform was established to realize the integration of the design and manufacturing technology of prosthetic sockets[4, 5]. China Rehabilitation Research Centre and Beijing University of Aeronautics and Astronautics studied a kind of method about prosthetic surface modeling and mold repairing[6-8], and developed a rapid prototyping prosthetic device which is being further researched and applied in clinical[9, 10]. However, the prosthetic socket made by these systems or devices is still high degree of customization. The degree of wearing comfort is related with the manufacturers' experience, techniques, skill and so on. Traditionally, in order to meet amputees' individual needs, every prosthetic socket need to be redesigned and remade for several or even dozens of times in the production process, and it requires experienced prosthetist to measure and repair the mold constantly. So, the prosthetic socket's fabrication is a time-consuming, high cost labor-intensive complicated work, and unable to meet the patients' economical, rapid and individual requirements.

Mass customization (MC) integrates two completely different modes of mass production and customized production to provide customized products with low cost, high quality and short lead time of mass production[11]. Digital design supports innovation design, product data management (PDM), development process control and optimization. Generally, product modeling is the basis, optimal design is the subject and PDM is the core[12]. Prosthetic sockets design is deeply degree of customization. How to utilize design method for MC and digital design techniques to get a complete and detailed description of prosthetic economically becomes critical. This paper studies the digital design of prosthetic socket for an above–knee amputee in MC, proposes design framework and some key techniques. Via making full use of existing resources, overall optimization and dynamic configuration, handmade prosthetic sockets defects can be avoided furthest.

DIGITAL DESIGN SYSTEM OF PROSTHETIC SOCKETS

Prosthetic socket design for MC is based on three principles, i.e. the similarity, reuse and overall principle. By discovering the structural similarity of different amputees, the standardized, modularization methods and configuration design techniques are used to minimize the custom part, to simplify the design, and to improve the reusability of the digitized model of sockets, which not only meets the actual needs of patients, but also achieves the goal of low cost, high quality, short delivery time of prosthetic sockets to avoid the waste of human and financial resources caused by repetitive design.

The prosthetic socket digital design for MC can be divided into three main design processes, i.e. the development, designing and gait analysis. The socket main structure throughout the entire designing process is established based on modular design approach and parametric modeling technology. A quick response design of a prosthetic socket that meet the patient's need is achieved by using configuration design, variant design and other methods to product master model.

The digital design technology system of human prosthetic sockets shows in Figure3. It includes three layers, i.e. the theoretical layer, the development and design layer, the application and tool layer.

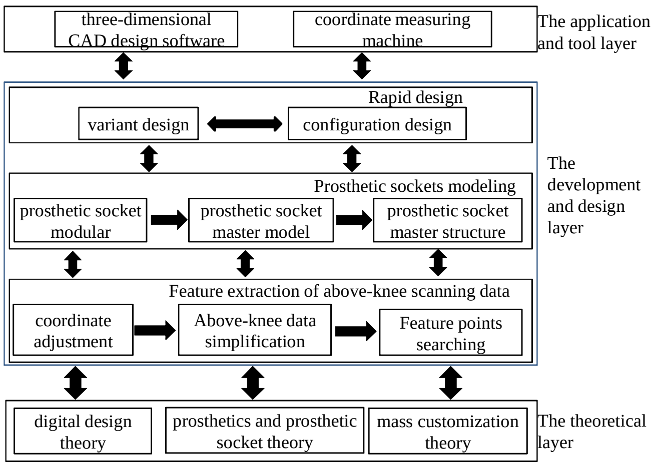

Figure 3 : digital design system of prosthetic sockets

The theoretical layer involves the theory of digital design, prosthetics and prosthetic sockets, MC and so on. It is the theoretical basis to model prosthetic socket and implement sockets design for MC.

The development and design layer is the key and core technology to achieve rapid design of prosthetic sockets. It can be divided into three parts: the feature extraction of above-knee canned data, prosthetic sockets modeling and rapid design, involving the modular modeling, configuration design, variant design and other key technologies of the digital design model of prosthetic sockets. The main task of this phase is to build prosthetic socket master model and the master structure. The quick design of customized prosthetic sockets for MC can be realized through configuration design and variant design based on the main structure and main model according to the patient's specific conditions and needs.

The application and tool layer is to use 3D CAD design software to realize rapid design of a customized socket's based on the main structure and master models by analyzing and processing the point cloud data of an amputee's stump obtained by CMM. Modeling feature points can be acquired after the processing of a series of human above-knee point cloud data. Then the master models of key modules are created through the design table and 3D CAD system. New variant sockets can be generated quickly by modifying the data in the table.

KEY TECHNOLOGIES OF SOCKETS DESIGN

Feature extraction of above-knee scanning data

The human above-knee data can be represented in the form of triangular facets. The data stored in the triangular mesh surface model just shows the coordinate points of the model and the triangular mesh. These data have no semantic information related to the model itself so that the specific location of a coordinate point in the above-knee model can't be known exactly. In this paper, a sampling algorithm is proposed to obtain the contour line of the above-knee model.

Pretreatment of above-knee model

Firstly, the model needs to be pre-treatment which consists of two steps, coordinate adjustment and model simplification of the above-knee model before feature searching in order to easy post-processing and improve search speed. Then these feature data can be located and calculated quickly from the 3D model data. The calculation process shows in Figure 4.

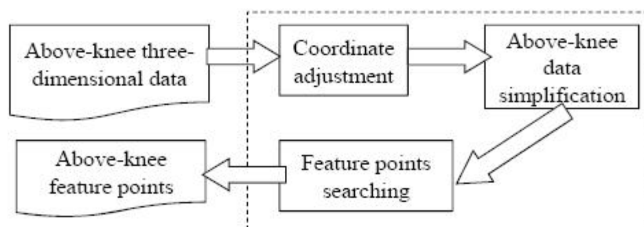

Figure 4 : Above-knee feature points extracting process

Coordinate adjustment: since 3D scanned data is generally expressed in the Cartesian coordinate system scanning equipment requires. These data need to be convert into a new coordinate system by using PCA (Principal Component Analysis)[13]. In the new coordinate system, the geometric center of original scan data was defined as the origin point, and the maximum span of the original scan data is defined as Y-axis direction, and minimum span of that is defined as Z-axis direction. Define the new coordinate system X, Y, Z axis as the width, height and thickness direction of the above-knee model.

Simplification of above-knee model: untreated scan data usually contains lots of redundant vertices and triangles. Meanwhile, lots of operations to strike section of the model firstly are necessary during the search pro-

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cessing for feature points because excessive triangles would consume time and reduce the sampling rate. Therefore, it is necessary to simply model before the search to reduce resources consumption.

Extraction of contour line and feature points

As the shape of above-knee is simple, equidistant segmentation method is utilized to get the sampling model during extracting the above-knee's contour lines referring to traditional measuring method. A kind of algorithms shows in the literature[14] was adopted, which defined the point O (x, y, z) as the center and generated a ray every 36° in the sampling plane. A series of point information were obtained due to the intersection of those rays with the outer surface of the above-knee model which is desired sampling points.

Because the source data of above-knee model is triangular mesh data, it needs to consider how to get intersection points when rays intersect with triangular meshes. Intersection coordinates were obtained by the method in literature[15]. This algorithm is as follows: a point, U (k, t) on a triangle is described by

$$U(k,t)=(1-k-t)T_0+kT_1+tT_2 \quad (1)$$

Where (k, t) is the triangle relative coordinates, which must meet k e" 0, t e" 0, k + t d" 1. The ray vector R (v) of which the origin is O and the direction vector is unit vector L is defined as:

$$R(v)=O+vL \quad (2)$$

Calculating ray R (v) the triangular U (k, t) is equivalent to the intersection R (v) = U (k, t), then the following equation produced:

$$O+vL=(1-k-t)T_0+kT_1+tT_2 \quad (3)$$

Rearranging the terms gives:

$$\left[-L, T_1-T_0, T_2-T_0\right]\begin{bmatrix} v \\ k \\ t \end{bmatrix} = O-T_0 \quad (4)$$

As seen above, the triangles relative coordinates (*k*, *t*) and the distance *v* that radiation from the starting point to the intersection can be obtained by solving the linear equations and get all the intersection coordinate.

Modularization modeling of prosthetic sockets

The basic idea of modularization is developing some modules with independent functions based on comprehensive analysis and research on the customer needs. These modules make up a complete product family. Modularization is the basis to reuse product design resources and the key to realize configuration design and variant design[11, 16]. The middle part of prosthetic socket can be divided into several modules logically. Each module is mutual reference either bottom-up or top-down. This middle part consisted of the shared module which is functional independence can be constructed a variable prosthetic socket main structure. The more a module constituted a product family is shared, the greater reduction of the cost of customized products[17], and the more amputees' customization needs are met.

A prosthetic socket model is integration of all the technical and data and it manages a variety of information and its dynamic linkages effectively during its product life cycle[18]. Prosthetic socket modeling includes the creation of master model and main structure of prosthetic sockets.

Prosthetic sockets master model

The main model of parts is composed of its geometrical model and the corresponding TLAC (tabular layouts of article characteristics). In TLAC, article characteristics and conduct characteristics are used to describe the link between shape and size. When entering a set of data in TLAC. A variant instance will be derived automatically[11].

As the shape of the mouth-ring of the prosthetic socket remains the same, just the caliber varies with the circumference of the ischialtuberoses while the change of the middle part is regular. Different sockets of prosthetic amputees just change on appearance and the geometry size on the whole. Therefore, the prosthetic socket is logically divided into three parts: the upper section (mouth-ring), the middle section (intermediate regular change area) and the lower section, as shown in Figure 5. The prosthetist measured the above-knee circumference every 30/50mm on the traditional method which lead to measurement error and require constant resizing[19]. In order to overcome these limitations, the middle part is divided every 10mm during designing the prosthetic socket here. The middle section can be seen as the virtual "component" composed by a number of modules from the design point of view. The upper, the lower sections and every module divided from the middle can be seen as "part" The module 1 and its design table forms the middle module master model, change of the

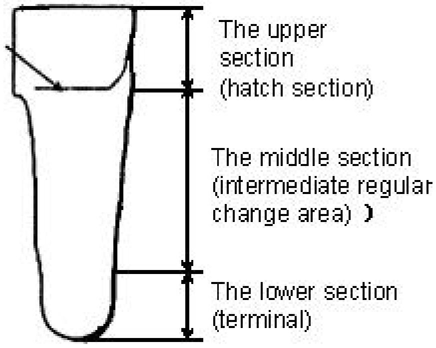

Figure5 : Segment Description of prosthetic sockets in the height

design data in the table can derive a variant of the other modules.

With above approach, the associated component module or part module will changes accordingly when a particular instance of master model changes.

Prosthetic socket main structure

In theory, the main products structure describes the composition of a modular product that is order independent, configurable and includes all basic modules and expansion modules. Customized products structure is derived from the main structure according to customers' needs. Expansion modules typically include mandatory modules and optional modules. The constraint and choices among various modules can be described by the configuration rules[11, 18]. The main structure of a prosthetic socket can be seen in Figure 6.

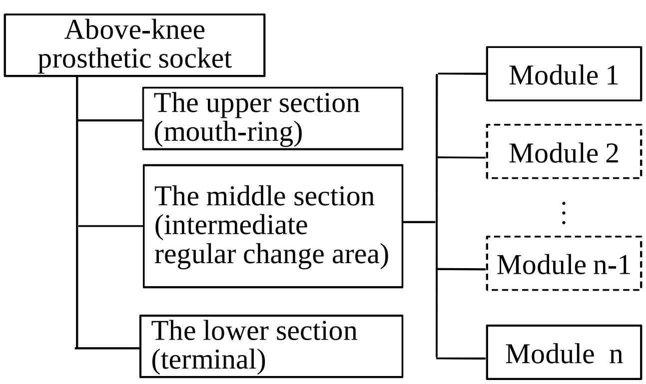

Figure 6 : Above-knee prosthetic socket master structure

In Figure 6, the solid-box means a mandatory module and the dashed-box represents an optional module. Moreover, the lines among the master models describe their relations at all levels as the main structure. The upper segments, the lower segments, the middle of modules 1 and n belong to mandatory modules, and the modules 2 to n-1 are optional modules. The upper segments' size corresponds to the module 1. Similarly, the lower section corresponds to the size of the module n. The middle segment of a satisfied prosthetic socket is composed of optional modules by spliced to each other based on the length of patient's residual limb amputation, namely using the design table of 3D CAD system, configuration design and variant design are conducted to produce a satisfied middle instance and to configure the corresponding upper and lower sections. Thus rapid design of the prosthesis socket is achieved.

Variant design of prosthetic sockets

On the basis of the product development process, and combination with variant design technology for MC, the target that reduces components variety and improves using frequency of components from the methodological level can be achieved. With the design table of SolidWorks[20], variant structure segment would be generated, and then they are configured to be a prosthetic socket that meets the amputees.

INSTANCE ANALYSIS

The above-knee data of a 28-year-old, 178cm and 74kg male amputees is selected as the instance. The length of its stump is 270mm, the upper (mouth-ring) is 50mm and the lower segment (terminal) is 50mm, so the middle (intermediate rule change area) is 170mm. Different module instances are generated by changing the size in design table of SolidWorks to realize configuration design and variant design and to achieve rapid design of a above-knee prosthetic socket.

Firstly, the number of optional modules can be determined through the middle length, and ten feature points coordinate data determine the layers girth (some parameters shown in TABLE 1), thus the prosthetic socket can be determined roughly with the use of these parameters. During actual variant design process, assigning specific data to these parameters as seen in Figure 7, and combining the corresponding data in each row in the table with the master model of each segment prosthetic, a customized prosthetic socket for an amputee can be designed quickly. The configuration processes of the upper and middle and customized prosthetic socket model are shown in Figure 8.

TABLE 1 : Design table of the middle section

Name	D1	X10	Y10	X11	Y11	X12	Y12	X13	Y13	X14	Y14
Module1	10	71.43	41.24	65.38	37.75	33.39	57.83	47.70	82.62	27.15	47.03
Module2	10	63.11	36.44	65.07	37.57	32.84	56.88	47.57	82.40	25.22	43.69
Module3	10	67.67	59.48	64.41	37.19	32.36	56.05	47.05	81.50	24.21	41.93
Module4	10	64.36	57.48	63.64	36.74	31.98	55.39	46.28	80.16	24.17	41.86
Module5	10	62.31	59.02	62.58	36.23	31.67	54.86	45.37	78.57	24.64	42.37

Figure 7 : The middle section module instance of a prosthetic socket

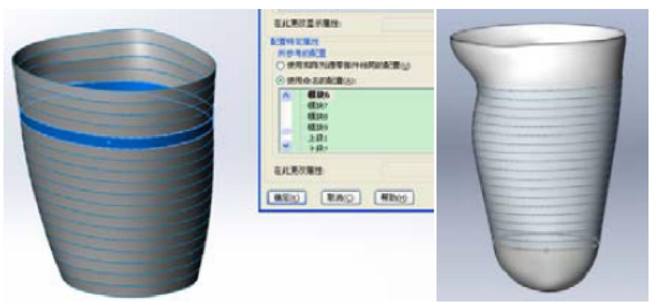

Figure 8 : Configuration process of the middle section and a prosthetic socket model

Duplication design apparently can be reduces via this method by transforming whole prosthetic socket's design into configuration and variant design of 3 structure segments. Compared with the traditional methods, it reduces design time greatly, speeds up the delivery and reduces production costs significantly.

SUMMARY

To support digital design of the prosthetic socket for MC, two conditions need to be met. Firstly, according to the modular idea, master model of the parts supporting variant design need to be developed to build a product main structure. Secondly, 3D CAD systems are needed to support configuration design and variant design of the digital model of prosthetic sockets. Compared with the traditional fabrication methods, the digital design of prosthetic sockets for MC overcomes the shortcomings of a single customized way, reuses the existing design resources effectively, and shortens product delivery time significantly.

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