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Toward automation in hearing aid design

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ABSTRACT

In the manufacturing of *customized medical prostheses*, such as in-the-ear hearing aids, the design process often is dictated by a source template representing the anatomy of a patient and a set of work instructions representing the description of surface modifications. Instead of carrying out the work instructions by hand with knife, file or drilling tools, the state-of-the-art relies on modern software tools, such as computer-aided-design and computer-aided-manufacturing. Work instructions are usually defined in terms of anatomical landmarks of a given template. Following the design phase, the virtual model of the customized prosthesis is produced by a rapid prototyping system, like selective laser sintering or stereolithography. An outstanding problem in prostheses design is that the work instructions are often vaguely defined, and a suitable outcome largely depends on the knowledge, experience and skill of the designer. In this paper, we present a solution to minimize the influence of human interaction. Our approach involves the abstraction of the work instructions into expert system rules that exploit a robustly identified canonical set of anatomic features. The versatility of our approach lies in *a priori* defining an entire design workflow through a rule set, thereby yielding a high degree of automation that is flexible, customizable, consistent, and reproducible. The proposed solution is extensively evaluated in a real world application, and is shown to yield significant improvement in manufacturing. For instance, the consistency of the outcome was improved by about 10% and the design time was reduced by about 8.4%.

1. Introduction

A major development in medical prostheses manufacturing in the past two decades has been the introduction of the computer-aided-design (CAD), and the computer-aided-manufacturing (CAM). The usage of these technologies precipitated an increase in the quality and the availability of various kinds of medical prostheses. So far, the focus of the CAD tools has been to improve the quality and the fitting of prostheses. The basic idea is to acquire an accurate account of the underlying anatomy via CT or 3D laser scan to generate a 3D model, which is utilized by an expert operator to design the desired target shape. Special attention is given to ensure the conformity of the target shape to the anatomy. Nonetheless this approach just replaces the physical cutting, grinding and filing tools with the virtual ones, controlled with a computer mouse. Neither it reduces the amount of manual labor involved, nor does it improve the consistency or reproducibility of the finished device. In this article, we specifically address these limitations of the existing CAD tools.

The general problem of *automating* the computer-aided-design is highly significant in various medical areas, such as hearing aid (HA) manufacturing, orthopedics, orthotics, and orthodontics. In general, medical prostheses manufacturing has to follow two fundamental requirements. First, a prosthesis has to fulfill its core functions, such as amplifying sound for HAs, resisting perpetual corrosion and pressure exerted on dental prostheses or achieving the desired shape to disguise deformations in the case of cosmetic prosthetics. Equally important, it should demonstrate a tolerable degree of conformity with the underlying anatomy. This is particularly important to ensure that it conveniently fits the anatomy of a patient. Due to the large amount of variability in size and shape, the design of such prostheses has traditionally been carried out manually. Thus, the resulting prosthesis has depended on the skills and the expertise of an operator and has failed to demonstrate desirable consistency.

Our proposed solution is to formalize the available knowledge and to augment the CAD system with an expert system that employs a feature detection unit. The resulting system is capable of designing a medical prosthesis (semi-) automatically.[1]

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[1] The framework is capable of achieving full automation, with further tweaking of the currently employed features and associated rules.

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The remainder of the paper is structured as follows. We start with an overview of the related work on the automatic manufacturing of medical prostheses and the detection of features on organic shapes. Section 3 provides a brief introduction to HA manufacturing. Section 4 formalizes the automation problem, followed by a discussion of the employed anatomical features and the associated feature detection algorithms in Section 5. Section 6 explains the knowledge base and the construction of associated rules. Before concluding, we validate the proposed system in Section 7.

2. Literature review

First attempts toward automatic manufacturing of medical prostheses were initiated in the late 1980s by Dooley et al., who introduced the ORTHOPERT system [1]. The ORTHOPERT consisted of a knowledge based system, helping biomedical design engineers and clinicians in the design of implantable devices. The ORTHOPERT was able to deduct from a given set of patient parameters a customized design for a femur prosthesis including a finite element analysis of the design. Similar work with focus on below-the-knee prostheses was done by Riechmann et al., who exploited the advantages of CAD/CAM for this task [2].

In the field of dental prostheses, Hammond and Davenport introduced the RaPiD system as a logic-based model of prostheses design [3]. RaPiD was a declarative system that employed predicate logic for designing a removable partial denture. A CAD/CAM solution for dental restoration was presented by Zhu et al. [4]. Their work focused on the fabrication of customized dental crowns based on CT data. Furthermore, Yan et al. [5] presented a semi-automatic rapid prototyping framework for the fabrication of removable partial dentures, which lacks the seamless and transparent integration of expert knowledge and feature detection compared to our approach. An extensive review of the advantages and the limitations of the existing CAD/CAM systems for dental technology may be found in [6]. So far combining knowledge based and CAD systems resulted in applications working with non-organic shapes. Lin et al. [7] developed a framework for drawing dies, which reduces the development time and costs. Sanders et al. [8] integrated a multi-expert system into a CAD system, which is capable of identifying designs which are easily assembled by machines or humans. In contrast to our work, these systems focus on combining existing or designing non custom parts, while we focus on the automatic design of organic shapes to a unique shape using expert knowledge and on the fly detected features.

The detection of anatomical features on organic shapes is relatively less studied in the context of CAD systems, where major focus has been on well-defined industrial parts. For instance, Sunil and Pande [9] dealt with non-organic shapes, and Zhang et al. [10] provided the detection of geometric features based on NURBS representation of the underlying shapes in the form of CAD models. Ye et al. [11] went a step ahead by considering laser scanned surfaces, and employed geometrical feature detection for reverse engineering. The problem is more complicated for organic shapes, where clear boundaries between various regions usually do not exist. Similar to [11], we work with the 3D scanned surfaces of the input shapes. But in contrast, we consider organic shapes, and focus on the forward design problem, which involves the detection of anatomical features. Recently, Razdan and Bae [12] addressed the problem of organic shapes, such as bones and blood vessels, where they utilized a hybrid approach that combines vertex and edge based feature recognition techniques. Despite some compositional similarities with [9,12], we address a completely different problem, and consider more diverse set of features.

Recently, the digital manufacturing of customized hearing aids has started to gain interest of the research community. A group led by Larsen worked on several topics including statistical shape models of ear impressions, analysis of deformations in the human ear canal caused by mandibular movement and the generation of a one-size-fits-most hearing aid shell [13–16]. Unal et al. [17], on the other hand, formulated the manufacturing process as a shape estimation problem. Their statistical shape model resulted in promising results on a limited set of ear impressions. Similar to their work, we validate the proposed approach with application to the customized HA design and manufacturing. However, our method differs significantly from theirs. In contrast to their one step solution, we decompose the design process into several well-defined and physically intuitive shape modification steps. Each step, in turn, is represented by a set of rules in a *knowledge base* (KB). Each rule in conjunction with some well-defined anatomical features leads to a shape modification operation. An *inference machine* of the resulting expert system applies the resulting operations on an input shape via the integrated CAD tools. This essentially simulates the design work instructions, i.e., the physical steps carried out by an expert operator. An added advantage is that it allows the integration of every detail of the design process, including various input constraints necessary for perfect customization and proper functioning of the resulting device [18]. Hence, our method is much more flexible as the previous approaches, which require a sufficiently large training set in order to incorporate process changes.

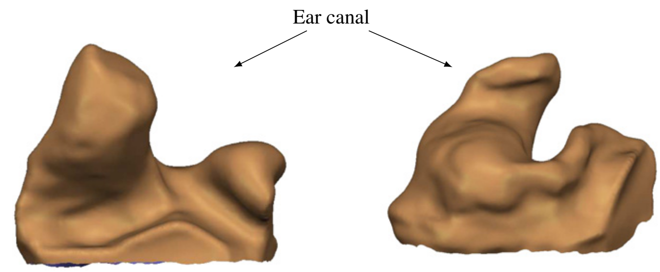

Fig. 1. Examples of two ear impressions (ear negatives) after triangulation. Ear impressions display large variability in size and shape. In addition, the quality of the triangulated surface can be poor, either due to the complexity of the underlying shape, or due to improperly acquired impressions.

3. Customized hearing aid manufacturing

Customized HA manufacturing is a delicate, complex and time consuming process. First, a template shape (ear impression) is acquired. Usually, an audiologist fills a malleable material into the ear of a patient, which is allowed to settle before it is taken out as the "negative" of the ear. The ear negative (ear impression) is then laser scanned to acquire a point cloud, which is triangulated using a specialized CAD software to reconstruct a mesh that represents the surface of the outer ear as shown in Fig. 1 [19,20]. In this paper, we assume that the triangular mesh has already been reconstructed, and the design of the HA is required. Currently, this is done manually through the application of a series of interactive CAD operations representing a mesh transform.

Major CAD operations include cutting, rounding and smoothing of the input mesh. Virtual placement of electronic components (Fig. 2) is carried out to ensure that the selected electronics will fit in the HA shell during the actual physical assembly. In addition, operations to integrate other mesh structures, like the ventilation tube are performed. A vent is required, because a HA hermetically closes an ear, thereby causing pressure differences and acoustic feedback. The integration of a vent reduces these negative effects [21,22]. Vents come in various sizes and shapes (Fig. 2) to accommodate different feedback properties, and their selection and placement is crucial for proper functioning of the device. In summary, the design of a HA involves various