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Custom-made titanium devices as membranes for bone augmentation in implant treatment: Modeling accuracy of titanium products constructed with selective laser melting

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ABSTRACT

Objective: The purpose of this study was to verify the modeling accuracy of various products, and to produce custom-made devices for bone augmentation in individual patients requiring implantation.
Materials and methods: Two-(2D) and three-dimensional (3D) specimens and custom-made devices that were designed as membranes for guided bone regeneration (GBR) were produced using a computer-aided design (CAD) and rapid prototyping (RP) method. The CAD design was produced using a 3D printing machine and selective laser melting (SLM) with pure titanium (Ti) powder. The modeling accuracy was evaluated with regard to: the dimensional accuracy of the 2D and 3D specimens; the accuracy of pore structure of the 2D specimens; the accuracy of porosity of the 3D specimens; and the error between CAD design and the scanned real product by overlapped images.
Results: The accuracy of the 2D and 3D specimens indicated precise results in various parameters, which were tolerant in ISO 2768-1. The error of overlapped images between the CAD and scanned data indicated that accuracy was sufficient for GBR. In integrating area of all devices, the maximum and average error were 292 and 139 μm, respectively.
Conclusions: High modeling accuracy can be achieved in various products using the CAD/RP-SLM method. These results suggest the possibility of clinical applications.

1. Introduction

In the 1970s, the benefits of computer-aided design (CAD) began to become apparent in the industrial fields of automobile and aerospace design (Calamia, 1995). The rapid development of CAD has led to increased opportunities to apply CAD in various fields, not only in relation to industrial product development but also in fields such as art, manufacture of electric parts, drug design, and so on (Sanders et al., 2011; Kimura et al., 2013; Narayanan and Banerjee, 2013; Sanchez-Lite et al., 2013; Veselovsky et al., 2014; Pevzner et al., 2014).

The use of CAD in the medical field began somewhat later, in the middle of the 1980s. At first, CAD meant 'computer-aided detection' or 'computer-aided diagnosis' among physicians and radiologists (Horsch et al., 2008). Consequently, it took some time to develop the capacity of the elements of CAD, such as image processing methods, computer operating systems, design software, etc., for medical applications (Giger et al., 2008). Nevertheless, mainly due to the efforts of physicians and radiologists, CAD techniques for medical applications have matured rapidly. In the 1990s, some reviews of the literature on medical applications of CAD were published, mainly in the field of orthopedics (Pho et al., 1990; Goh et al.,

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1990; Gelalis et al., 2001). The application of CAD techniques soon spread to many other fields (Peltola et al., 2008: Garcia, 2009).

In the past decade, medical CAD techniques have advanced particularly rapidly in dentistry (Duke, 2001; Fasbinder, 2013; Boitelle et al., 2014). This rapid development could not have been achieved without the development of manufacturing methods using CAD data. In the dental field in particular, computer aided manufacturing (CAM) has been most popular since the middle of the 1990s as a component of 'CAD/CAM systems' (Rekow, 1992) for producing dental products, which are usually very small.

More recently, the technique for rapid prototyping (RP) based on CAD data has developed rapidly (Sallica-Leva et al., 2013). Additive manufacturing techniques for three-dimensional (3D) printing are among the many processes that exist for making a 3D object in almost any shape from a 3D model or other electronic data source, primarily through additive processes in which successive layers of material are laid down under computer control. Rapid prototyping can be performed by many different methods that allow porous titanium (Ti) parts with complex geometries and controlled internal architectures to be obtained. One such method is selective laser melting (SLM) (Mullen et al., 2009; Warnke et al., 2008), which has begun to be used in the dental field to produce restorative materials, removable partial dentures (Lima et al., 2014), and metal and ceramic crowns (Cho and Chang, 2013), and in oral surgery (Abdel-Moniem Barakat et al., 2014).

Furthermore, with the benefit of 3D printing, RP from a patient's data can be applied to both medical examination and treatment (Shqaidef et al., 2014). Because RP builds up 3D data layer by layer, it can be used for complicated shapes. Ti is one of the prosthetic materials used in the dental field that can be used in SLM to produce custom-made Ti devices. Custom-made Ti devices produced for clinical use with the CAD/RP-SLM technique have been employed in orthopedic surgery (Otsuki et al., 2013). In this study, we verified the feasibility of using CAD/RP-SLM to produce Ti devices that can be used in the field of dentistry in the near future.

The ultimate goal of this study was to construct custom-made Ti devices with a high level of accuracy that can be applied to bone augmentation using the CAD/RP-SLM method.

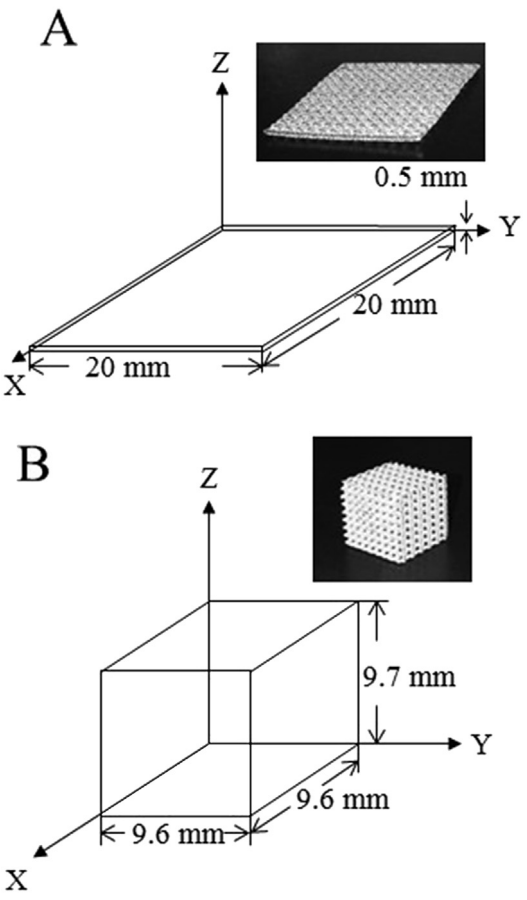

Fig. 1. Design of the experimental specimen and the real product. (A) Two-dimensional (2D) specimen and design documentation made with a width (X-axis) of 20.0 mm, length (Y-axis) of 20.0 mm, and thickness (Z-axis) of 0.5 mm. (B) Three-dimensional (3D) specimen and design documentation made with a width (X-axis) of 9.6 mm, length (Y-axis) of 9.6 mm, and height (Z-axis) of 9.7 mm. Ten 2D and ten 3D specimens were made.

2. Materials and methods

2.1. Design of products with CAD

First, two-dimensional (2D) specimens with many 1.0 mm diameter pores were designed using CAD, performed with the Geomagic Freeform software (3D Systems, Rock Hill, SC). The 2D specimens were 20.0 mm in width, 20.0 mm in length, and 0.5 mm in thickness (Fig. 1A). The 3D cubic specimens with pore structures were designed in the same manner and were 9.6 mm in width, 9.6 mm length, and 9.7 mm in height (Fig. 1B). According to the CAD data, the porosity of the 3D specimens was designed to be approximately 65%.

Custom-made devices were then designed for use in clinical trials in the dental field. Such devices have complicated forms with many curves because they are intended to be used as barrier membranes for guided bone regeneration (GBR) that can achieve ideal alveolar bone augmentation. Each device is designed using a CAD technique that takes into consideration the surrounding tissue. Each device has a different shape and size because the bone defect is different for each patient. Every defect should be covered with a custom-made device, providing each patient with the ideal bone shape for implantation. The widths of the devices produced in this study ranged in size from 13.6 mm to 55.1 mm and had 1.0 mm diameter pores. A total of ten custom-made devices were designed. Computed tomography (CT) scans were conducted using the Digital Imaging and Communications in Medicine (DICOM) standard to obtain data on patients' alveolar bone defects, and the data obtained were used as input to the implant simulation software BioNa (Wada Precision Dental Laboratories Co. Ltd., Osaka, Japan). Metal artifacts were removed, and the roots of teeth, blood vessels, and nerves were superimposed. To determine the shape and strength of the bone, interactions were conducted between BioNa and the virtual reality haptic device Phantom in the Geomagic Freeform operating software, which allowed for CAD manipulation. This procedure was indicated as an example of a CAD process used to produce the completed design, as shown in Fig. 2A.

As mentioned previously, the thickness of the 2D devices as manufactured was 0.5 mm. The design mesh aperture was 1.0 mm. A measuring device was then used to polish each custom-made device to a final thickness of 0.3 mm. The hole for the screw that retains the device was also designed using CAD. The diameters of the screw holes were 1.5 mm. For patients with mandibular implants, the mandibular canal was extracted using BioNa, and simulations were performed to avoid damage to the mandibular canal and roots of teeth.

Ten patients participated in the study, and all gave informed consent when necessary. The experimental protocol of this part of the study included the collection and use of data from individual humans. Therefore, approval for the experimental protocol as an observational study was obtained from the Institutional Review