Case Report

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A Customized Transmucosal Titanium Implant for a Cleft Palate Patient Using Layered Fabrication. A Clinical Case Study

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Abstract

Purpose: New manufacturing technologies such as additive-manufacturing (AM) make it possible to produce complex-three-dimensional shapes in a wide variety of materials. The aim is to use AM to develop a transmucosal implant for a cleft-palate patient that can repair both the bony defect and resolve the problem of the gap in the dentition of the upper arch.

Method: A patient with a unilateral-cleft-palate was selected. A CT-image of the patient was taken and 3D-model of patients jaw were reconstructed using Mimics software 10 (Materialise Co., Ltd). The haptic technology was employed to design the implant. The file of the implant was transferred to a selective laser melting machine to produce the implant in cp-Ti. The implant was cleaned and sterilized and fitted to the patient using standard surgical procedures. Three months after healing, a new crown was fitted to the transmucosal part of the implant to complete the dental arch. The patient was reviewed at 6 months, 1 year and finally eight years

Results: The patient was provided with a customized implant, which healed uneventfully. Three months after surgery the patient had the crown fitted to the transmucosal aspect of her implants, thus restoring the dental arch. After eight years the patient had experienced no adverse reaction to the treatment.

Conclusions: Additive manufacturing has been used in order to produce a close fitting customized implant for a cleft palate patient. The implant was successful in both closing the defect and simultaneously providing a solution to the prosthetic problem.

Keywords: Computer tomography; Additive manufacturing; Cleft palate; Titanium implant; Transmucosal

Introduction

Recent advancements in image processing, computational design and additive manufacturing (AM) has provided new opportunities for providing patients with customized implants in a wide variety of materials and with an ever increasing complexity [1]. Soon after their introduction, the advantages of this new technology were realized and researchers started to look at potential medical applications. The first applications
involved a combination of data capture using Computed Tomography (CT) or Magnetic Resonance imaging (MRI) and additive manufacturing with stereolithography (SLA). SLA allows the production of complex 3D shapes from a photocurable resin built up in layers [2,3]. Since medical data resulting from CT/MRI is usually provided in a slice format, it seemed only natural to be able to produce physical models directly by the new layered-manufacturing techniques used in AM. By combining image processing and AM, medical applications have evolved very quickly. Nevertheless these digital technologies are still developing and many challenges lie ahead to get the best out of them and be able to see what they can and cannot deliver. In this example we are exploring the use of AM in the treatment of patients with a cleft palate defect.

In the developed world, patients with cleft palates are treated surgically at an early age and every effort is made to close the defect [4]. This is then followed up by lengthy orthodontic treatment to realign the teeth in the upper arch [5]. However, there are many parts of the world where patients with cleft palate grow into adulthood without any treatment and by then surgical intervention such as bone grafting may have failed or may not even be a viable option [6]. In such situations a customized implant may be the only long term solution. For many years now in dentistry they have used prefabricated transmucosal implants made out of cp-Ti to provide support for a crown, bridge or denture [7]. As long as good soft tissue seal is obtained and oral hygiene is maintained the fact that part of the implant protrudes through the soft tissues should not pose a problem. For the cleft palate patient often there is a gap in the dentition due to the lack of bone [8]. When the teeth adjacent to this gap are perfectly sound it would be a shame to prepare such teeth to accept a conventional bridge. The flexibility in the design and manufacture of customized implants afforded by AM means that there is an opportunity to solve both problems simultaneously.

In this paper we describe a clinical case study of a procedure developed out of a collaboration between the Universities of Sheffield (UK) and Tabriz (IRAN) for the near optimal design and manufacture of transmucosal implants for cleft palate patients. The aim of this study is to use AM to develop a transmucosal implant for cleft palate patients that can repair both the bony defect and resolve the problem of the gap in the dentition of the upper arch.

Case Presentation

The patient is a 23 years old female with a unilateral lip and cleft palate problem (Figure 1). At the age of 2, her lip was repaired surgically. Her main concerns were related to the treatment of the cleft palate and replacing the missing upper lateral incisor. She has not been convinced by the traditional treatment and when this new approach of providing a customized transmucosal implant has been explained to her she consented to have this treatment carried out.

Following comprehensive medical, dental and social assessments, no relevant contraindications observed. The detailed treatment procedure was explained to the patient and informed consent was obtained. The CT-Scan data was generated to capture the details of the bony defect of the maxillary area and construct a virtual and a stereolithographic model.

Design and manufacture of the implant

The most commonly used techniques for capturing internal medical data are Computed Tomography (CT) or Magnetic Resonance Imaging (MRI). Either of these techniques provide cross sectional images of a scanned part of the human body. The following three steps summarizes the conversion process:

1. **Reading the scanned data from the appropriate medium.** Typically, the CT/MRI equipment can supply scanned data on magnetic tape or optical disk.

2. **Converting the data into a manipulative format.** At this stage, the CT/MRI format is translated into an image format specific for the conversion software.

3. **Creation of 3D-model.**

In this instance the CT images of the patients were reconstructed in 3D using Mimics software (Materialise, Leuven, Belgium). To generate a 3D-model from the 2 dimensional scan images, contours had to be identified for the targeted element using statistical analysis and the gray scale of the target region. Once selected, the different layers were be tied together to enable generation of the CAD model in the form of a solid object. The STL file of the CT data was sent to a SLA machine to produce a model of the patient's bony structures. This was done in order that the implant can be assessed for quality of fit and ensure that there is a simple path of insertion, which aids surgical planning.
The data was imported into Freeform software (Geomagic, Wilmington, USA) to design the implant using a Haptic device (SensAble Technologies, Inc.). With the availability of a 3D model, customization of implants can be achieved using different design tools and patient data. The data used is dependent on the implant being designed and may include patient's gender, age, weight, and activity. Coupled with the natural bone design and the patient bone density, special formulas and certain designs can be selected to achieve near optimal fit. Traditional and nontraditional design criteria may be used in the shaping up the final design. Using the Haptic device, virtual waxing was undertaken on the virtual model assembled using the Freeform software (Geomagic, Wilmington, USA).

Once the design of the implant was agreed with the surgeon, the file of the implant, which is in an STL format, could then be sent to a selective laser melting machine to produce the implant in cp-Ti. The SLM implants were manufactured using an SLM Realizer 250 (MCP Tooling Technologies, UK). The machine employs an ytterbium fibre laser (200 W power CW, λ=1.071 μm with a nominal 50 μm laser beam diameter). An optical system was used to focus and control the movement of the laser beam over the build area to a positional accuracy of +/- 5 μm. The implant was built in a layer-wise fashion on a titanium substrate plate that is secured to an elevator plate that moves vertically downwards allowing controlled deposition of titanium powder at 50 μm intervals. The system operates in a positive pressure argon environment with processing chamber oxygen levels below 2%. Various stages of the process are shown in figure 2.

Once removed from the SLM machine, the supports were removed and areas not in contact with bone were polished (Figure 3). The fitting surface was sandblasted with 50 μm aluminium hydroxide. The implant was then washed under running water and transferred to a container of de-ionised water and ultrasonically cleaned to remove any surface debris. The implant was then dried in a jet of medical air. Finally it was packed in a sealed bag and autoclave sterilized ready for implantation.

Surgical procedure

The implant was presented to the patient and the surgical procedure was explained (Figure 4).

Restorative treatment

Three months after healing a new machined CAD/CAM crown was fitted to the transmucosal part of the implant (Figure 5a).

Final assessment

After 6 months the patient recalled and the status of the implant has been checked. Other assessments was carried out along the way up to eight years (Figure 5).

Discussion

For cleft palate patients where surgical intervention has been unsuccessful or wasn't an option the patient has to live with an obturator. This leaves the patient with a lifetime of problems arising from sinus infections as the obturator cannot provide a perfect seal against the migration of food into the sinuses. Added to this is the problem that such patients do not have a full dentition due the missing bone, The provision of a bridge to fill the gap brings its own problems as the teeth adjacent to the gap may well be perfectly sound as is the case for the patient presented in this study.

The treatment described above provides the patient with a solution to both these problems. The bony defect is permanently and hermetically filled such that there is no further risk of sinus infections and simultaneously the missing tooth is replaced without the need to prepare the adjacent teeth. A major concern with the use a metallic implant is the occurrence of a post-operative infection and this is even more of c concern when part of the implant is transmucosal. However, the concept of a transmucosal implant has been around in dentistry for well over 25 years and has proved to be highly successful when using cp-Ti. Thus it was felt that the idea of using this idea with a customized implant should not present any major problems. In order to be confident that the transmucosal implant as described in this clinical case study will not give rise to any adverse effects we purposely desisted from reporting on this case study until a reasonable time had elapsed. Given that we have seen no problems six years after the treatment was provided gives us great confidence that this approach to the treatment of cleft palate defects is a viable alternative to the use of obturators. It is gratifying that after all this time there are no signs of rejection of the implant and no signs of infection. The soft tissue around the transmucosal part of the implant is healthy and shows no sign of recession. This is a testament to the patient’s excellent oral hygiene that she has been able to maintain.
**Figure 1:** Pre-surgical presentation of the patient.

(a) CT scan data in Mimics software.

(b) The STL design of the implant as it presents in the 3D model of the bone.

(c) SLA model showing the defect in the maxilla.

**Figure 2:** Various stages in the production of the implant.
since the implant was placed six years ago. The provision of a customized implant has provided this patient with the optimum solution to her clinical problems.

Conclusions

Additive manufacturing has been used in order to produce a close fitting customized implant for a cleft palate patient. The implant was successful in both closing the defect and simultaneously providing a solution to the prosthetic problem.

References

Figure 5: (a) A close-up view of the final result six months after the surgery and placement of the crown (b) A close-up view of the final result eight years after the surgery and placement of the crown.


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