Toward Identifying Specification Requirements for Digital Bone-Anchored Prosthesis Design Incorporating Substructure Fabrication: A Pilot Study

Dominic Eggbeer, BSc (Hons)[a]/Richard Bibb, PhD[b]/Peter Evans, MIMPT[c]

Purpose: This paper is the first in a series that aims to identify the specification requirements for advanced digital technologies that may be used to design and fabricate complex, soft tissue facial prostheses. ***Materials and Methods:*** Following a review of previously reported techniques, appropriate and currently available technologies were selected and applied in a pilot study. This study uses a range of optical surface scanning, computerized tomography, computer-aided design, and rapid prototyping technologies to capture, design, and fabricate a bone-anchored auricular prosthesis, including the retentive components. The techniques are assessed in terms of their effectiveness, and the results are used to identify future research and specification requirements to direct developments. ***Results:*** The case study identifies that while digital technologies may be used to design implant-retained facial prostheses, many limitations need to be addressed to make the techniques clinically viable. It also identifies the need to develop a more robust specification that covers areas such as resolution, accuracy, materials, and design, against which potential technologies may be assessed. ***Conclusion:*** There is a need to develop a specification against which potential technologies may be assessed for their suitability in soft tissue facial prosthetics. The specification will be developed using further experimental research studies. *Int J Prosthodont 2006;19:258–263.*

Computer-aided design and rapid prototyping (CAD/RP) technologies have been utilized in maxillofacial surgery to produce physical models of patient anatomy for many years.[1–4] Recent technologic developments have increased awareness and encouraged their use in soft tissue facial prosthetics.[5–15] One study has compared digital and conventional methods directly,[15] but the majority have focused on transferring tools more commonly found in engineering and product design to prosthesis design and manufacture. This has been hindered by the lack of technologies dedicated to capturing, manipulating, and reproducing anatomic forms. Despite CAD technologies such as FreeForm (SensAble Technologies) providing a more intuitive solution to the manipulation of anatomic forms, many of the case studies reported to date have been relatively simple and have not considered substructure design for implant-retained prostheses. Issues surrounding the need for digital technologies, potential solutions, and their limitations are identified below.

[a]*Research Assistant, The National Centre for Product Design and Development Research, University of Wales Institute, Cardiff, United Kingdom.*
[b]*Head of Medical Applications, The National Centre for Product Design and Development Research, University of Wales Institute, Cardiff, United Kingdom.*
[c]*Chief Maxillofacial Prosthetist, Morriston Hospital, Swansea, United Kingdom.*

Correspondence to: *Dominic Eggbeer, The National Centre for Product Design and Development Research, University of Wales Institute, Western Avenue, Cardiff, CF5 2YB, United Kingdom. E-mail: Deggbeer-pdr@uwic.ac.uk*

Limitations and Characteristics of Conventional Methods

Prosthesis design and construction techniques have changed little in 40 years and are described well in textbooks[16,17] and papers.[18,19] By nature, prostheses are unique, patient-specific devices and require labor-intensive handcrafting techniques to produce. The over-

all construction process typically takes 2 to 4 days and involves a lot of waiting for the patient and intensive work for the prosthetist, who is restricted to completing the design with the patient present. In addition, the skills required to produce a realistic prosthesis take many years to develop and the end result is therefore typically reliant on the prosthetist's experience. However, conventional techniques have become well adapted to meeting the specific needs encountered with custom fabrication, and previous research has shown that new techniques should be sympathetic to this.[13–15]

Identification of Current Advanced Technologies

A review of previous research and current technologies highlights a range of techniques that may be suitable for this application:

- Noncontact surface scanning to digitize the skin topography. For example: structured white light, laser, or photogrammetry.
- CAD software. For example: FreeForm, Magics (Materialise), or Rhinoceros (Robert McNeel & Associates).
- Rapid prototyping to produce the components. For example: ThermoJet wax printing (3D-Systems), selective laser melting (SLM), stereolithography (3D-Systems), Perfactory (EnvisionTec).
- Computer numeric controlled (CNC) machining to produce bar components.

The use of each of these technologies has already been reported in the design and fabrication of specific patient devices.[6–15]

Identification of Potential Challenges

Past research has identified limitations of current technologies and challenges that must be considered at each stage of the construction process, including:

Capturing the anatomy and abutment locations. Research has highlighted limitations of noncontact scanning techniques when capturing areas of hair, undercuts, or when the subject moves.[7–10] Insufficient data resolution and errors in the form of "noise" may also limit the ability of scanning technologies to capture sharp edges, pointed geometry, and small flat surfaces.[20] This makes it particularly challenging to accurately record facial topography and abutments.

Aligning and designing prosthesis components. Typical engineering CAD software handles geometric shapes. Alignment tools that enable components to be accurately positioned in relation to one another are a common feature in engineering CAD, but they are not suitable for aligning or representing anatomic forms and do not provide the physical tactile feedback to which prosthetists are accustomed.[13,14] Computer-aided design software such as FreeForm allows the manipulation of complex anatomic forms and provides tactile feedback but does not provide alignment tools and is less able to represent geometric shapes. Therefore, component alignment may require further software tools.

Producing the components in suitable materials. Material requirements for maxillofacial prostheses are varied. Currently no technology is capable of building the final prosthesis form directly from CAD in a suitable color-matched material. Therefore, a pattern must be produced instead. Research has shown that producing the pattern in a material compatible with conventional sculpting techniques allows for adjustment during test fitting on the patient.[13–15] Retentive components should be noncorrosive and unreactive with each other, resist the effects of conventional processing such as mold heating, provide adequate wear resistance to repeated use, resist permanent distortion during everyday use, and provide adequate retention for the prosthesis.

Technology specification. There is currently no specification that identifies the performance and economic and clinical requirements of digital technologies for facial prosthesis production. A conclusive, clearly defined specification is required to direct the development of these technologies to meet the needs of the prosthesis provider and health care system.

Research Objectives

Issues discussed in the introduction highlight the need to explore the application of digital technologies in implant-retained facial prosthesis design and to develop a specification against which technologies may be assessed. Therefore, this research aims to identify the degree to which current digital technologies are capable of assisting in the design of an implant-retained auricular prosthesis. The results of this research will then contribute to the development of a target specification against which future technologies may be assessed.

Materials and Methods

Study 1: Direct Patient Scanning

An implant-retained auricular prosthesis that required a bar and clip retention method was selected. A single-stage operation to place 2 Brånemark (Nobel Biocare) 4-mm implants and 3-mm abutments had been undertaken and a healing period of 6 weeks allowed before commencing prosthetic construction.

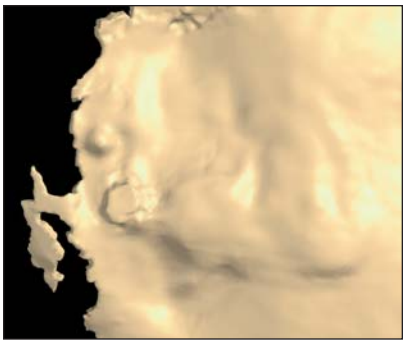


Fig 1 The abutments and surrounding tissue, as captured by the Konica-Minolta scanners.

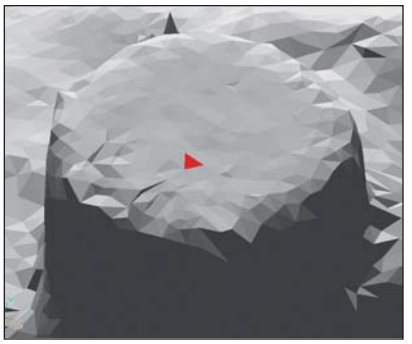


Fig 2 A triangle was selected on the abutment cap surface (also illustrating the unevenness of the surface).

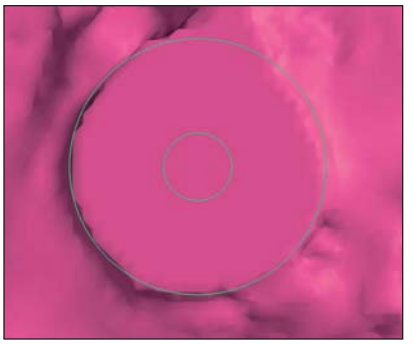


Fig 3 The center of the abutments located in FreeForm.

Paired Konica-Minolta Vivid 900i laser surface scanners (Konica-Minolta) with a 14-mm lens were used to scan the patient. Surface data of the subject are represented as a cloud of points with a higher density, resulting in more detailed information of the surface. The patient was seated 1.35 m from the lenses and an area of 445 × 333 mm was captured, resulting in a point density of 1 point per 0.69 mm^2. This technology was chosen because of relatively fast capture times and good accuracy identified in previous research.[21,22] Research by Kau et al[21,22] has shown that although the specified capture time is 0.6 seconds, the functional capture time per camera is around 2.5 seconds, including a short pause between each scan, which meant that the patient had to remain still for approximately 8 seconds. The point-cloud data was aligned and converted to an STL (stereolithography) file using Rapidform software (INUS Technology) and imported to the sculpting CAD package, FreeForm, using the "thickness" option to make a solid model.

At this point, it was clear that the abutments were not defined with sufficient resolution to design the retentive components of the prosthesis (Fig 1). The data were, however, sufficient to identify abutment locations, which allowed the overall prosthesis form to be designed. The healthy ear from the CT data was mirrored to the prosthesis site, blended into the anatomy, and subtracted to leave an accurate fitting surface. This technique has been reported in the design of orbital and auricular prostheses.[3–15]

The prosthesis pattern design was produced directly from the CAD data in a wax material using ThermoJet printing. The wax pattern was adapted by hand to include the retentive components made using conventional methods. A silicone prosthesis for the patient was then fabricated from this pattern using conventional methods.

Study 1 Results

Study 1 highlighted the limitations of noncontact scanning to capture anatomy and abutment details with sufficient resolution. An alternative method using a higher-resolution scanner was required to capture abutment details.

Study 2: Cast Replica Scanning

An impression and dental stone model were made using methods adapted from those described by McKinstry.[17] Implant replicas were used to record the abutment locations. A more accurate and higher-resolution Steinbichler Comet structured white light scanner (Steinbichler Optotechnik) was used to digitize the replica. Sykes et al[15] have discussed a similar method. This scanner captures approximately 9 points per mm^2 (3 mm in the x, y plane) and around 140,000 points per scan. The area captured is approximately 435 × 350 mm with a working range of approximately 450 mm. Magnetic keepers (Technovent) were screwed onto the abutments to provide a simple flat surface and the model was coated in a fine matte white powder to reduce reflectivity. Six overlapping scans were taken and the data aligned using Polyworks software (InnovMetric Software). The point-cloud data was converted to the STL file format using Spider (Alias/Wavefront) and the data imported into Magics. Alignment, sectioning, and cut tools in Magics were used to remove each cap to leave a perfectly flat surface representing the abutments. Figure 2 shows the abutment cap before removal with 1 triangle selected. The data were re-saved as an STL file and imported into FreeForm. The circular profile and flat surfaces of the abutments were much clearer, allowing the location of the center screw holes to be identified (Fig 3).

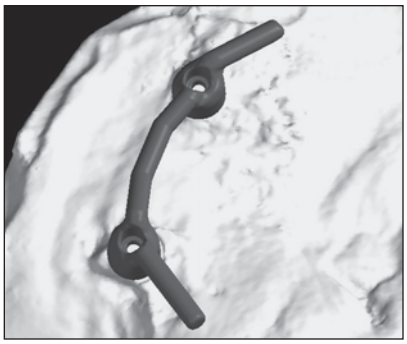


Fig 4 The completed bar design in FreeForm.

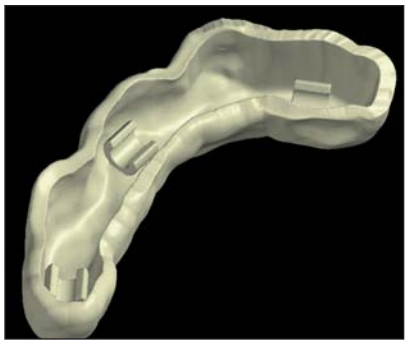


Fig 5 The substructure shell in FreeForm.

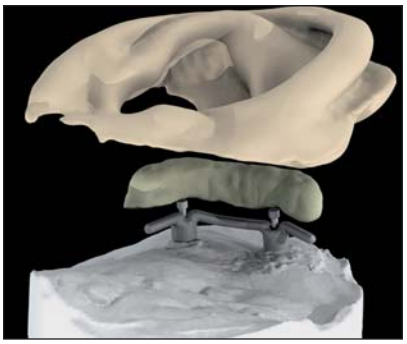
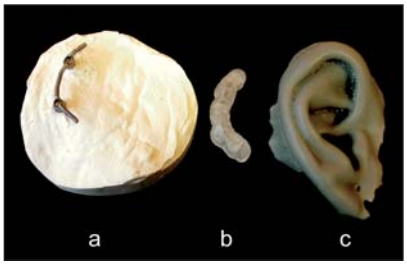


Fig 6 A computer-generated image of the components in FreeForm.



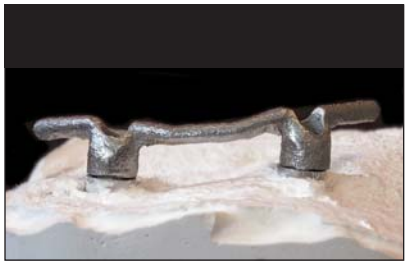


Fig 7 *(left)* The individual components: SLM bar (a), stereolithography substructure (b), ThermoJet pattern (c).

Fig 8 *(right)* Fit of the bar before finishing.

Component design. The ear profile from the CT data was manually aligned to the digital cast based upon the estimated esthetic requirements and possible substructure location. FreeForm was used to create digital versions of the screws used to attach frameworks to the abutments and cylinder components and a circular-section framework linking the 2 cylinders. "Smoothing" tools were used to blend the cylinders into the frame. Hemispheric dimples were created where cylinders were located on the abutments, and holes were created for the screws (Fig 4).

Clip designs were created, copied 3 times, and located along the bar structure. A substructure shell that would be bonded to the silicone was required to secure the clips into the prosthesis body and to assist application. This had to provide enough clearance for the clips to spring open and closed, as well as firm anchorage for bonding to the silicone. A 1.5-mm-thick shell covering the clips and bar was created and joined to the top points of the clips, leaving space for them to open and close (Fig 5).

The prosthesis profile was modified slightly to accommodate the shell component and a Boolean subtraction operation was used to create a fitting recess for the shell.

Figure 6 shows a computer-generated image of the components in the FreeForm environment. Components were then exported as high-quality STL files ready for RP fabrication.

Fabrication. The bar component was built with 316L stainless steel using SLM, in 0.05-mm-thick layers. SLM is a relatively new technology that produces solid metal parts in a layer-by-layer method directly from CAD data.[23] Once completed, the support structures were removed using a high-speed cutting disk. The component then received grit blasting and polishing to achieve a visibly smooth surface.

The shell component was built using stereolithography in 0.1-mm layers in DSM Somos 10110 epoxy resin. Stereolithography is a well-established RP process and is capable of producing extremely fine detail in resin materials.[1–4] ThermoJet wax printing was used to produce the prosthesis pattern. The physical components are shown in Fig 7.

Study 2: Results

Although the finished components were not used in a definitive prosthesis, it was possible to assess the performance of the components on the dental stone model. The bar did screw onto the abutment, but it did not sit correctly (Fig 8).

The surface finish was relatively rough compared to conventionally produced gold bars, but this may be

attributed to the machine parameters, which may be improved with more experimentation. Grit blasting and polishing produced an acceptable result, but some pitting was noted. The shell and clip components did clip onto the bar, but repeated application caused wear that weakened the retention strength. This would be unacceptable for prosthesis retention. Fit between the ThermoJet pattern and shell structure was tight, but very small undercuts prevented the shell from slotting straight into the recess without minor modifications. The fragile nature of the ThermoJet wax would have prevented the edges from being made any thinner. Conventional sculpting techniques would be required to achieve the necessary edge thickness to blend into the surrounding skin.

Discussion

While this study has demonstrated potential, it has also highlighted many limitations that would currently prevent the technologies identified from being clinically and commercially viable. These limitations include:

- The difficulty of directly scanning patients with sufficient resolution to describe abutment details while also overcoming issues that cause poor data capture
- Limitations in computer software that result in an inefficient process to align, manipulate, and design components
- The inability to produce components directly in materials with sufficient mechanical and esthetic properties
- The difficulty in predicting and accounting for the mechanical behavior of components designed in CAD

The difference in results between scanning the patient directly using the Minolta scanners and scanning the cast using the Steinbichler highlights the limitations of optical scanning technologies. While the Minolta offered sufficient speed to scan the patient directly, the resolution was insufficient to describe abutment details. The Steinbichler was capable of capturing the keeper surfaces, but noise in the data meant that flat surfaces were visibly uneven in the CAD software, and sharp edge details were generally rounded (Fig 2). It may also be argued that directly scanning patients is a more efficient method that eliminates the need to make an impression.

The efficiency of the design and manipulation stages was compromised by the need to use multiple software packages. Component alignment was particularly difficult. From the research conducted to date it appears that an ideal solution that allows accurate component alignment and manipulation for prosthesis design does not yet exist. This will likely become a more significant problem in larger facial prosthesis cases.

The conventional Dolder bar and gold clip design allows for adjustable retention strength according to patient requirements, but while the clips produced in this study did function (albeit for a limited period), the retention strength could not be predicted at the design stage or adjusted postproduction. The choice of clip and substructure material should also be refined to improve the durability and wear resistance. Although the techniques for prosthesis retention are well established, very little research has been undertaken to identify the ranges of required retention strength for individual patient needs. Once this has been identified, a specification level against which digital methods may be assessed can be developed.

Galvanic corrosion between the stainless steel bar produced by SLM and the titanium abutments should not be an issue (the anodic index is within 0.2 V), but if required, SLM is able to produce components in a range of metals and alloys including commercially pure titanium.

Conclusions

This and previous studies have shown that while the technologies exist to enable full digital design and production of soft tissue facial prostheses, they are often not ideally suited to the application. There is a need for future research to define the specifications required for digital technologies and to refine the techniques before they can be applied appropriately in a clinical environment. Development is required in the following areas:

- Scanning technologies that are capable of capturing patients directly with a speed < 0.6 seconds to avoid noise caused by movement and with a resolution of at least 9 points per mm^2 (preferably higher) to capture features with a diameter of 4 mm accurately. Ideally, scanners should be capable of capturing abutment details without the need to coat in a matte finish or to remove detail using flat keepers.
- Software that provides alignment and design tools in an intuitive single solution for prosthetists.
- A specification for prosthetic material requirements and the development of RP materials and technologies that meet this specification.

In future studies, the authors intend to identify more appropriate methods with the aim to develop a specification against which digital technologies may be assessed.

Acknowledgment

The authors would like to thank Frank Hartles, Head of the Dental Illustration Unit, Media Resources Centre, Wales College of Medicine, Biology, Life and Health Sciences, Cardiff University, for use of the Konica-Minolta scanners.

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Literature Abstract

Incision design in implant dentistry based on vascularization of the mucosa

The delivery of an adequate amount of blood to the tissue capillaries for normal functioning of the organ is the primary purpose of the vascular system. Preserving the viability of the soft tissue segment depends on the soft tissue incision being properly designed in order to prevent impairment of the circulation. A knowledge of the course of the vessels as well as of their supply area are crucial to the decision of the incision. The aim of this study was to visualize the course of the arteries using different techniques, to perform macroscopic and microscopic analyses, and to develop recommendations for incisions in implant dentistry. The vascular systems of 7 edentulous human cadavers were flushed out and filled with either red-colored rubber bond or Indian ink and formalin mixture. After fixation a macroscopic preparation was performed to reveal the course, distribution and supply area of the major vessels. In the area of the edentulous alveolar ridge specimens of the mucosa were taken and analyzed microscopically. The analyses revealed the major features of mucosal vascularization. The main course of the supplying arteries is from posterior to anterior, main vessels run parallel to the alveolar ridge in the vestibulum and the crestal area of the edentulous alveolar ridge is covered by an avascular zone with no anastomoses crossing the alveolar ridge. The results suggest midline incisions on the alveolar ridge, marginal incisions in dentated areas, releasing incisions only at the anterior border of the entire incision line, and avoidance of incisions crossing the alveolar ridge.

Kleinheinz J, Büchter A, Kruse-Lösler B, Weingart D, Joos U. *Clin Oral Implants Res* 2005;16:518–523. **References:** 28. **Reprints:** Dr Johannes Kleinheinz, Department of Cranio-Maxillofacial Surgery, University of Münster, Waldeyestraße 30, d-48129, Münster, Germany. Fax: +49 251 834 7020. E-mail: Buchtea@uni-muentser.de—*Tee-Khin Neo, Singapore*