Designing and manufacturing an auricular prosthesis using computed tomography, 3-dimensional photographic imaging, and additive manufacturing: A clinical report

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The method of fabricating an auricular prosthesis by digitally positioning a mirror image of the soft tissue, then designing and using rapid prototyping to produce the mold, can reduce the steps and time needed to create a prosthesis by the traditional approach of sculpting either wax or clay. The purpose of this clinical report is to illustrate how the use of 3-dimensional (3-D) photography, computer technology, and additive manufacturing can extensively reduce many of the preliminary procedures currently used to create an auricular prosthesis. (J Prosthet Dent 2011;105:78-82)

Traditionally, the fabrication of an auricular prosthesis is a complicated task involving multiple procedures. Several of these procedures are time consuming and require the patient to be present for an extended period. The process of creating an auricular prosthesis involves: (1) making impressions to duplicate the affected area and replicate the unaffected side, if applicable; (2) creating a clay or wax sculpture of the future prosthesis; (3) producing a 3-piece fabrication mold of the sculpture; and (4) fabricating and hand painting the prosthesis. With 3-D photography, computer technology, and additive manufacturing/rapid prototyping (RP), the first 3 procedures in the conventional process can be extensively shortened. Prosthesis fabrication and insertion that would usually require a week can now be accomplished in 1 to 2 days.

Three-dimensional scanning, computer-aided design/computer-aided manufacturing (CAD/CAM), and RP mold fabrication have been described.[1-9] None of these studies, however, have incorporated the use of 3-D photography systems. Moreover, many of these investigations demonstrated computerization of prostheses and digital reconstructions of the opposing ears, but extensive laboratory work was still required after placement.[1,2,6,10] Computerized tomography (CT) scans have been used to mirror the contralateral, unaffected ear and offer significant benefits in the production of a cast for the affected ear. CT scans, however, are expensive and may needlessly expose the patient to radiation.[4,11] Other forms of 3-D surface renderings, such as laser scanners, have also been used to obtain 3-D representations of the ear,[2,3,8,9] but surface scanning can require the patient to remain still for several minutes, a challenge that can result in incomplete data gathering.

Additive manufacture/rapid prototyping is a relatively new tool and has recently been used in the production of molds for facial prostheses.[11] Furthermore, 3-D digital technology along with additive manufacturing technology can be a substitute for the more traditional custom sculpture technique with wax or clay currently used by trained technicians. The conventional process is time consuming and can take several days to weeks to complete. Unlike the physical model produced from the more traditional prosthetic fabrication techniques, a digital replacement of the missing structure using a mirror image of the contralateral, unaffected side or the anatomy from another individual can be positioned, a corresponding mold created, and the prosthesis manufactured in a matter of hours. The purpose of this clinical report is to illustrate how the use of 3-D photography, computer technology, and additive manufacturing can simplify many of the preliminary procedures currently used to create an auricular prosthesis.

CLINICAL REPORT

A 30-year-old white man presented with basal cell carcinoma. As

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1 3DMD acquisition system consisting of 5 synchronized cameras/projectors used to digitally reconstruct patient's facial soft tissue.

a result of surgical resection, the patient lost his right ear and a section of the mastoid process. Typically, the initial step in manufacturing a digital 3-D representation of a missing ear is to make a CT scan of the contralateral, unaffected ear. When the patient is missing both ears, another individual's ear can be used for the initial design and then scaled and morphed appropriately. In this patient's situation, there was a preexisting CT scan due to a bone grafting procedure to replace the missing section of the mastoid process. Therefore, additional radiation exposure from a second CT scan was deemed unnecessary. The CT scans were made using a soft tissue algorithm and 1.25- or 0.625-mm-thick slices. Digital imaging and communications in medicine (DICOM) images were imported, and 3-D reconstruction of the soft tissue was accomplished using software (MIMICSx64, v. 13.1; Materialise NV, Leuven, Belgium). After processing the CT scan, a mirror image of the ear was generated and a stereolithography (STL) file was exported.

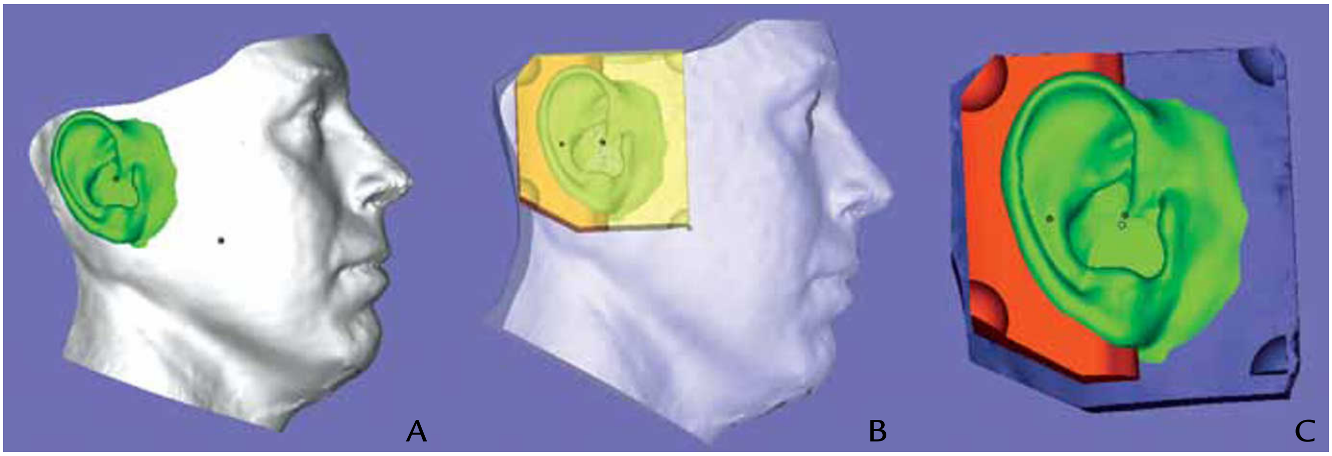
The external tissue contours of the patient's defect were captured using 3-D photography/imaging (3dMDcranial System; 3dMD, Atlanta, Ga) (Fig. 1). This noninvasive imaging system obtains surface data of the soft tissue with accuracy, purported by the manufacturer to be better than 0.2 mm in a 2-ms window. The system consists of multiple synchronized cameras and projectors, which mathematically reproduce the facial shape. After the patient's data was obtained using the 3dMDcranial System, an STL file of the patient's face was exported. The facial surface STL file of the soft tissue anatomy was imported into the software program (Magicsx64 v13.02; Materialise NV) and thickened to provide bulk for the mold fabrication.

The previously obtained STL file of the missing ear was then positioned on the STL file of the face. Measurements were made from soft tissue landmarks on the ear to the face to obtain an approximate idea of the ear's position and orientation. Ultimate positioning of the prosthesis was still user defined based on facial esthetics. The image was saved as an STL file and imported into a haptic modeling system (Freeform Modeling Plus; SensAble Technologies, Woburn, Mass), which was used to push/pull the soft tissue borders of the surrounding ear tissue into the soft tissue contours of the patient's existing soft tissue on the affected side. This generated a smooth transition between the patient's soft tissue contours and the digital prosthesis.

After the ear was properly positioned and the soft tissue contours were deemed to be appropriate, the digital mold was designed. The digital mold was made by exporting the new ear STL file from the haptic modeling system (Freeform Modeling Plus; SensAble Technologies) and importing the STL file back into the software program (Magicsx64 v13.02; Materialise NV) (Fig. 2). A Boolean operation was then performed, subtracting any overlap between the soft tissue contours of the patient's face and the digital prosthetic ear. In essence, the Boolean operation removes the extra sections of the ear that were previously occupied by the patient's soft tissue, thus creating a perfect match to the patient's face. Next, a box was placed over the digital ear and the corresponding surface of the patient's face. Several Boolean operations were then performed to obtain a 2-piece mold with the patient's soft tissue contours as the base mold and the negative of the future prosthetic ear as the other part of the mold. The final step in the initial mold design was to cut the piece of the mold containing the negative of the ear into 2 separate pieces along the outside edge of the ear lobe, perpendicular to the computer screen.

Registration elements enabled the pieces of the mold to articulate with each other and helped to maintain proper positioning during the fabrication of the prosthesis. This interface was developed by first digitally placing spheres along the edges of the mold and then using Boolean operations to subtract or add portions of the spheres to the corresponding pieces, thereby creating the proper mold interface.

The ear mold was then manufactured on a 3-D printer (ZPrinter 450, using zp130 Powder and zb59 Binder; Z Corp, Burlington, Mass), which manufactured the mold in a layer-by-layer process in 0.102-mm increments. During the printing process, each section was maintained in the same orientation to ensure the mold layers articulated well with one another. Once the 3-D printer completed the mold, it was depowdered and allowed to dry thoroughly before infiltration with cyanoacrylate



2 A, Digital representation of face and prosthesis. B, Two pieces of digital mold over ear and soft tissue. C, Middle section of auricular mold aids in removal of definitive silicone prosthesis.

3 Three-piece auricular mold digitally designed and then manufactured on ZPrinter 450.

4 A, Preprosthetic clinical presentation. B and C, Definitive placement of prosthesis.

(Z-Bond 90, Z Corp, Burlington, Mass) and placement on wax paper. The mold was again allowed to dry while rotating every few minutes to prevent adhesion to the wax paper. Once completely dry, the mold was ready for use (Fig. 3).

The method used for fabrication of the prosthesis by the dental laboratory technician was similar to the traditional stone cast method. The mold was prepared by applying 2 coats of separator (Acrylic and Plaster Separator; Dental Ventures of America, Inc, Corona, Calif) to both the cope and the drag. The patient was evaluated for skin tones and color by the maxillofacial laboratory technologist. Intrinsic colorants (Functional Intrinsic Skin Colors; Factor II, Inc, Lakeside, Ariz) were added to silicone (Platinum Silicone Elastomer (A-2000); Factor II, Inc) for the base shade. Additional colorants were mixed to small amounts of the base shade to establish a variety of intrinsic staining colorants. Intrinsic colorants were applied, as appropriate, to the mold, and then the mold was filled with the base shaded silicone. The cope and the drag margins were approximated to the indices, and the mold was closed and placed in a 100°C heated vise (Carver Heater Press; Carver, Inc, Wabash, Ind), at 1000 psi for 15 minutes to polymerize. When the resultant prosthetic ear was fully polymerized, it was easily removed from the mold, trimmed, and readied for extrinsic enhancement and insertion (Fig. 4).

DISCUSSION

Computer tomography is often used to capture images for 3-D medical modeling techniques. In the present clinical report, the 3dMDcranial System (3dMDcranial System; 3dMD) allowed not only capture of the area of interest, but eliminated the need for the patient to undergo any radiation exposure. In addition, unlike the CT scan, an STL file is available directly from the 3dMD reconstruction. One disadvantage is that there can be a loss of undercut areas if certain areas cannot be directly recorded by the lenses. However, this disadvantage can be reduced and eliminated by optimally positioning the patient and using digital manipulation of the STL file to create any additional undercuts present on the ear that were not incorporated into the computational file from the 3-D photography system. This approach, without the use of a CT scan, was slightly more complicated, but can produce the complex undercuts present in a human ear. A less complicated prosthesis, such as a prosthetic nose, can be easily created using the process described in the present report.

A single software package does not provide all of the needed tools for the computational manipulation of the STL file and creation of the digital mold; therefore, the 3-D files are imported and exported through 2 or more software packages to produce an end product. This may result in some information degradation if the import and export resolutions/accuracies are not set appropriately in the different software packages.

Laboratory technicians prefer a 3-part mold for the fabrication of an auricular prosthesis due to the ease of recovery, the position of the seams, and ease in placement of a retentive device. The creation of these seams computationally was noted to be complicated and took several attempts. Often, maxillofacial laboratory technologists can customize textures on the prosthetic surface using different techniques. In contrast, one has little influence over the texture from the mold manufactured by the printer. However, it was noted by the technologist that the prosthetic surface was easy to work with and could be made to appear realistic, due to the slightly grainy and finely layered surface of the mold mimicking the natural texture of human skin.

The molds were finished with a cyanoacrylate sealer that infiltrates through capillary action, but the sealer does not achieve full penetration. Although the mold appears to stand up to the pressure and heat of the press, it tends to fracture after a couple of uses. There are, however, processes that can achieve full infiltration/penetration of printer materials, which may reduce the amount of mold deterioration over time or after repeated use. This technique allows for digital storage of molds and prosthetic designs; accordingly, new molds can easily be fabricated if the initial mold was damaged during the manufacturing process, lost, or destroyed. One advantage of the RP-produced molds is that they are devoid of the color often found in many of the traditional dental stones; these colored molds have been known to contaminate prostheses.

Currently, expense and technical skills are the deciding factors in the use of many of the newly developed technologies, such as 3-D photography, computational software, and RP machinery.[5,10] To purchase the equipment used to fabricate the prosthesis described in this clinical report would cost approximately $200K USD. Furthermore, many prostheses may have to be produced over the patient's lifetime to compensate for soft tissue changes and wear of the prosthesis. In addition, alterations can likely be performed to fabricate an implant-retained facial prosthesis. This modification would require multiple 3-D images after the implants are placed and the acrylic resin substructure is manufactured.

Future endeavors are underway to make these techniques and technologies available to the single provider or group practice. The only equipment necessary is the 3-D photography system. Once the images are captured, the digital files can then be transferred to another institution or a service facility to design, manufacture the mold, and ship the end product, which could occur within a couple of days.

The patient featured in this clinical report has been wearing his auricular prosthesis for more than a year and is currently in the process of scheduling surgery for implants. He has not reported any problems associated with the fabrication technique. To date, the authors have used the described methods to digitally create and produce 2 auricular prostheses and 2 nasal prostheses, with a high level of patient satisfaction.

SUMMARY

A technique for the fabrication of an auricular prosthesis was described using 3-D digital imaging/photography, design software, and additive manufacturing. The prosthesis was fabricated using a rapid prototype mold in conjunction with traditional techniques, including intrinsic staining and layering of silicone. The prosthesis was designed, manufactured, and provided to the patient within 2 days, a significantly shorter period than can be achieved by methods that require the creation of a diagnostic wax or clay pattern. Using the techniques described in this clinical report for prosthesis fabrication, contours were achieved for the auricular prosthesis that corresponded well to the soft tissue geometry of the patient's face.

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NOTEWORTHY ABSTRACTS OF THE CURRENT LITERATURE

Surface characterization of zirconia dental implants

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Dent Mater 2010;26:295-305.

Objectives. The aim of the study was to characterize the chemical composition, microstructure and roughness of two commercially available zirconia dental implants (WhiteSky and Zit-Z).

Methods. The chemical composition of the cervical collar and threaded root parts of the implants (n = 2) were studied by XPS and HV-EDX. LV-SEM was used for morphological assessment, Raman microanalysis for microstructural characterization and optical profilometry for surface roughness measurements. XRD, HV-EDX and Raman microanalysis of bulk regions (longitudinal sections) were used as reference.

Results. XPS showed the presence of C, O, Zr and Y (collar) plus Al (root) at implant surfaces. More C (10−26 at%) and a lower Al/Zr ratio were found in WhiteSky (1.05 vs 1.26 in Zit-Z). Zr, Y and Al were detected in single, fully oxidized states. The same elements, plus Hf, were identified by HV-EDX at bulk and surface regions, with a Al/Zr ratio higher in WhiteSky (0.17 vs 0.09 in Zit-Z). Na, K and Cl contaminants were traced at implant root parts by both methods. XRD analysis of cross-sectioned specimens revealed the presence of monoclinic and tetragonal zirconia along with cubic yttria phases. Raman microanalysis showed that the monoclinic zirconia volume fraction was higher at root surfaces than the collar. No monoclinic phase was found at bulk regions. Significantly higher Sa and Sq values were recorded in WhiteSky than Zit-Z, whereas Zit-Z showed higher Rt value.

Significance. The differences found between the implants in the extent of carbon contamination, residual alumina content, tetragonal to monoclinic ZrO2 phase transformation and 3D-roughness parameters may contribute to a substantial differentiation in the cellular and tissue response.