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Technical Note
Craniofacial Implants

Computer-aided design and manufacturing construction of a pilot guide for a bone-anchored epithesis to replace an absent pinna

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Abstract. Bone-anchored epitheses have acquired an important role in auricle reconstruction. The purpose of this technical note is to present a fully in-house digital workflow for the design and three-dimensional (3D) printing of an optimal ear epithesis guide. Two hemifacial microsomia patients with grade IV microtia were treated accordingly. The upper dental arch was optically scanned and a cone beam computed tomography scan of the cranium was obtained. The composite and soft tissue models created were exported into 3D sculpting software. The unaffected ear was virtually mirrored onto the affected side and two ideal implant positions were defined in relation to bone thickness, contralateral symmetry, and housing of the retaining bar. A bite wafer was virtually designed on the upper dental arch and connected to the mirrored ear. The pilot guide was 3D-printed and allowed for correct positioning and orientation during surgery. The prosthetic pinna was manufactured in a conventional way. A bar with retaining clips was used to anchor the prosthetic pinna. Clinically satisfactory results were obtained in two grade IV microtia cases. The fully digital workflow presented to design and 3D-print an optimal ear epithesis guide offers a good alternative to the existing techniques.

Key words: ear auricle; reconstructive surgery; CAD/CAM; temporal bone; Congenital microtia.

Accepted for publication

Bone-anchored prosthetic devices have acquired an important role in the rehabilitation of craniofacial defects[1], particularly for auricle reconstruction. Temporal bone quality and thickness are critical for osseointegration of the fixtures. Ipsilateral anatomical landmarks can be used as a guide for the future position of the ear epithesis, but they give little information about the underlying bone and can be distorted in congenital malformations.

Many techniques have been described for the orientation of a surgical template, but most of them are convoluted and none

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of them uses a fully digital workflow[2–4]. This article describes a digital workflow for computer-aided design and manufacturing (CAD/CAM) of a diagnostic and surgical template.

Technique

Materials

A Trios three-dimensional (3D) scanner (3Shape, Copenhagen, Denmark) was used to optically scan the upper dental arch. A cone beam computed tomography (CBCT) scan of the cranium was obtained and the DICOM (digital imaging and communications in medicine) dataset was uploaded into ProPlan CMF software (Materialise, Leuven, Belgium). The hard tissues were segmented and fused with the dataset of the upper dental arch (Fig. 1) to create a composite model. This allowed for a detailed reproduction of the occlusal surfaces within the bony cranium. The temporal bone thickness was measured and the craniofacial soft tissues were segmented.

The composite model and the soft tissue model were exported as stereolithography (STL) files and imported into 3D sculpting software Geomagic Sculpt (3D Systems, Rock Hill, SC, USA). The unaffected ear was virtually mirrored onto the affected side and checked for symmetry (Fig. 2), thereby eliminating the need to make an impression of the defective side, trial waxing, and indirect fabrication of a stone mould[5]. Once the healthy ear had been virtually mirrored and positioned on the defective side, two ideal positions and orientations for the placement of the fixtures were defined to fit within the volume of the mirrored virtual ear and taking into account the previously measured bone thickness. Two identical hollow cylinders were positioned in relation to the virtually defined implant positions and orientations. A bite wafer was virtually designed on the upper dental arch and connected to the mirrored ear and the guiding cylinders with a rigid extension. Care was taken for the extension not to interfere with the soft tissues (Fig. 3).

The guide was 3D-printed using a Replicator 3D printer (MakerBot Industries, Brooklyn, NY, USA) and checked for its proper fit on the patient prior to surgery (Fig. 4).

The pilot guide allowed for correct positioning and orientation during surgery, following the conventional protocol for the insertion of craniofacial implants. After osseointegration, the silicone prosthetic pinna was manufactured in a conventional manner (Centre for Craniofacial Epithetics, Zaventem, Belgium). A bar with retaining clips was used to anchor the prosthetic pinna.

Fig. 1. The segmented bony skull fused with the optic scan of the upper dental arch.

Patients

Two hemifacial microsomia patients with grade IV microtia were treated using this

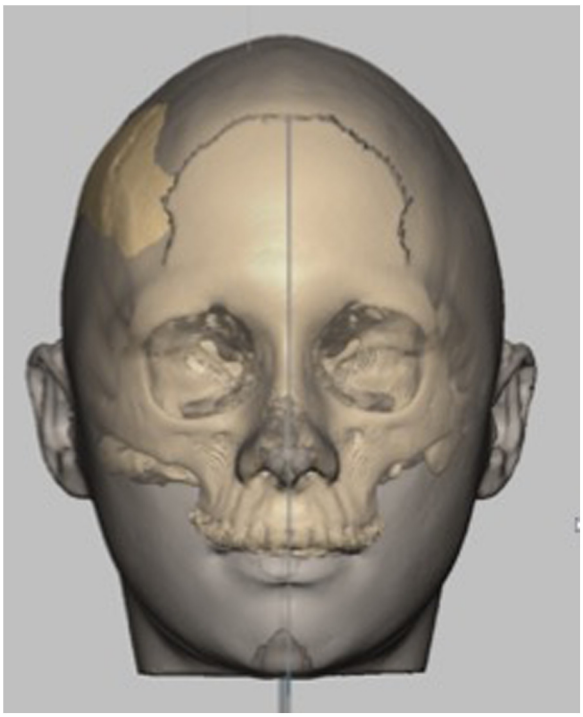

Fig. 2. Virtual mirroring of the unaffected side onto the affected side to check for symmetry.

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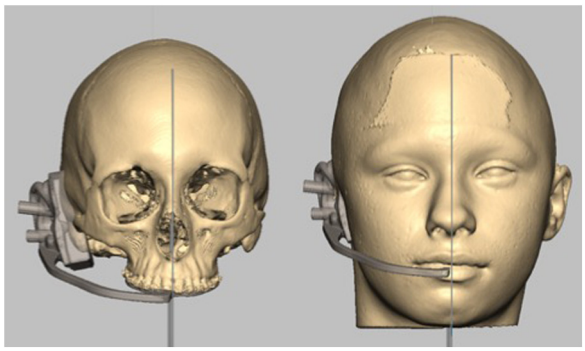

Fig. 3. Checking for interferences between the guide and the virtual soft tissue model.

Fig. 4. Proper fit of the guide on the patient prior to surgery.

technique (Fig. 5). Informed consent was obtained from the individual participants included in the study. Additional informed consent was obtained from the individual participant for whom identifying information is included in this article.

Discussion

Pinna epitheses can be attached securely onto titanium fixtures or grouped implants[6,7]. One- and two-stage implant placements are used[8]. Complications are observed in 10–15% of cases[9]. Implant failure, skin infection around the fixture, and the formation of granulation tissue can occur. In the two patients treated with the technique presented here, one failing implant had to be replaced because of failed osseointegration. The technique is contraindicated in patients under 14 years of age, whose temporal bone thickness is not sufficient to support the implants[9]. Preoperative evaluation of bone thickness on computed tomography (CT) or CBCT scans should also be a mandatory part of the surgical planning in adults.

The exact position of the fixtures in relation to the symmetrical positioning of the pinna epithesis, its thicker part to include the patrix–matrix system, and the bone thickness needs a reliable guide. Many techniques have been proposed for proper orientation of such a guide. In 1997, Reisberg and Habakuk were the first to report the use of a positioner (surgical template) to guide implant placement[10]. They used a cast of the facial deformity and the contralateral ear to produce a positioner in clear autopolymerizing acrylic resin after manual positioning of a wax prototype on the patient to verify shape, size, and orientation. This method is prone to error due to the accumulation of multiple single-step errors and does not allow for evaluation of the underlying bone. Furthermore, the transfer to surgery is inaccurate since no reproducible anatomical reference is used for guide positioning.

Asher et al. used a similar method but advised placing the template prior to surgery and marking its correct position with an indelible surgical marker in case of a lack of observable surface anatomy[3]. They also advised preoperative CT scans to assess bone thickness, as well as the proximity of mastoid air cells, the dura, and the sigmoid sinus. Wang added duplication of the diagnostic wax ear to fabricate the surgical template, reducing the sculpting time for the final auricular prosthesis[11]. Alfano et al. were the first to use the maxillary arch as a fixed reference for proper placement and positioning of the surgical guide and to include radiographic evaluation of the underlying bone by placing gutta-percha over the planned implant placement locations[12]. The guide, however, only indicates the location and not the inclination of the implant. Furthermore, the connection between the splint and the surgical guide is realized manually and is consequently prone to error, as is positioning of the diagnostic ear. Ciocca et al. introduced optical scanning of the unaffected side to create a mirrored volume of the healthy ear, which was rapidly prototyped (3D-printed) for a clinical trial in and consequently transformed into a surgical template[2]. They used a positioning arm extending to the eye commissure to stabilize the position of the guide, which is less stable and reproducible in our opinion.

Ozçelik and Tanner used an alternative procedure for fabrication of an acrylic resin surgical template by using a 6-inch

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Fig. 5. Treatment of a grade IV microtia patient. Clinical pictures taken before fitting of the guide (a, d), upon fitting of the guide (b, e), and after surgery (c, f).

contour duplication gauge[13]. This fully analogue procedure is cumbersome and of no added value in an era of 3D innovation and virtual planning. Charkawi and Sharkawy presented a very simple yet effective technique including drawing of the intact ear on a transparent celluloid paper or radiographic film, flipping it to the opposite side and relating it to the fixed anatomical features on the face of the patient[4]. The latter is a very helpful alternative if no 3D planning software is available.

In the fully digital protocol described herein, the advantages of some of the techniques mentioned above are combined. Fabrication of the clinical trial in (soft tissue 3D model; Fig. 2), the diagnostic template (hard tissue 3D model; Fig. 1), and surgical template (combined soft- and hard-tissue 3D model; Fig. 3) are all performed in a fully digital environment without any analogue intervention. Including a virtual 3D soft tissue model in the planning procedure permits the correct dimensions and positioning of the ear relative to the face in a fully virtual environment. As already presented by Alfano et al. in 2005[12], the upper dentition provides a stable and reproducible landmark on which such a guide can be precisely fitted and stabilized during the surgical procedure. Transfer to the operation field is very accurate since no intermediary steps are needed. The polylactic acid (PLA) filament can be disinfected, but not autoclaved. With a desktop Formlab 3D printer, hospital-based manufacturing and sterilization is achievable[14].

We have presented a fully digital workflow to design and 3D-print an optimal ear epithesis guide in-house, to replace an absent pinna.

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This study did not receive funding.

Competing interests

The authors have no conflicting interests.

Ethical approval

All procedures in studies involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethical approval was given by the Ethics Committee of the 'Vrije Universiteit Brussel'.

Patient consent

Signed patient consent was obtained.

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