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Fabrication of ear prosthesis with the integration of CAD/CAM system

Wykonanie protezy ucha z wykorzystaniem systemu CAD/CAM

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Abstract

Aim: The article aims to describe the technique of designing and fabricating ear prosthesis with the integration of computer-aided design and computer-aided manufacturing (CAD/CAM) versus a conventional method. **Background:** The use of rapid prototyping for prosthesis fabrication preceded by the generation of ear prosthesis design utilising the computed tomography data of the patient are recent advance technologies. **Case description:** A 6-year-old boy came with congenitally missing right ear. The healthy left ear was mirrored and printed using the 3-dimensional (3D) printer. Since there was a tissue remnant on the affected side of the patient's ear, the printed ear model was copied in wax. The incorporation of CAD/CAM eliminated the conventional technique involving impression taking of normal ear as a model. Thus, fabrication procedure was simplified, ensuring rapid production. **Conclusion:** The dimension, shape, and anatomic contour of the ear prosthesis were quite similar to those of the normal ear. This outcome suggested that using the CAD/CAM system to fabricate ear prosthesis from computed tomography data is a practical technique which can be used in a clinical setting. **Clinical significance:** Rapid prototyping techniques used in this case gave the highest possible level of accuracy in size, shape, and position of the prosthesis. It also decreased the patient appointments and fabrication time compared to the conventional technique.

Keywords: CAD/CAM, 3D model, CT data, mirror imaging, ear prosthesis, rapid prototyping, silicone

Streszczenie

Cel: Celem artykułu jest przedstawienie techniki projektowania i wytwarzania protezy ucha z wykorzystaniem metody wspomaganej komputerowo (*computer-aided design/computer-aided manufacturing*, CAD/CAM) oraz porównanie jej z techniką konwencjonalną. **Wstęp:** Zastosowanie szybkiego prototypowania do produkcji protez poprzedzonej wygenerowaniem projektu protezy ucha z użyciem danych tomografii komputerowej pacjenta to obecnie najnowsze, zaawansowane technologie. **Opis przypadku:** W pracy przedstawiono przypadek 6-letniego chłopca z wrodzonym brakiem prawego ucha. Zdrowe lewe ucho zostało odzwierciedlone i wydrukowane przy użyciu drukarki trójwymiarowej (3D). Ponieważ po chorej stronie znajdowała się tylko pozostałość tkanki i brak było wzorca, model ucha wykonano w wosku. Zastosowanie systemu CAD/CAM wyeliminowało konwencjonalną technikę polegającą na uzyskiwaniu odcisku zdrowego ucha jako modelu – w ten sposób procedura została uproszczona, zapewniając szybkie wykonanie protezy. **Wnioski:** Wymiary, kształt i anatomiczny kontur protezy ucha były bardzo zbliżone do parametrów normalnego ucha. Uzyskany wynik sugeruje, że system CAD/CAM do wytworzenia protezy ucha na podstawie danych z tomografii komputerowej może być wykorzystywany w warunkach klinicznych. **Znaczenie kliniczne:** W powyższym przypadku zastosowane techniki szybkiego prototypowania dały najwyższy możliwy poziom dokładności rozmiaru, kształtu i położenia protezy. Zmniejszyły się także – w porównaniu z konwencjonalną techniką – liczba wizyt lekarskich pacjenta oraz czas produkcji.

Słowa kluczowe: system CAD/CAM, model 3D, dane uzyskane na podstawie tomografii komputerowej, odzwierciedlenie, proteza ucha, szybkie prototypowanie, silikon

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INTRODUCTION

Application of computer technology in the medical field is rapidly evolving. The recent powerful technologies could enhance some critical clinical procedures. Medical imaging data such as computed tomography (CT) and magnetic resonance imaging (MRI) are essential for clinicians as they can be utilised in treatment planning, diagnostic and prosthesis fabrication[1,2].

The treatment plan chosen by the clinician depends on the type of the defect. Treatment options for ear malformation are either reconstructive surgery or the construction of a prosthetic ear[3]. The CT data has been applied in the management of ear problems such as ossicular reconstruction and cochlear implant[4,5]. Therefore, good CT data are crucial in presenting clear and informative information to the clinicians to ensure accurate replication of the anatomical structure. As in ear prosthesis design, the CT data were used to design an ear prosthesis on the defected side.
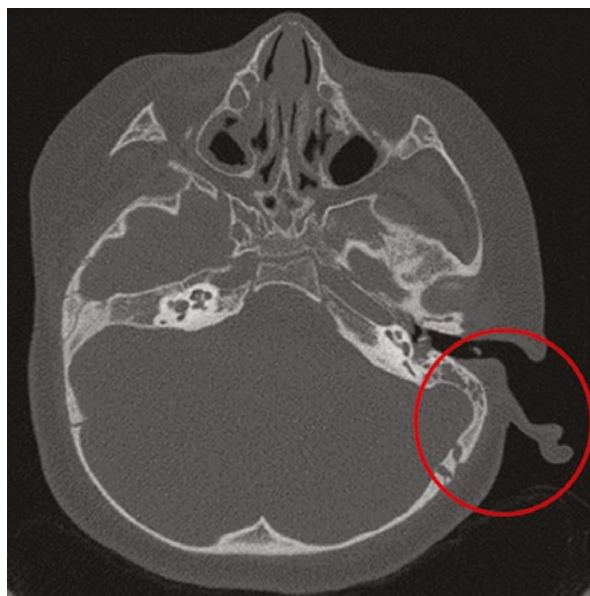

Fig. 1. A CT data slice showing the representation of soft tissue and bone of the right ear (in red circle)

The high-quality CT data will result in a good and smooth design of the ear prosthesis. Medical imaging software was used to reconstruct the 2-dimensional (2D) CT data into 3-dimensional (3D) images. There are commercial and open-source pieces of software available that can be used for digital image processing such as MIMICS, MITK, and 3D Doctor.

The standard Digital Imaging and Communications in Medicine (DICOM) format of an image can be used in any medical software. The virtual 3D model generated from the CT data, after the mirror imaging process, can then be printed using a 3D printer. This model can provide a better visualisation to assist the clinician in their procedures[6,7]. This study presented the use of CT data to facilitate the construction of an ear prosthesis utilising computer-aided design and computer-aided manufacturing (CAD/CAM) in the fabrication process.

CASE DESCRIPTION

A 6-year-old boy was referred to the Maxillofacial Prosthetics Unit, Universiti Sains Malaysia (USM), for ear prosthesis. The CT data evaluation showed an absence of the right external auditory canal, tympanic membrane, and ossicles (Fig. 1). It also showed the absence of the right ear. Therefore, the treatment plan was decided adhesive retained ear prosthesis due to the patient's age and the unwillingness of surgery.

3D reconstruction

The CT scan (TOSHIBA, Japan) data of the patient were retrieved from the Radiology Department, Hospital USM, and saved in DICOM format. The data were converted into 3D images using MIMICS (Materialise, Leuven, Belgium) and later processed using 3-matic module (Materialise, Leuven, Belgium). The standard thresholding value of soft tissue was selected to get the 3D images of the face (Fig. 2). There was tissue remnant at the bottom of the abnormal right ear. However, the patient refused to remove it.
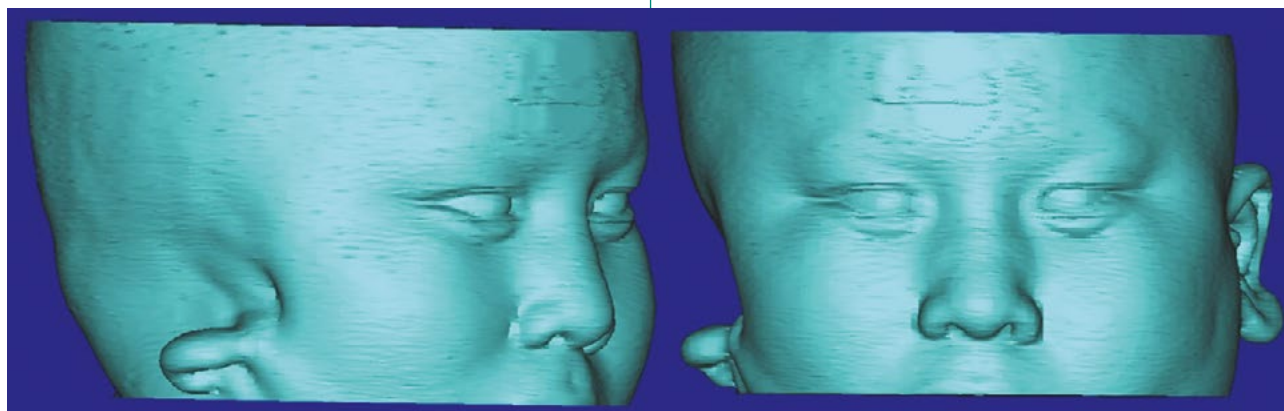

Fig. 2. 3D images of the patient showing the abnormal ear on the right side. Left ear is normal
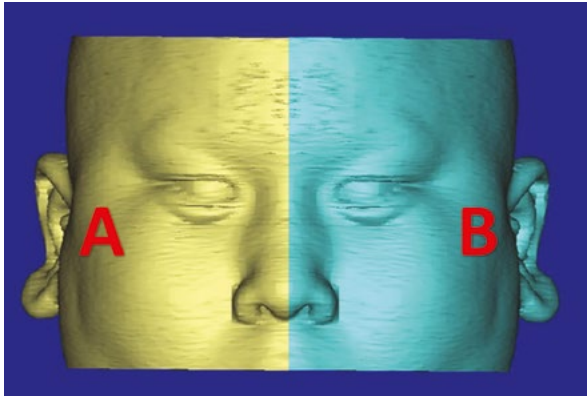
Fig. 3. Mirror imaging technique was used to mirror the contralateral defective ear (A) to mimic the normal ear (B)
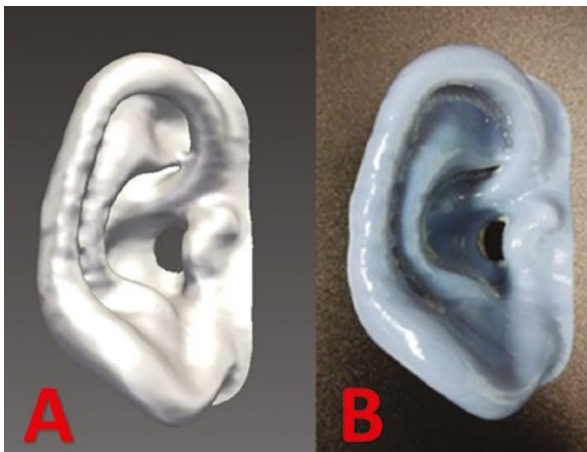

Fig. 4. The right ear extracted from the face (A) was saved in STL format and printed using 3D printer to produce the master pattern (B)

Fig. 5. The ear wax was carved following the master pattern and adapted to the base of the cast model of the deficient side

Fig. 6. Assessment of the fitting of the waxed ear

Mirror imaging process

Half of the anterior view of the 3D image of the face was cropped using facial midline as the axis of symmetry in Mimics Software. Mirror imaging technique was used to duplicate the cropped face with the normal ear (Fig. 3). The final image was the full face with 2 similar ears.

3D printing of master pattern

The software-generated right ear segment was separated from the face by highlighting its surface. Then, it was cropped from the whole face. To smoothen the surface of the ear, editing was performed by doing wrap function, and the ear model was saved in stereolithography (STL) format (Fig. 4A). The final model of the ear was transferred into another computer to be printed using the Stratasys Objet30 Scholar 3D printer (Fig. 4B). The time taken to print the ear model was 5 hours. 3D printing photopolymer (RGD240 Scholar Blue, Stratasys GmbH Europe, Germany) material was used to print this model. The printed ear, which is called the master pattern, was used as a reference to carving the ear using dental wax.

An impression of the defect ear with the remnant tissue was taken and a model was created as the base to carve the waxed ear (Fig. 5). The conventionally technique of carving wax to match the normal ear is a challenge. With the mirrored 3D printed master pattern, the carving process can be done easily, and fitting of the waxed ear to its cast needed minimal effort and time. The benefit of using wax was that it could be easily adjustable and the addition of skin texture can be possible[8].

Once the waxed ear was completed, fitting was carried out to evaluate its angulation, position, size, and margin. The adaptation was crucial as the patient had some remnant tissues as shown in Fig. 6.

After the angulation, position, size, and margin of the waxed ear were finalised, a 3-piece mould was fabricated using Type IV dental stone (Elite Stone, Zhermack, Italy) as in Fig. 7. The wax was then removed with boiling water. The colour of the silicone was selected based on the

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Fig. 7. 3-piece mould to process the silicone

Fig. 8. Patient with ear prosthesis 1 week post-insertion

patient's skin tone and colour. Room-Temperature-Vulcanization Silicone A-2000 from Factor II (Factor II, Inc, USA) was mixed homogenously as prescribed with the Intrinsic colorants (KT-599, Functional Intrinsic II, Factor II, USA) and made bubble free. The silicone was then poured into the 3-piece mould and left for curing for 72 hours. After 72 hours, the final ear prosthesis was deflasked from the mould and trimmed. After some minor Extrinsic coloration (KT-199, Extrinsic, Factor II, USA), the prosthesis was delivered to the patient. The finished prosthesis was retained to the skin of the defect side using Daro adhesive hydrobond (B-200-30, Factor II, USA). Proper instructions were provided regarding use, care, and maintenance of the prosthesis. One week later, the patient came back to the clinic for post-insertion assessment (Fig. 8). He was satisfied with the ear prosthesis and had no complain. The further clinical assessment was carried out after one month. The patient was happy with the prosthesis and a subsequent appointment was given after 6 months.

DISCUSSION

This study demonstrated the fabrication of ear prosthesis using the conventional method with the integration of CAD/CAM. The conventional method was normally used in hospitals to fabricate ear prostheses. The steps of the process involve impression taking, wax carving, mould preparation and colouring of the prosthesis. Impressions of the normal and defective ears have to be taken and their casts used to produce the waxed ear for fitting. Technologists have to use their imagination to reproduce the normal ear on the other side of the face. It is time-consuming and involved tedious process, and needed highly skilled technologists. However, the method used in this prosthesis fabrication does not involve impression taking of the healthy ear. Hence, it does not cause discomfort to the patient. Instead, it used available CT data of the patient to obtain the morphology of the normal ear. Once mirrored to the defective ear, it can be printed out and used as a reference to produce the waxed ear for fitting. Alternatively, a laser scanner could also be used for similar purpose.

The conventional method is quite challenging due to the complexity of the ear shape. It involved wax carving which depends on the artistic skill and experience of the technologist[9]. This process is simplified using the method described herein.
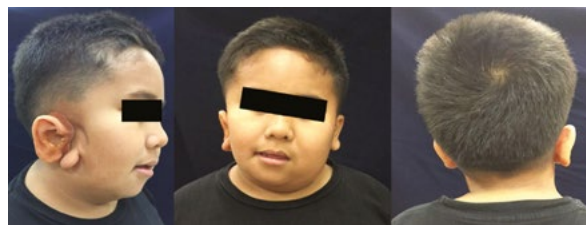
The number of appointments can also be reduced when applying CAD/CAM method in prosthesis fabrication. This method allows the clinician and technologist to work on the patient's case without his/her presence. For example, if the CT data are available, impression taking and carving of the ear to replicate its normal side can be skipped. Patient waiting time will also be reduced. Usually, the conventional method took about 2 to 3 hours per appointment, depending on the process. For instance, during the trial waxed ear fitting, it normally consumed a lot of time when the clinician needed to check for the angulation, alignment, and the shape of the ear to match with the normal side. The technologist would help in adjusting the wax. The process would be repeated until the ear looks acceptable to the patient's facial profile.

It is quite a challenge to achieve a natural look of the prosthesis. Shape, colour, and texture of the prosthesis are 3 factors that define a good prosthesis. One of the limitations of using the mould from the 3D printer is the staircase effect, which could affect its texture. The final outcome of the prosthesis is based on the surface of the printed mould. Therefore, to overcome this problem, sandpaper is used to smoothen the surface texture of the mould. Alternatively, acetone could be used to achieve the same result[10]. The smoother surface of the mould will produce a smooth prosthesis. To match the look of a natural skin, the prosthesis should show a stippled texture, which can be achieved by using the combination of fine sand and white polysynthetic resin adhesive glue instead of using antiskid epoxy resin[11]. The materials will be mixed together and put in the cast before silicone casting. This technique helps to get the good prosthesis in term of colour and texture to match the patient's skin.

Adhesive method to secure the ear prosthesis was used in this case. Another retention method which could have been used were implants. CT data will be needed for the insertion of the implant to locate the suitable position for the bone placement[8,12]. Each of the retention methods has its own drawbacks and advantages. The implant is expensive and involves surgery but can last longer once fitted. On the other hand, the adhesive is much cheaper but can only last for a few hours. Considering the patient is still growing, the adhesive was the best option.

Using technology application such as software and high-end equipment may involve an excessive cost, but

the process of prosthesis fabrication can be simplified and it does not depend heavily on the technologist's skill. Thus, the time to complete the prosthesis can be reduced. If the patient has no remaining tissue on the deficient side, the duplication process can be skipped as the whole ear on the unaffected side can be used as a template. Therefore, the mould can be designed and printed straight away using the 3D printer without the need to prepare the 3-part mould. The use of printed mould is becoming more popular due to its many advantages such as affordable cost, time-saving, and durability[13,14].

CONCLUSION

This study demonstrated the integration of CAD/CAM to the conventional method of producing an ear prosthesis. Cases with partial auricular defects rather than complete ones are more difficult to rehabilitate[15]. CT data can be utilised in maxillofacial prosthesis fabrication whereby the steps were made simpler compared to the conventional manual method. Hence, the time taken for each patient can be shortened and the number of patient's appointments is reduced.

CLINICAL SIGNIFICANCE

The Rapid prototyping technology employed in this case report made the adhesive retained auricular prosthesis fabrication easier, time-saving, a sustainable clinical outcome that resemblance to contralateral ear in shape, texture, orientation and skin tone as similar as possible. Individual patients who cannot go on surgery, can be rehabbed by this fabrication technique which is affordable and less complicated.

Manufacturer names

1. Stratasys Objet30 Scholar 3D printer; Stratasys Ltd, 28309 Ave Crocker Valencia, CA 91355, USA.
2. 3D printing photopolymer – RGD240 Scholar Blue; Stratasys GmbH Europe, Airport Boulevard B 120, 77836 Rheinmünster, Germany.
3. Elite Stone; Zhermack SpA – Bovazecchino, 100 45021 Badia Polesine (RO), Italy.
4. Silicone A-2000; Factor II, 5642 White Mountain Avenue Lakeside, AZ 85929 USA.
5. Complete Functional Silicone Coloring Kit, KT-199 (Extrinsic) and KT-599 (Intrinsic); Factor II, 5642 White Mountain Avenue Lakeside, AZ 85929 USA.
6. TOSHIBA Aquilion 64 CT Scanner; TOSHIBA, JAPAN.

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